Egyptian Drug Authority

هيئة الدواء المصرية

BIO INN Lot Release

Activity REPORT

2023-2024

https://edaegypt.gov.eg

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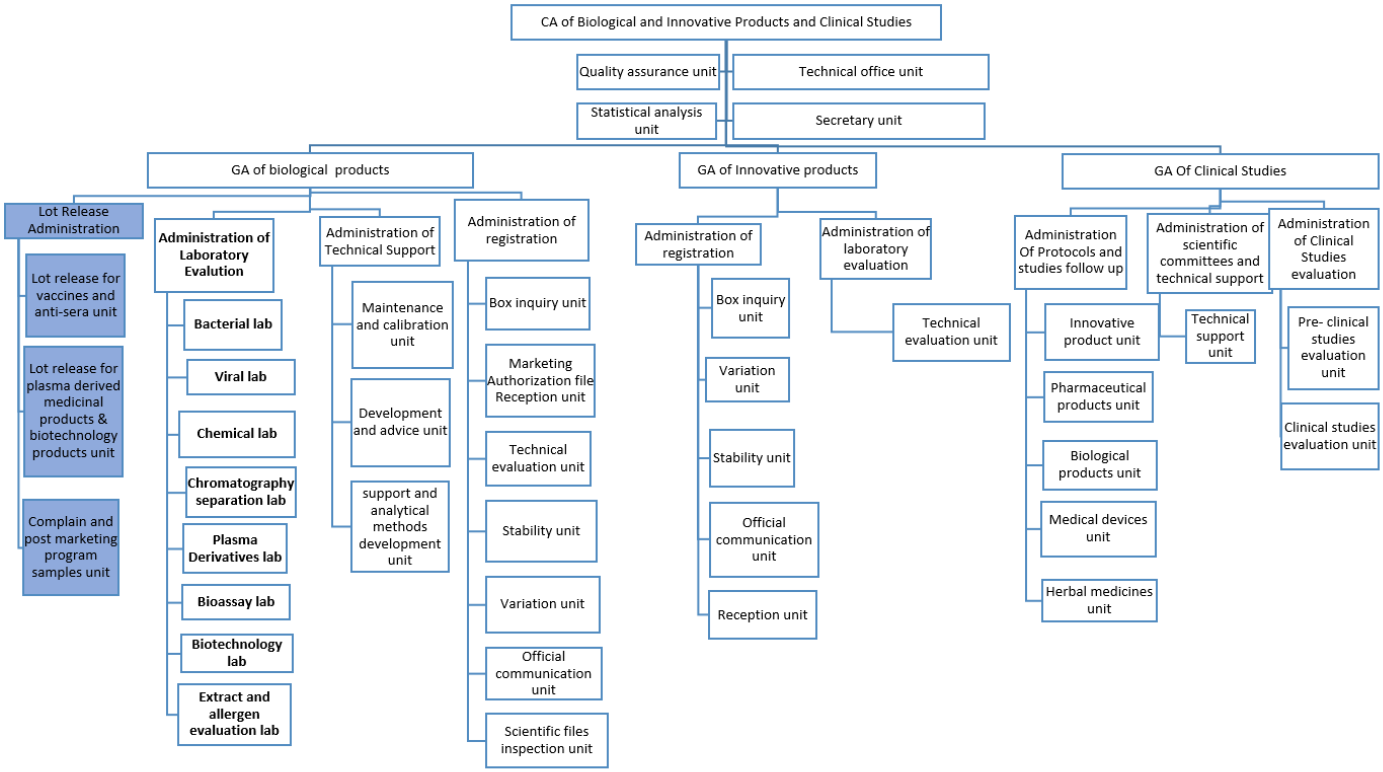
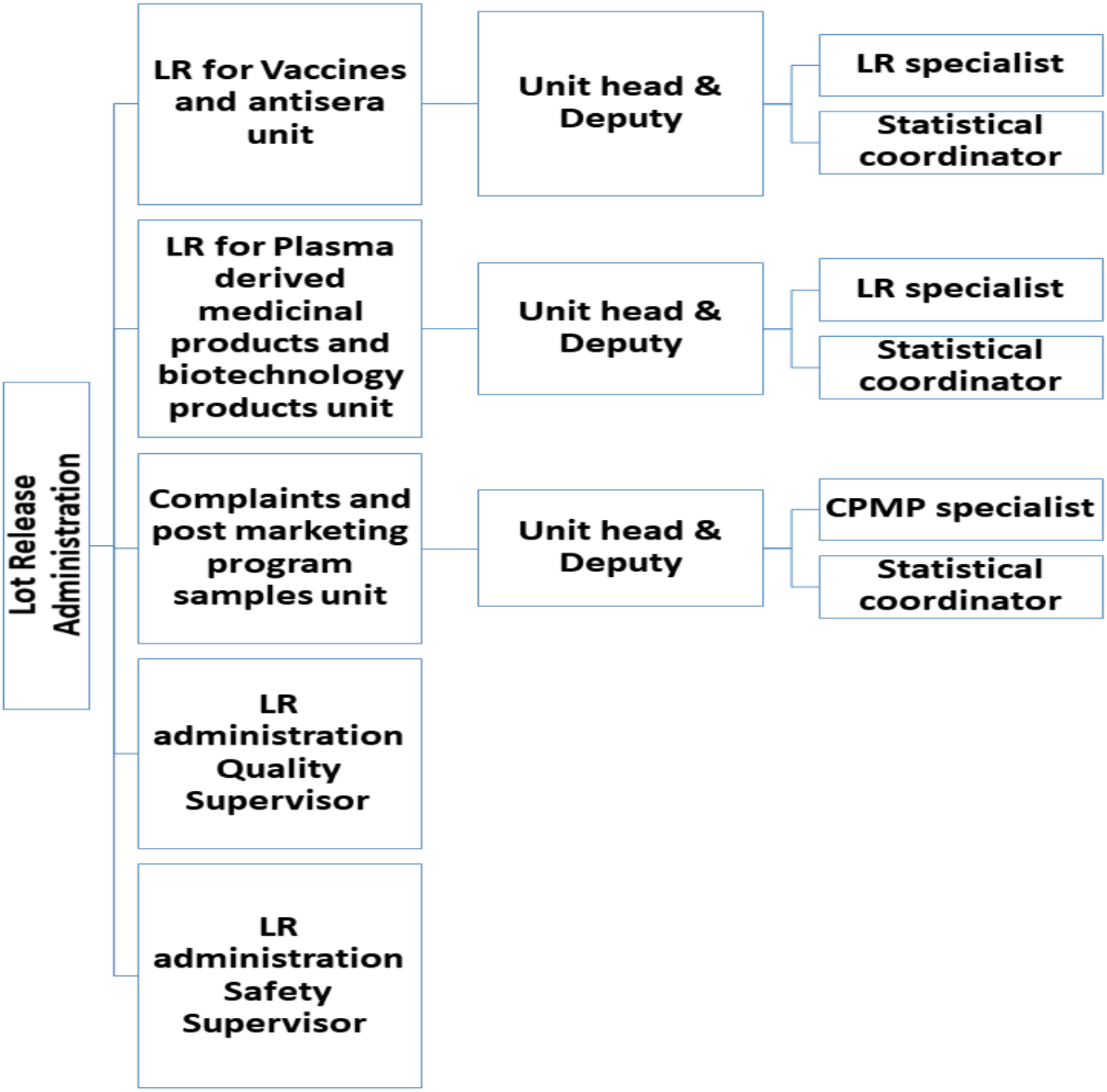
Organizational chart

BIOINN ORGANOGRAM



LOT RELEASE ADMINISTRATION ORGANOGRAM



Responsibilities of Lot Release

· Manage and coordinate lot release activities for biological products to ensure appropriate regulatory control before market distribution.

· Apply risk-based approaches and reliance/recognition pathways to support efficient and proportionate regulatory oversight.

· Review batch documentation, testing outcomes, and quality-related information to support release and certification decisions.

· Coordinate with relevant laboratory, regulatory, inspection, and post-marketing stakeholders, including follow-up on quality issues and continuous improvement activities.

STATISTICAL DATA

Lot Release administration is intended to ensure the quality and efficacy of biological products. As a result, Key Performance Indicators (KPIs) are routinely monitored to ensure that lot release is conducted efficiently and in accordance with defined regulatory standards.

Risk-based Lot release system

Lot release administration

✓ National lot release is governed by:

- EDA establishment law 151/2019 and its executive regulation 777/2020
- Policy for lot release of biological products in Egypt
- EDA chairman decree 425/2022 for LR regulation in Egypt
- Guideline for Lot Release of Biological Products in Egypt

✓ Risk-based Lot release system

- The Egyptian Drug Authority (EDA) has adopted a Risk-Based Lot Release (RB-LR) system to enhance the efficiency and effectiveness of the lot release process for biological products. This approach aligns with international best practices and aims to ensure the timely availability of high-quality biological products in the Egyptian market.

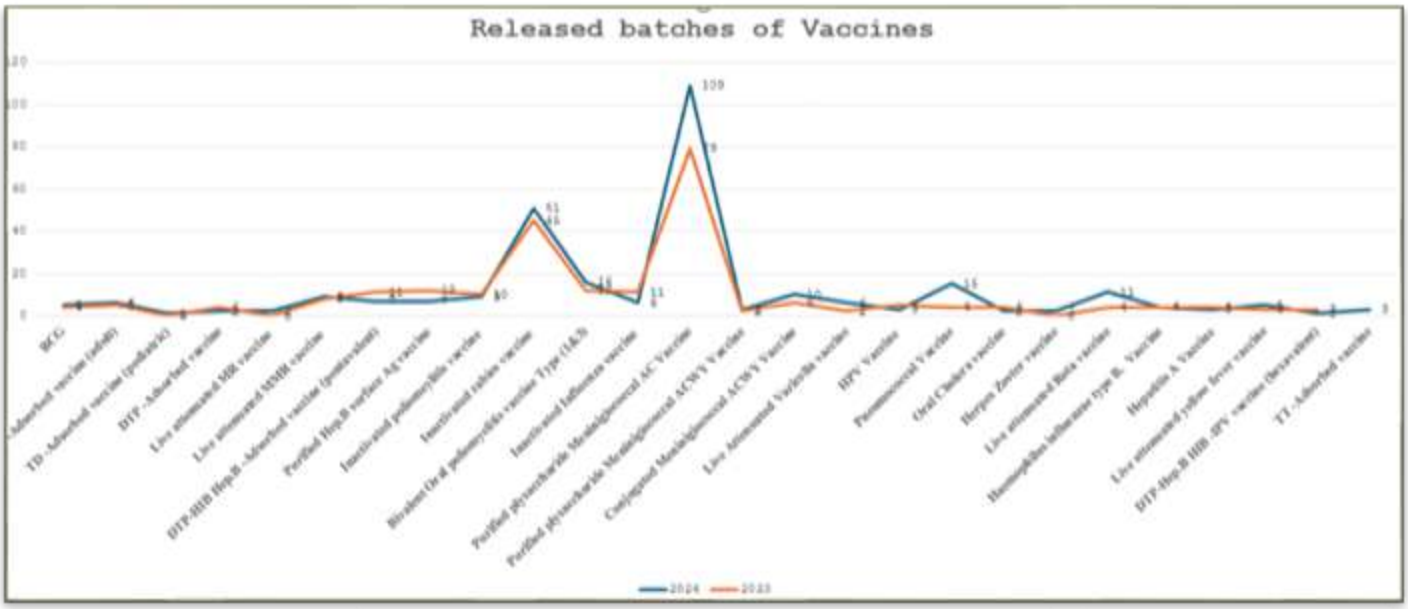
Risk factors

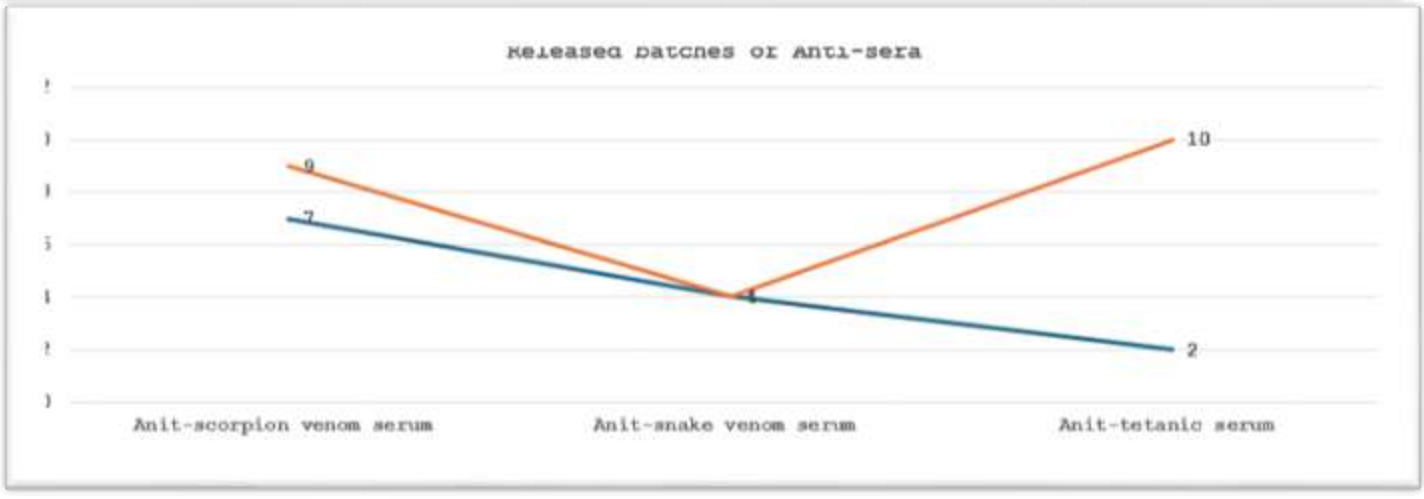
Statistical outcomes

Batch Release

Vaccines & antisera Unit

- The unit oversees the end-to-end Lot Release process for vaccines and antisera through electronic submission of batch documentation and risk-based laboratory testing at the National Control Laboratory (NCL), leading to final regulatory decisions and batch certification.
- It ensures efficient coordination with manufacturers and relevant EDA administrations, supports data-driven oversight through trend analysis, and supports product availability in the market..



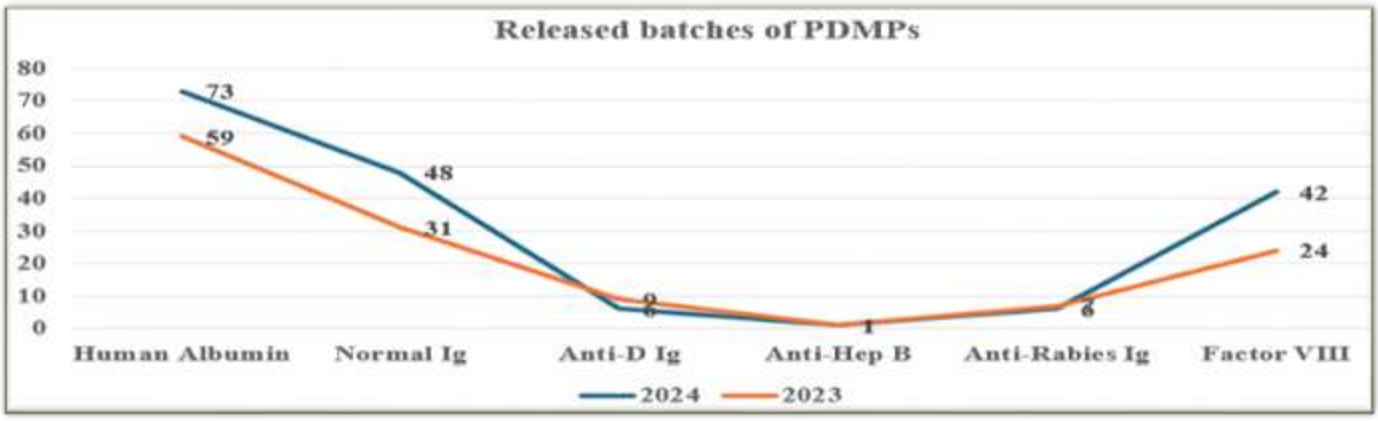


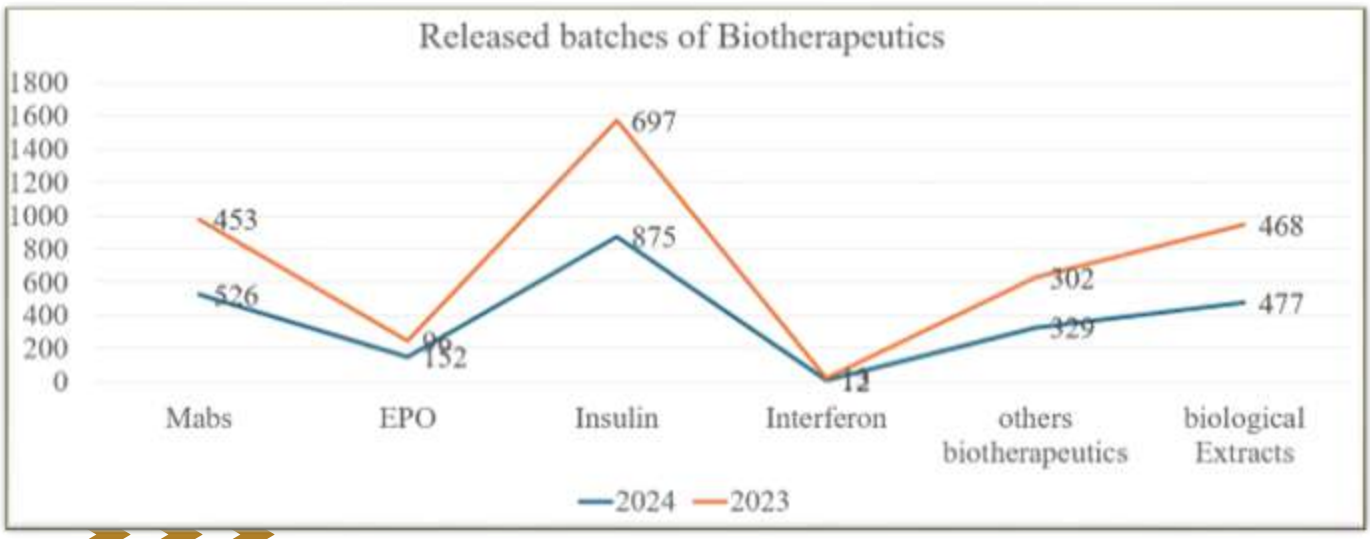
Statistical outcomes

Batch Release

Plasma & Biotechnology products unit

- The unit plays a critical role in ensuring that each manufactured batch of plasma derived medicinal products and other biologicals meets predefined quality, safety, and efficacy standards before being released to the market. This process follows a risk-based approach aligned with WHO guidelines, where batches may undergo full evaluation, partial review, or reliance-based exemption depending on product classification, manufacturing history, and certification from recognized reference authorities.



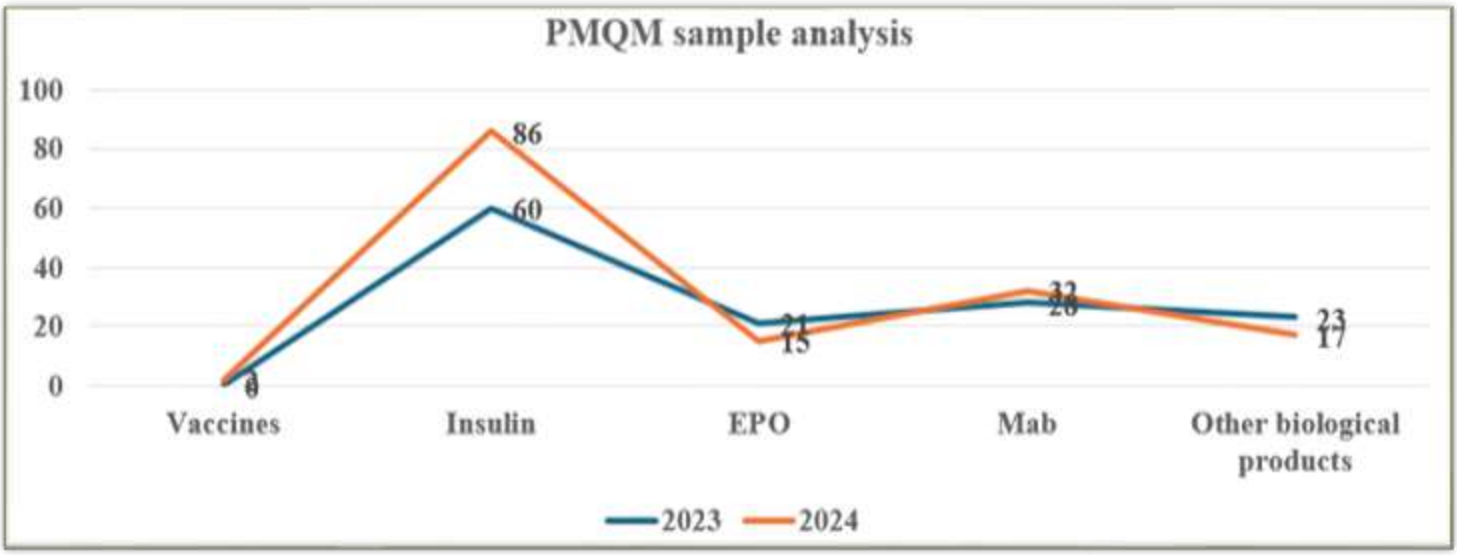


Statistical outcomes

SAMPLE ANALYSIS

Complaints & PMP unit

- The unit operates as a core component of the national post-marketing surveillance system applying a risk-based approach to ensure the ongoing quality and safety of biological products after market entry. It combines proactive monitoring (planned sampling and laboratory testing) with reactive investigation of complaints related to suspected product defects. Findings are assessed in coordination with the National Control Laboratory and inspection teams to detect quality issues, identify trends, and trigger appropriate regulator actions such as recalls or corrective measures. Through this integrated system, EDA maintains continuous lifecycle oversight of biological products and safeguards public health.



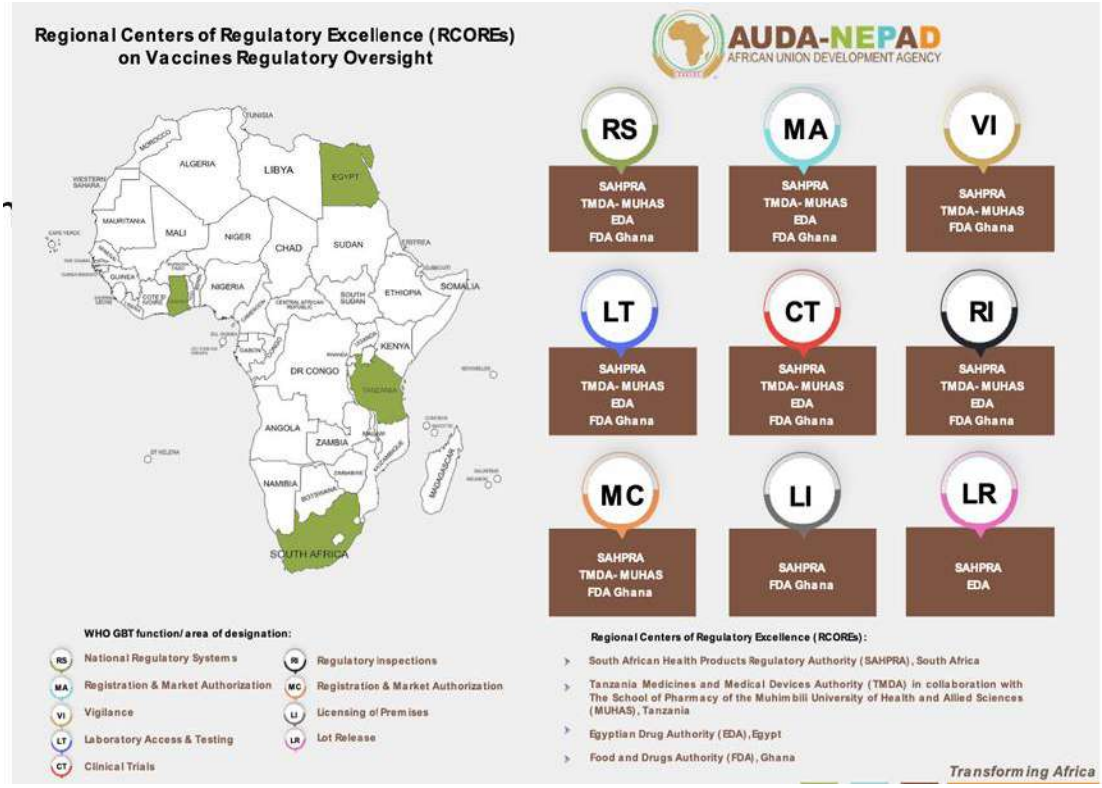
Recognition/ Membership

WHO

- In March 2022, the Egypt Drug Authority (EDA) was accredited by the World Health Organization (WHO) for its ability to regulate and evaluate vaccines, both locally produced and imported. EDA's National Regulatory Authority reached Maturity Level 3 (ML-3)—the second-highest level in WHO's global regulatory system. Egypt become the first African country to achieve WHO Maturity Level 3 (ML3) for its lot release function—demonstrating a stable, well-functioning regulatory system. In April 2024, EDA also joined the WHO National Control Laboratory Network for Biologicals (WHO-NNB), reinforcing its role in ensuring the quality and safety of biological products in line with international standards..

AUDA-NEPAD

- EDA-LR has been formally designated by AUDA-NEPAD as a **Regional Centre of Regulatory Excellence (RCORE)** in lot release function as well Staff member of the lot release administration representing EDA in the AMQF vaccines and other biological subcommittee, playing a key role in advancing global regulatory standards and scientific collaboration.



International Activities

African Regulators platform- PTB/PEI/AMRH

Paul-Ehrlich-Institut

Physikalisch-Technische Bundesanstalt Braunschweig und Berlin

AMRH African Medicines Regulatory Harmonisation Programme

Participation of lot release staff from the Egyptian Drug Authority in PTB-supported study tours and benchmarking workshops has played a key role in strengthening technical capacity and promoting harmonization of regulatory practices. Through engagement in regional platforms—including visits to institutions such as the South African National Control Laboratory (SANCL) and hosting the benchmarking workshop in Cairo—staff were exposed to international best practices in **risk-based lot release**, reliance models, and laboratory testing strategies. These activities facilitated knowledge exchange with global partners such as WHO, PEI, EDQM, and USP, and enhanced understanding of critical aspects including lot summary protocol review, data integrity, and post-approval changes.

german cooperation

Regulators' meeting at SACNL BP–
27 February until 1 March 2023

Group picture: 27 March 2023

AfriSummit

PHARMAREG AFRISUMMIT ONLINE ON-SITE

Participation of lot release staff from the Egyptian Drug Authority in **AfriSummit Pharma Reg 2023** as speakers highlighted EDA's leadership in advancing **harmonization of vaccine lot release regulations** across Africa. Their contribution focused on promoting risk-based approaches, reliance models, and alignment with international best practices to improve efficiency and ensure timely access to quality-assured vaccines, while strengthening collaboration among African regulatory authorities.

AUDA-NEPAD Laboratory Twining Program

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

LR staff actively contributed to the **Laboratory Twinning Program** as a key regional capacity-building initiative, coordinating multi-round engagements across Egypt, Senegal, and Botswana to strengthen vaccine testing and regulatory laboratory systems. The program combined **hands-on training, technical knowledge exchange, and joint problem-solving**, covering areas such as bioanalytical testing, lot release processes, laboratory infrastructure, and quality management systems. Facilitated structured needs assessments, delivered practical training on critical assays, and supported participating NRAs in applying risk-based lot release and reliance principles in real settings. The initiative also enabled **inter-laboratory collaboration, harmonization of practices, and development of joint action plans**, ultimately contributing to building sustainable technical capacity, advancing WHO-GBT maturity goals, and strengthening regional regulatory convergence

International Activities

AUDA-NEPAD/ RCORE

EAC RCE-VIHSCM (East African Community) & Ghana FDA

The Lot Release administration (LR) team together with laboratory evaluation administration team have played a pivotal role in advancing regulatory capacity across African countries through active participation in Regional Centres of Regulatory Excellence (RCORE) training programs, particularly in the domains of lot release and laboratory testing functions. Leveraging their technical expertise and practical experience, LR team members contributed as subject matter experts, delivering structured training modules aligned with WHO guidelines on independent lot release and quality control laboratory practices. These sessions covered key areas such as risk-based lot release decision-making, reliance and recognition pathways, evaluation of summary protocols, handling of out-of-specification (OOS) results, and integration of National Control Laboratory (NCL) testing within regulatory workflows.

In addition to theoretical instruction, the LR team facilitated case-based learning and scenario-driven discussions, drawing on real-world regulatory experiences to enhance participants' understanding of complex decision-making processes. The training also emphasized Good Review Practices (GRP), documentation standards, and cross-functional coordination between regulatory functions. Through these contributions, the LR team supported the strengthening of regulatory systems, promoted harmonization of lot release practices, and enabled participating National Regulatory Authorities (NRAs) and National Control Laboratories (NCLs) to adopt more efficient, science-based, and reliance-oriented approaches.

WHO NNB Meeting

World Health Organization

the LR team actively participated in the Sixth General Meeting of the WHO National Control Laboratory Network for Biologicals, where they engaged with global experts and peer National Control Laboratories to exchange experiences and best practices in lot release and laboratory testing. The meeting provided a platform to discuss advancements in reliance-based approaches, strengthening of quality management systems, and strategies to optimize laboratory efficiency while avoiding duplication of testing. Through this participation, the LR team contributed to global discussions on enhancing collaboration among NCLs, aligning with WHO standards, and advancing the implementation of risk-based and reliance-driven lot release systems.

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