Central Administration of Pharmaceutical Care
General Administration of Pharmaceutical Vigilance

Guideline

Guidelines on

Reliance Practices for Pharmacovigilance in Egypt

Year 2026

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Contents

I. Introduction

Since reliance pathways bring benefits to patients, industry and government, by facilitating and accelerating access to quality assured, effective and safe Human Products, Vaccines, Biomedicines products while saving resources and decreasing burden on assessors and regulators at Egyptian Drug Authority (EDA). Pharmaceutical Vigilance General Administration (PVGA) shall implement different reliance strategies for pharmacovigilance practices in Egypt.

II. Purpose

The purpose of this document is to promote a more efficient approach to implementing pharmacovigilance practices, by providing guidance, definitions, key concepts and illustrative reliance mechanisms and activities that are adopted and implemented by the Pharmaceutical Vigilance General Administration (PVGA) in assessment and evaluation of Human products, vaccines and biomedicines products.

III. Scope

This practice (reliance pathways) applies for the pharmacovigilance requirements in the frame of registration/re-registration of Human products, vaccines and biomedicines products as well as post authorization activities/decisions for the registered products in the Egyptian market.

IV. Abbreviations

EDA	Egyptian Drug Authority
PVGA	Pharmaceutical Vigilance General Administration
WHO	World Health Organization
WLA	WHO-Listed Authority
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
UMC	Uppsala Monitoring Centre
RRA	Reference Regulatory Authority
MAHs	Marketing Authorization Holders
EU-PSMF	European Pharmacovigilance System Master File
PV	Pharmacovigilance
NRA	National Regulatory Authority
ICSRs	Individual Case Safety Reports

V. Definitions and Concepts

- **Reliance:**

  The act whereby the regulatory authority in one jurisdiction may consider and give significant weight to assessments performed by another RA or trusted institution such as the WHO. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

- **Recognition:**

  Acceptance of the regulatory decision of another regulatory authority or trusted institution. Recognition should be based on evidence that the regulatory requirements of this reference regulatory authority are sufficient to meet the regulatory requirements of EDA. EDA adopts a unilateral recognition approach.

- **Abridged Registration:**

  Registration procedure that is facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. This allows saving resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained.

- **Information Sharing:**

  Exchanges and sharing of data and information on the safety of Human Products, Vaccines and Biomedicines products. This applies to sharing Individual Case Safety Reports, safety signals, and periodic safety updates with the reference regulatory authorities.

- **Reference Regulatory Authority:**

  A regulatory authority whose regulatory decisions, scientific evaluations, standards, and oversight activities are recognized as reliable and may be used by other regulatory authorities to inform or support their own regulatory decision-making processes.

VI. EDA's Approved List of Reference Countries

VI.1 Guiding Principles for Reliance

The Pharmaceutical Vigilance General Administration (PVGA) applies reliance practices in accordance with the principles of Good Reliance Practices issued by the World Health Organization (WHO).

Reliance activities implemented by PVGA shall be based on the following principles:

- Protection of public health and patient safety.
- Maintenance of the Egyptian Drug Authority's regulatory independence, accountability and responsibility for all regulatory decisions.
- Efficient use of available regulatory resources while maintaining appropriate scientific oversight.
- Transparency, consistency and scientific rigor in regulatory decision-making.
- Consideration of local factors including epidemiology, medical practice, healthcare infrastructure, product utilization patterns, and available national safety data.
- Application of a risk-based approach whereby the extent of reliance is proportionate to the nature of the product, complexity of the safety concern, public health impact, and availability of supporting evidence.
- Continuous monitoring of the effectiveness of reliance-based regulatory actions implemented in Egypt.

The EDA reference country list is approved by the Technical Committee for Drug Control in line with WHO criteria and as specified in the Notice to Applicants (Code: EDREX: NA. CAPP.089).

VII. Body of Data

Vigilance reliance can take many forms and encompasses a wide range of regulatory practices. It may be limited to certain regulatory process or functions or comprise the full scope of regulatory functions throughout the life cycle of human products, vaccines, and biomedicines.

The examples below illustrate the currently used reliance mechanisms in different pharmacovigilance regulatory activities/decisions at EDA.

VII.1 General Reliance Practices for Pharmacovigilance

VII.1.1 Sharing Information

- PVGA shares the safety of human products, vaccines, and biomedicines in the WHO global database of adverse event reports “VigiBase”, developed and maintained by the UMC and using EDA portals for sharing information such as official website and social media.

- PVGA may consider and give significant weight to regulatory assessments, safety communications, and regulatory actions issued by designated reference regulatory authorities and trusted institutions, while retaining full responsibility for the final regulatory decision taken within Egypt.

VII.1.2 Abridged Assessment

- PVGA reviews the published approved Risk Management Plan and Periodic Safety update Reports assessment by the reference regulatory authorities. Yet, PVGA assesses national reports, and may ask MAHs to perform additional pharmacovigilance activities and risk minimization measures tailored to the national context, if required.
- For the EU-PSMF, reliance practices may be applied whereby specific pharmacovigilance activities, processes, or system elements are supported through the established EU-PSMF. In such cases, the EU-PSMF serves as the primary reference document for the description of the pharmacovigilance system, and the information contained within it may be utilized to fulfil applicable regulatory requirements.
  When reliance on the EU-PSMF is used, the MAH remains fully responsible for ensuring that all pharmacovigilance obligations are met and that any nationally required adaptations, additional procedures, or supplemental documentation are implemented where necessary.

VII.1.1.3 Applying Reliance on the national level:

PVGA relies on the assessment of the stringent regulatory authorities of the PV documents and takes into consideration the information published concerning safety and efficacy issues by those authorities, PVGA may require specific changes/amendments/additional requirements to the recommended actions and implementation plan of risk minimization measures for it to be suitable and effective on the national level.
Examples of such situations:

1- When specific risks may be anticipated in (Egyptian population/ Egyptian Market or Healthcare system) that may not exist in the stringent regulatory authority.
2- When the suggested risk minimization activity implementation in Egypt is not applicable in the same method as in the stringent regulatory authority or may not be suitable to Egyptian Culture.
3- When different stringent regulatory authorities have different opinion/ assessment regarding a specific signal or risk.
4- In case local data provide additional evidence that may change the reliance on the stringent regulatory authority assessment.

VII.1.1.4 Reliance Decision Process

When applying reliance practices, PVGA may undertake the following activities, as applicable:

1. Identification of the regulatory decision, assessment report, safety communication, or regulatory action issued by a designated reference regulatory authority.
2. Verification of the authenticity and relevance of the information source.
3. Assessment of the applicability of the regulatory conclusions to the Egyptian context.
4. Review of available national safety data, local pharmacovigilance information, and product utilization patterns.
5. Determination of whether the foreign regulatory action should be adopted, adapted, supplemented, or not implemented within Egypt.
6. Communication and implementation of the resulting regulatory action.
7. Monitoring of the effectiveness of the implemented regulatory measures when applicable.

VII.2 Detailed Examples of Reliance Practices

VII.2.1 Evaluation of Emerging Safety Issues, Safety Variations, Safety Signals

For confirmed safety signals, safety variations and emerging safety issues identified by designated reference regulatory authorities, PVGA evaluates the available evidence and determines the applicability of the proposed regulatory actions to the Egyptian setting.

Based on this assessment, PVGA may adopt, adapt, supplement, or implement additional pharmacovigilance and risk minimization measures as deemed necessary to protect public health in Egypt.

VIII. References:

- WHO Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations, WHO Technical Report Series, No.1033, 2021
- EDA Chairman Decree 343 for the year 2021
- The list of EDA reference countries “Notice to Applicant” code: EDREX: NA. CAPP.089

  https://edaegypt.gov.eg/media/5d0kjyzg/notice-to-app-eda-reference-countries_ver2-2026.pdf

History Table

Version no.	Issue Date	Summary of Changes
Version 1.1	Nov 2024	Paragraph amended to reflect new technical decisions and country names removed Vl.2.1. Clarification added VII.1. Reference added
Version 2	Dec 2025	VI.1.2 Clarification added VI.1.3 Clarification added to clarify situations when the decision may vary from stringent authority
Version 4	May 2026	▪ Update the version number 4 ▪ Update cover letter content & the footer ▪ Page 2: ° Change “Document updates, Dec 2025” to “Document Changes Table” ° Version 4 to Version 4 ▪ Contents: ° Add IV. Abbreviations Section & rearrange Sections numbering. ▪ Change Medical Products to Human Products, Vaccines and Biomedicines products in the document. ▪ I. Introduction: ° Change EDA to full name Egyptian Drug Authority ▪ II.Purpose: ° Change EPVC to Pharmacovigilance General Administration PVGA ▪ V. Definitions and Concepts: ° Reliance: change NRA to regulatory authority ° Recognition: change “the” reference to this reference ° Sharing information: change WHO and other NRAs to reference regulatory authorities. ° Change SRA to reference regulatory authority and replace the criteria with the definition “*A regulatory authority whose regulatory decisions, scientific evaluations, standards, and oversight activities are recognized as reliable and may be used by other regulatory authorities to inform or support their own regulatory decision-making processes”.* ▪ VI. EDA’s list of Reference countries:

		a. Remove "on 31/12/2009, 16/09/2021, 18/1/2024 and 05/05/2026", change SRAs to reference regulatory authorities, and remove "EDA relies on the regulatory decisions and/or regulatory work products of the Regulatory Authorities of those countries while evaluating and assessing applications. b. Add new section "VI.1 Guiding Principles for Reliance" ▪ Add New Section After VI.1.3 Applying Reliance on the National Level "VI.1.4 Reliance Decision Process" ▪ Replace text "*PVGA relies on and takes into consideration the information published concerning safety and efficacy issues..."* with "*PVGA may consider and give significant weight to regulatory assessments, safety communications…".* ▪ *Replace the entire Section VI.2.1 as the current wording is still too close to automatic recognition.* ▪ VII. Body of data: Sharing information: Remove "of individual case reports of safety" and "for medicines and vaccines" Abridged assessment: replace "other stringent regulatory authorities such as EMA, MHRA, FDA, and/or Japan" with reference regulatory authorities. ▪ Add New Section Before References "VII.3 Documentation of Reliance Activities" ▪ VIII. References: Replace Technical Committee decision 18/1/2024 with the list of EDA reference countries "Notice to Applicant" code: EDREX: NA. CAPP.089. ▪ Remove Ministerial decree 820 for the year 2016.