Egyptian Drug Authority

هيئة الدواء المصرية

BIO INN Marketing Authorization

Activity REPORT

2025

https://edaegypt.gov.eg

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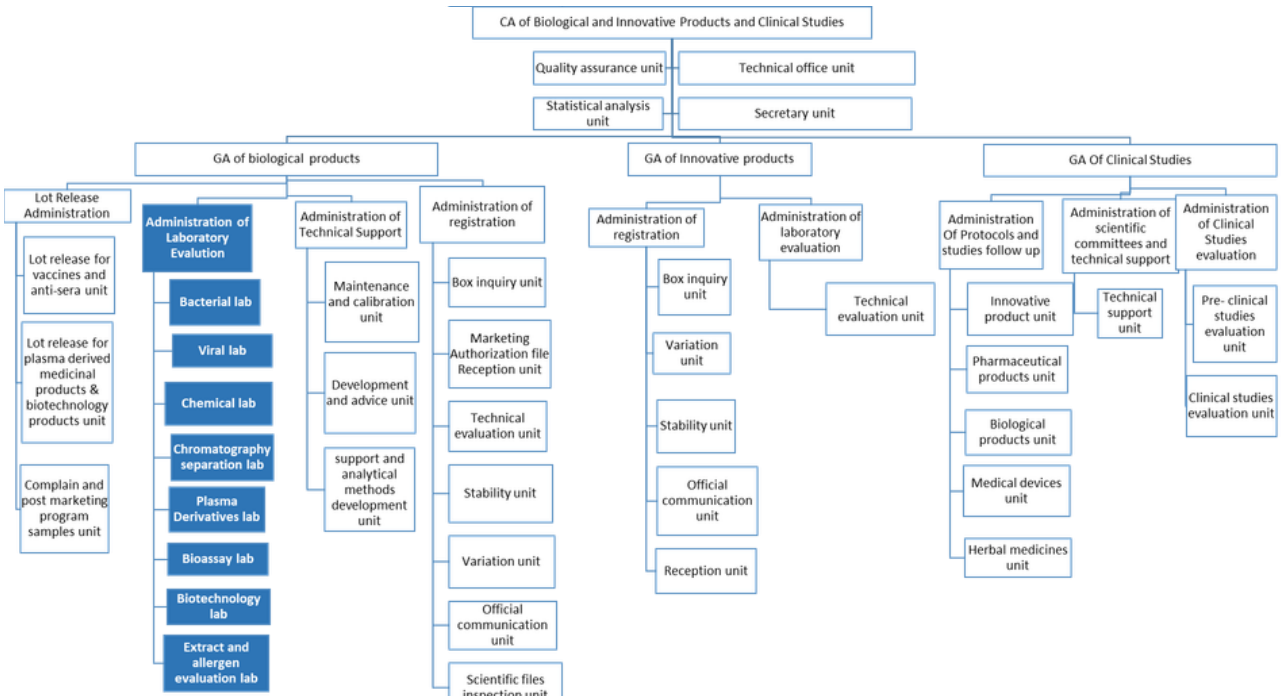
Organizational chart

BIOINN ORGANOGRAM



MARKETING AUTHORIZATION ADMINISTRATION – OVERVIEW

The Marketing Authorization Administration is a constituent administration of the General Administration of Biological Products, operating under the Central Administration of Biological & Innovative Products and Clinical Studies within the Egyptian Drug Authority (EDA).

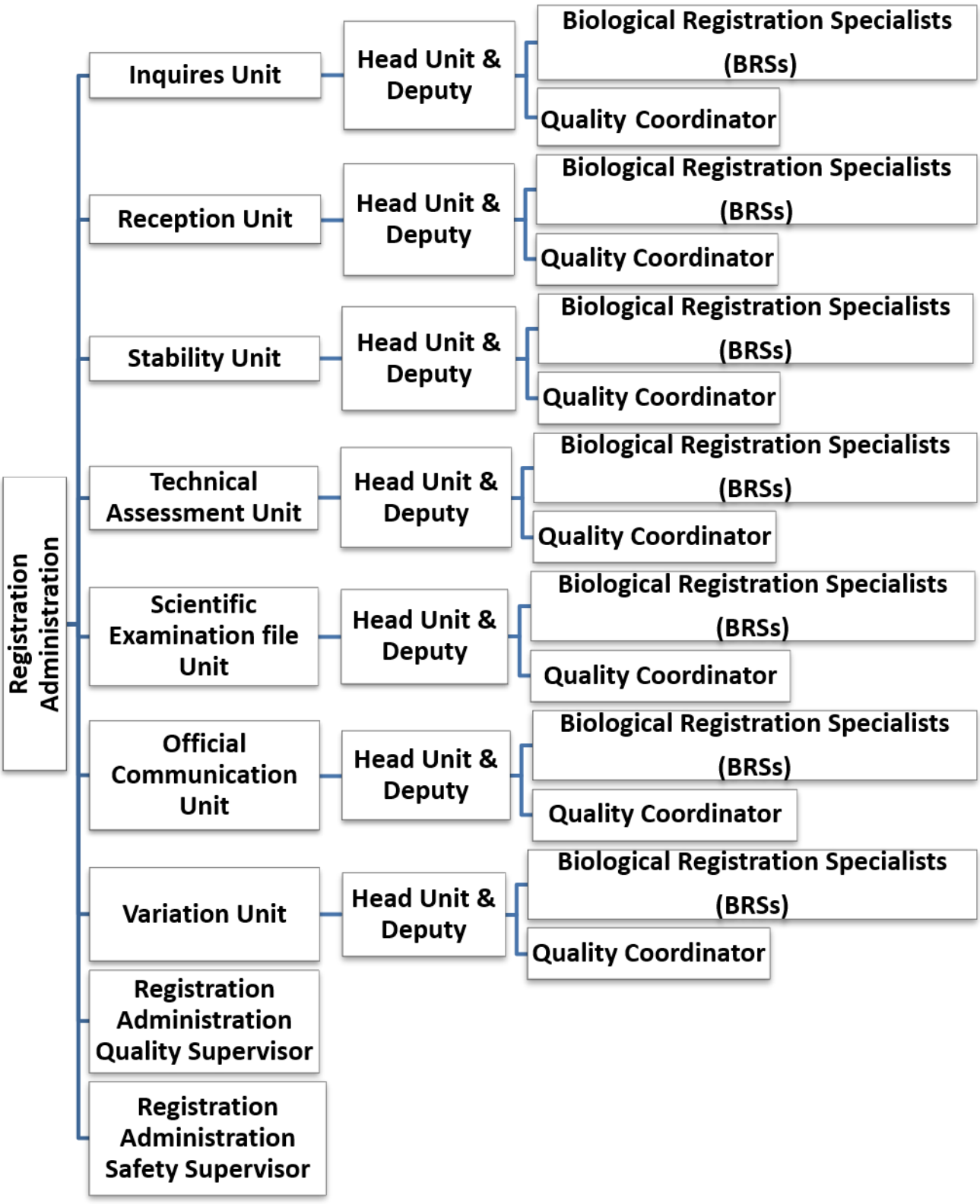
The Administration comprises seven units, each under the direction of an appointed Unit Manager.

The organizational structure is clearly defined and supports effective governance of marketing authorization activities. Overall leadership is provided by the Marketing Authorization Administration Manager, who is responsible for coordination, oversight, and supervise implementation of general policy and all work plans in compliance with the EDA strategic objective and plans.

Each unit is functionally supported by competent personnel with specific responsibilities essential to maintaining compliance with regulatory and quality requirements

This structured framework ensures that the Marketing Authorization Administration operates in a systematic, efficient, and quality-driven manner, thereby supporting the EDA’s mandate for regulatory oversight of biological products.

MARKETING AUTHORIZATION ADMINISTRATION ORGANOGRAM



Responsibilities of MA

- Review and Evaluate Common Technical Document (CTD) dossiers submitted for the marketing authorization of all biological products including vaccines.
- Technical & Scientific evaluation and assessment of documents related to the quality, non-clinical, and clinical of submitted products.
- Review post-approval changes & renewals applications to ensure continued compliance with regulatory and quality standards.
- Prepare, Review, and Issue official letters for internal / External queries related to marketing authorization activities.
- Participating in internal quality audits to evaluate system compliance and support continuous quality improvem efforts.
- Participating in the development and implementation of regulatory policies, guidance documents, and standard operating procedures related to biological products marketing authorization.

STATISTICAL DATA

Marketing Authorization Administration is intended to ensure the quality, efficacy and safety of all biological products including vaccine.

As a result, Key Performance Indicators (KPIs) are routinely monitored to ensure that marketing authorization process is conducted efficiently and in accordance with defined regulatory standards.

Statistical outcomes

MA ISSUANCE

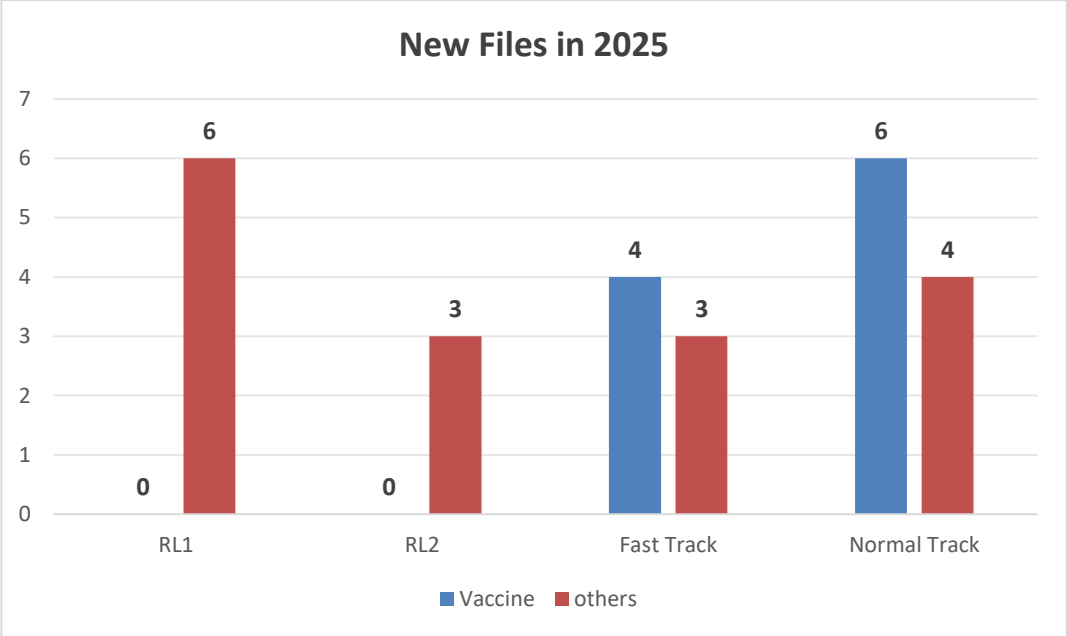
Marketing Authorization Administration

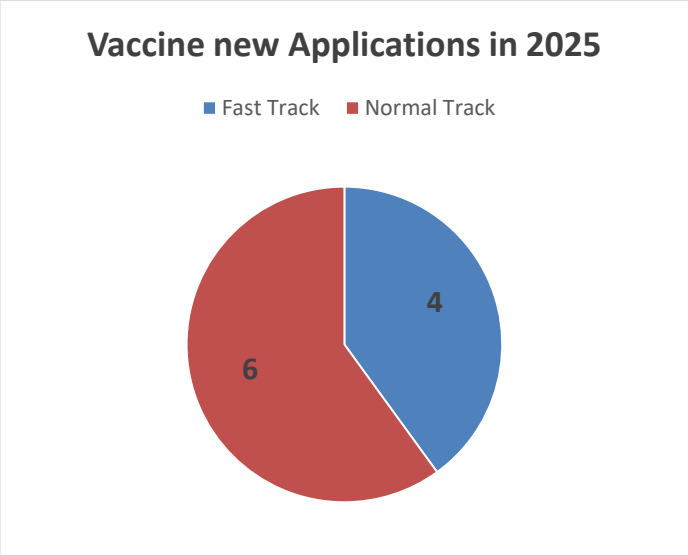
- Marketing authorization applications are evaluated by qualified regulatory assessors in accordance with established regulatory procedures and scientific guidelines
- The assessment covers a broad range of biological products, including vaccines, plasma-derived medicinal products, recombinant biological products, and advanced therapy medicinal products (ATMPs), in line with applicable regulatory guidelines.
- Marketing Authorization Activities are carried out across the seven units listed in the organogram provided above, with each unit responsible for its own specific regulatory functions.
- As part of routine quality and regulatory oversight, technical & scientific assessment were conducted throughout the year. These reviews include:
- Technical & Scientific evaluation and assessment of documents related to the quality, non-clinical, and clinical of product
- Review post-approval changes & renewals applications to ensure continued compliance with regulatory and quality standards.
- The following charts illustrate the total number of new marketing authorization applications received during 2025 (26), comprising 10 vaccine applications and 16 applications for other biological products, together with their distribution across the RL1, RL2, Fast Track, and Normal Track regulatory review pathways.

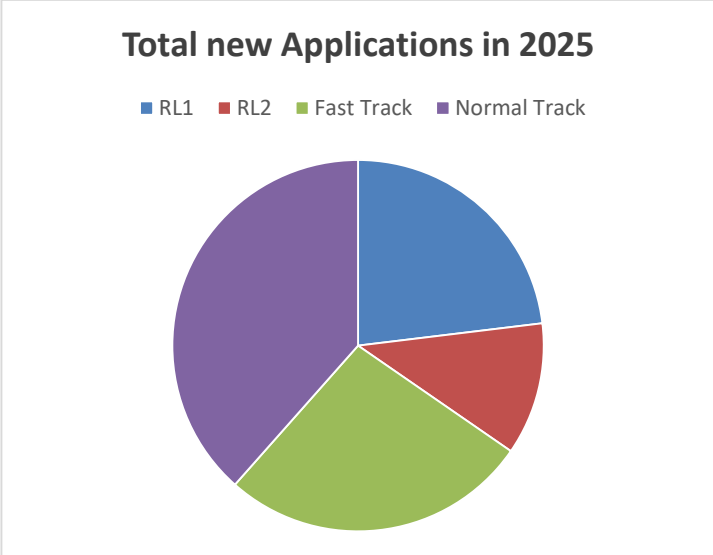
Statistical outcomes

MA ISSUANCE

Marketing Authorization Administration



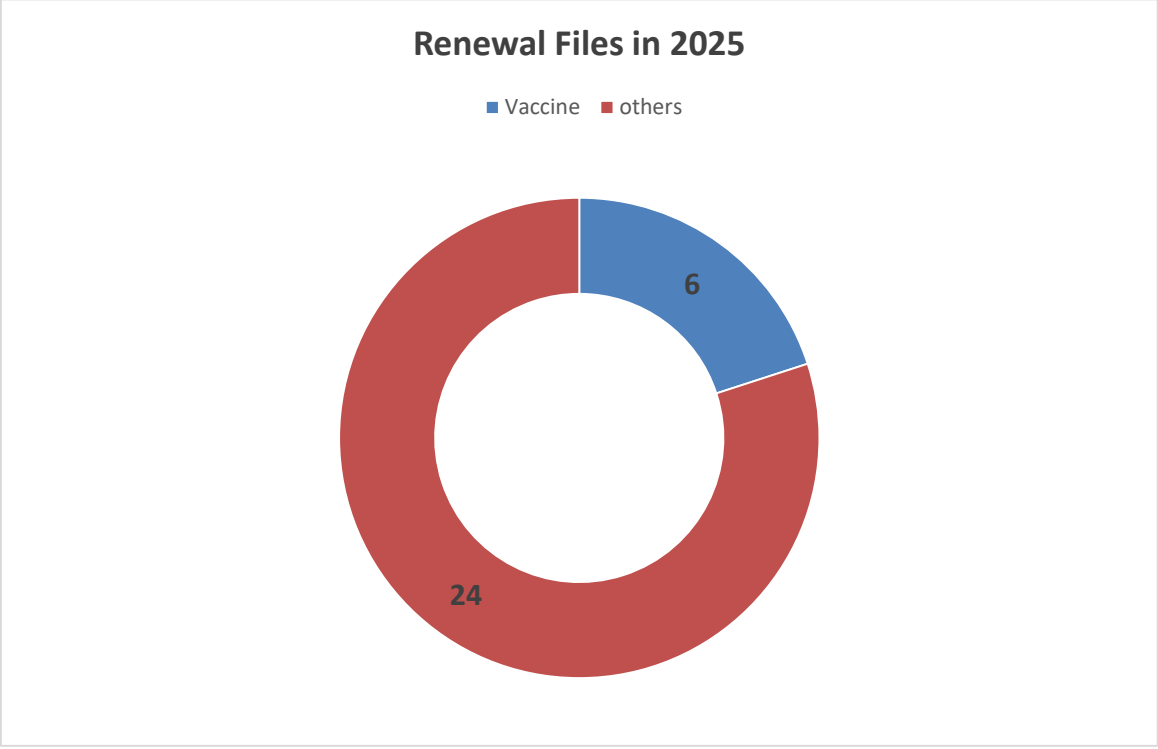




MA ISSUANCE

Marketing Authorization administration

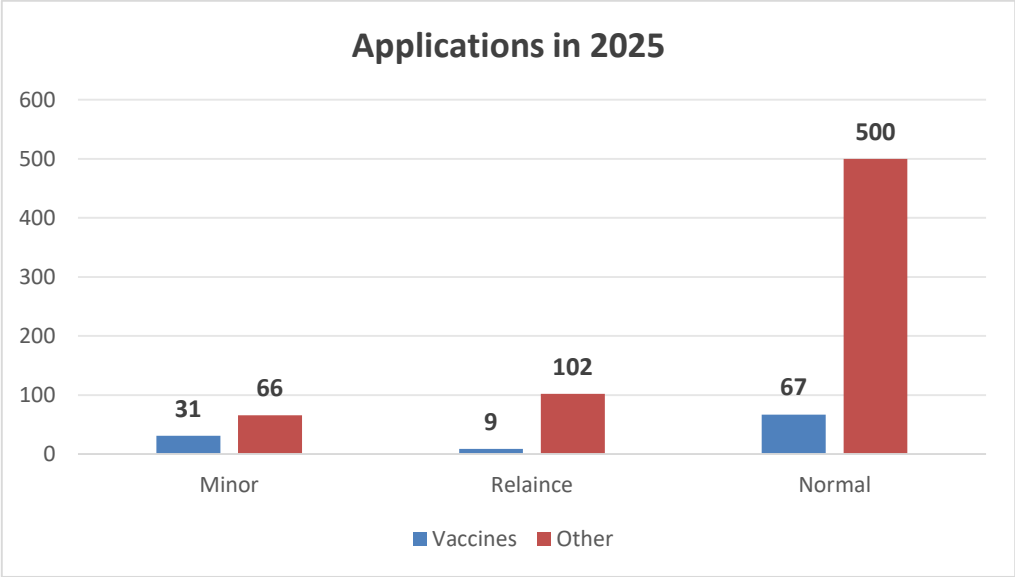
• The following charts illustrate the total number of renewal marketing authorization applications received during 2025 (30), comprising 6 vaccine applications and 24 applications for other biological products

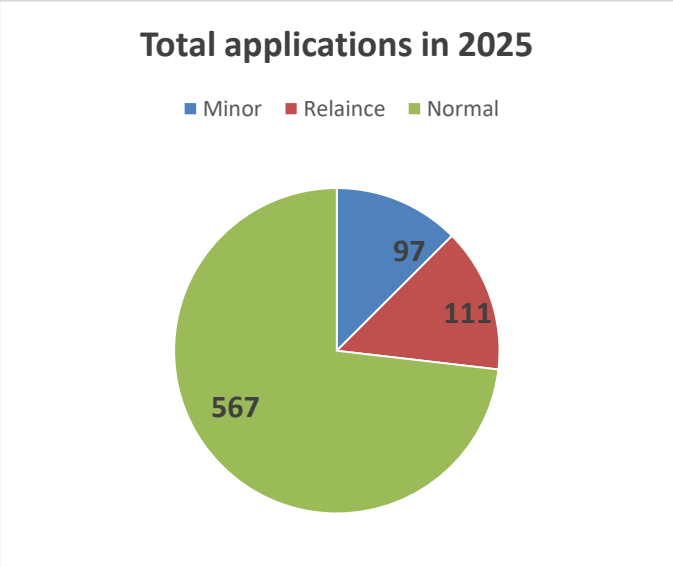


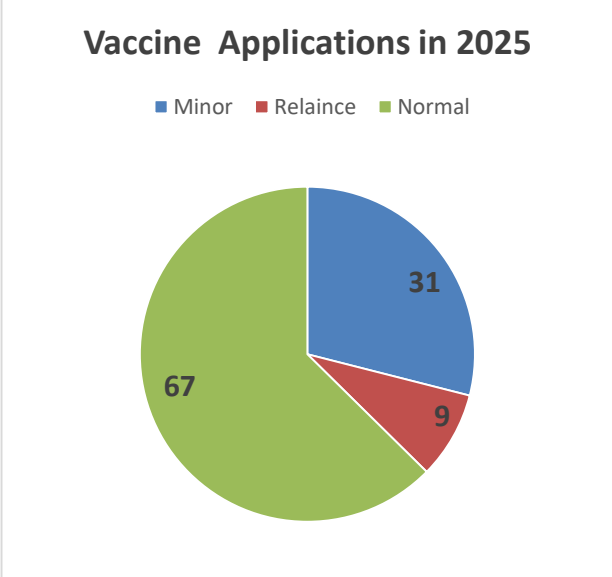
POST APPROVAL CHANGES (PACs) APPROVALS

Variation Unit

- The Variation Unit plays an essential role within the Marketing Authorization Administration by evaluating post-approval changes applications for authorized biological products including vaccines to ensure continued compliance with quality, safety, and efficacy requirements.
- The Variation Unit demonstrated sustained regulatory capacity throughout 2025, processing a total of 775 post-approval changes applications for biological products. These applications comprised 107 post-approval changes for vaccines and 668 post-approval changes for other biological products.



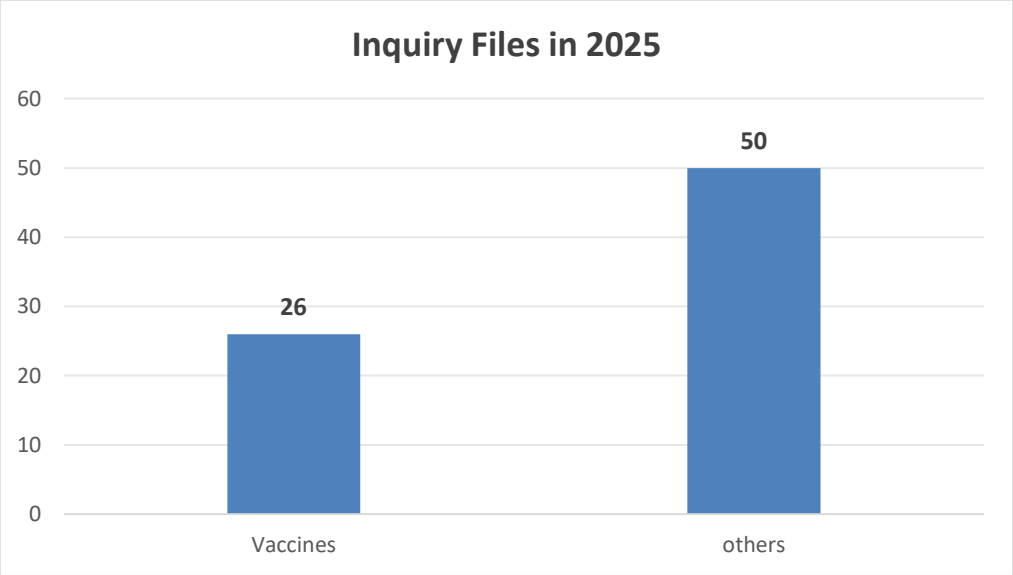




Inquiry approvals

INQUIRY UNIT

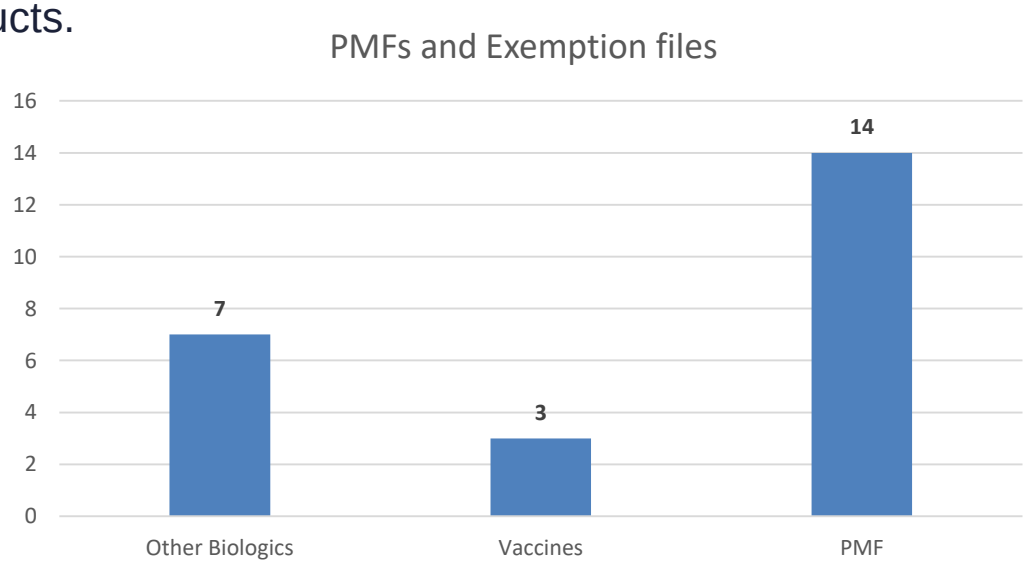
- The Inquiry Unit plays an essential role within the Marketing Authorization Administration by issuing inquiry approvals to facilitate the submission of marketing authorization dossiers (CTD)
- The Inquiry Unit demonstrated sustained operational capacity throughout 2025, processing a total of 76 inquiry files. These comprised 26 inquiries related to vaccines and 50 inquiries related to other biological products



Plasma master files and Exemption files

SCIENTIFIC EXAMINATION FILE UNIT

- The Scientific Examination File Unit plays an essential role within the Marketing Authorization Administration by performing scientific evaluation of all biological products, including non-clinical and clinical data assessment, to ensure compliance with national requirements and support informed regulatory decision-making throughout the marketing authorization process
- The Scientific Examination File Unit demonstrated sustained operational capacity throughout 2025, processing a total of 10 exemption files. These comprised 3 exemption files related to vaccines and 7 exemption files related to other biological products & processing a total of 14 plasma master files (PMFs) for plasma derived medicinal products.



Accreditation/Recognition/ Membership

ISO 9001/2015

- The Laboratory Evaluation Administration obtained ISO 9001 certification in 2008. Since then, all laboratory operations have been conducted in accordance with ISO 9001 and its subsequent revisions. Certification has been maintained through regular surveillance and periodic full recertification, ensuring ongoing conformity and continuous improvement of our quality management system

ISO 17025/2017

- The Laboratory Evaluation Administration first obtained ISO/IEC 17025 accreditation in 2010 for certain test scopes. Since that time, all activities under those scopes have been carried out in full compliance with the ISO/IEC 17025 standard and its subsequent revisions. Our accreditation has been maintained each year through regular assessments, surveillance audits, and full reassessments, ensuring that technical competence and quality remain at the highest standard.
- On 16 January 2024, the Laboratory Evaluation Administration expanded its ISO/IEC 17025 accreditation to include three additional test scopes. As a result, the total number of accredited scopes now stands at nine, which are:
  - Determination of Hepatitis B Surface Antibodies using ELISA Method
  - Identification and determination of Influenza heamagglutinin content SRID assay
  - Determination of prekallikrein activator by chromogenic assay
  - Determination of Total Protein in Anti-sera & Erythropoietin (Biuret Assay)
  - Determination of bacterial endotoxin
  - Determination of Tetanus and Diphtheria toxoid content with Flocculation method procedure.
  - In vivo Pyrogen test.
  - Impurities with molecular mass greater than that of insulin.
  - Sterility testing by direct inoculation.

- Staff members of the Laboratory Evaluation Administration actively participate in numerous international initiatives, including ICH Expert Working Groups and internal task forces focused on revising and updating ICH guidelines.
- Moreover, they involved in IPRP working groups and contribute to USP scientific programs, playing a key role in advancing global regulatory standards and scientific collaboration.

EGYPTIAN DRUG AUTHORITY JOINED THE AFRICAN NETWORK OF REGULATORY LABORATORIES (NARL)

In October 2025 , BioInn Laboratories played a key role in supporting the Egyptian Drug Authority's (EDA) successful engagement in the African regulatory landscape through joining the Network of African Reliance Laboratories (NARL) as a Reliance Laboratory.

The designation of EDA as a Reliance Laboratory reflects the growing continental confidence in its analytical and regulatory capabilities, as well as its leadership in strengthening quality control and accreditation systems. Within this context, BioInn Laboratories, as part of the National Control Laboratory (NCL) framework, contribute to advancing reliance-based practices by supporting data generation, quality evaluation, and laboratory excellence. This achievement reinforces the role of NCLs in promoting regulatory convergence, reducing duplication of testing, and enhancing the efficiency and reliability of medicines, vaccines quality assurance across Africa.

Strengthening Regulatory Capacity in Africa

NEPAD-AMRH

- EDA has officially announced in August 2023 to be one of NEPAD-AMRH Regional Centers of Regulatory Excellence (RCOREs) in the following functions: LT that focus on promoting and enhancing regulatory standards practices, strengthen the regulatory capacity and development in Africa
- As one of the NEPAD–AMRH Regional Centers of Regulatory Excellence (RCOREs), Laboratory evaluation administration submitted training programs targeted at several African countries in the East Africa region, as part of ongoing collaboration with African Union member states to strengthen regulatory capacity and harmonize practices across the continent.
- In corporation with lot release, Laboratory evaluation administration conducted specialized program (Hands-On Training Program on Vaccine and Antisera Lot Release Implementation) for the Ghana Food and Drugs Authority from 4-13 May 2025. Participants were provided with a comprehensive understanding of the manufacturing and quality control processes for selected vaccine and antisera products. It also included the evaluation of Quality Module 3 for each of the products studied, complemented by practical sessions and case studies designed to bridge theoretical knowledge with real-world application.
- Key topics covered during the training included the concepts and applications of Lot-to-Lot Consistency and the management of temperature excursions during the batch release process. Participants engaged in practical exercises on Batch Release Procedures ,as well as a dedicated workshop on the Quality Management System in Release and a session on the automation of batch release processes, highlighting EDA’s use of modern digital tools to enhance regulatory efficiency and transparency

Strengthening Regulatory Capacity in Africa

NEPAD-AMRH

- Laboratory evaluation administration conducted specialized program, Laboratory Tests for Snake Antivenom, Vaccine Batch Release from 17-26 August 2025 for six participants from the Food and Drugs Authority (FDA) of Ghan
- The training program explored to develop participants' skills in the evaluation and regulation of pharmaceutical and biological products, with a particular focus on improving efficiency in quality control and advanced analytical testing.
- The program included a combination of theoretical lectures and practical applications covering a range of technical and regulatory topics, including laboratory testing for snake antivenom, regulatory policies for vaccine batch release.
- Participants received in-depth training on antivenom manufacturing processes, critical quality standards, efficacy testing, data analysis and result interpretation, as well as best practices for sample handling, documentation, and integration with Quality Management Systems (QMS).

- In line with our dedication to upholding the highest global standards, BioInn Labs proudly participated in the "Comprehensive Training on Pharmacovigilance, Regulatory Documentation, and Good Clinical Practice (GCP)" from December 7-10, 2025. A primary focus of the program was to gain a deeper practical understanding of the Common Technical Document (CTD) modules, which are critical for efficient and compliant regulatory submissions. This valuable training initiative was part of a program sponsored by the Bill & Melinda Gates Foundation and organized in collaboration with the KEMRI Wellcome Trust and Biogeneric Pharma S.A.E. Our involvement underscores our commitment to continuous learning and maintaining expertise in the ever-evolving regulatory landscape.

National Achievement

EGYPTIAN PHARMACOPEIA

- Laboratory evaluation provided Experts for participating in issuing multiple Biological Products Monographs in Egyptian pharmacopeia starting in 2021/2022
- A total of six general monographs have been issued, with active contribution from the staff of the Laboratory Evaluation Administration in their preparation.

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