Central Administration of Pharmaceutical Care
General Administration of Pharmaceutical Vigilance

Guideline

GUIDELINE ON

Reliance Practices for Pharmacovigilance in Egypt

Year 2025

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Version 1.1 Nov 2024	V	• Paragraph amended to reflect new technical decision 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

Contents

I. Introduction

Owing to the fact that reliance pathways bring benefits to patients, industry and government, by facilitating and accelerating access to quality assured, effective and safe medicinal products while saving resources and decreasing burden on assessors and regulators at 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 pharmaceutical and biological products.

III. Scope

This practice applies for the pharmacovigilance requirements in the frame of registration/re-registration of pharmaceutical and biological products as well as post authorization activities/decisions for the registered products in the Egyptian market.

IV. Definitions and Concepts

- **Reliance:**

  The act whereby the NRA in one jurisdiction may consider and give significant weight to assessments performed by another NRA or trusted institution such as the World Health Organization (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 the 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 a pharmaceutical or biological product. This applies to sharing Individual Case Safety Reports, safety signals, and periodic safety updates with the WHO and other NRAs.

- **Stringent Regulatory Authority (SRA):**

  A regulatory authority which is:
  (a) a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan;
  (b) or an ICH observer,
  (c) or a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.

V. EDA's Approved List of Reference Countries

EDA's list of reference countries is approved by the Technical Committee of Drug Control on 31/12/2009, 16/09/2021 and 18/1/2024 chosen according to the WHO criteria and its definition to the SRAs.

EDA relies on the regulatory decisions and/or regulatory work products of the Regulatory Authorities of those countries while evaluating and assessing applications.

VI. 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 function or comprise the full scope of regulatory functions throughout the life cycle of medicinal product.

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

VI.1 General Reliance Practices for Pharmacovigilance

VI.1.1 Sharing Information

- Pharmaceutical Vigilance General Administration (PVGA) shares the safety of medical products in the WHO database of individual case reports of safety, VigiBase and VigiLyze, developed and maintained by the Uppsala Monitoring Centre and using EDA portals for sharing information such as official website and social media.

- Pharmaceutical Vigilance General Administration (PVGA) relies on and takes into consideration the information published concerning safety and efficacy issues of pharmaceutical and biological products from the global authorities' especially international organization as World Health Organization (WHO) and stringent regulatory authorities (SRAs) included in the approved list of reference countries.

VI.1.2 Abridged Assessment

- Pharmaceutical Vigilance General Administration (PVGA) reviews the published approved Risk Management Plan and Periodic Safety update Reports assessment (PSUSA) by other stringent regulatory authorities such as EMA, MHRA, FDA, and/or Japan. Yet, PVGA assesses local reports, and asks Marketing Authorization Holders (MAHs) to perform additional activities and risk minimization measures tailored to the national context, if required.
- For the European Pharmacovigilance System Master File (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 Marketing Authorization Holder (MAH) remains fully responsible for ensuring that all pharmacovigilance obligations are met and that any locally required adaptations, additional procedures, or supplemental documentation are implemented where necessary.

VI.1.3 Applying Reliance on the domestic level:

Although Pharmaceutical Vigilance General Administration (PVGA) relies on the assessment of the stringent health authorities of the PV documents, and takes into consideration the information published concerning safety and efficacy issues by those authorities, PVGA may requires specific changes/amendments/additional requirements to the recommended actions and implementation plan of risk minimization measure for it to be suitable and effective on the domestic 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 authority.

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

VI.2 Detailed Examples of Reliance Practices

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

- For confirmed safety signals, safety variations, and/or emerging safety issues published by other Stringent Regulatory Authorities (SRAs), the Pharmaceutical Vigilance General Administration (PVGA) relies on and considers them and ensures risk minimization measures' implementation in Egypt after PVGA assessment and according to the national setting.

VI.2.2 Public health emergency

- For products to be authorized for Emergency Use, the Pharmaceutical Vigilance General Administration (PVGA) reviews the Risk Management Plan and Periodic Safety Reports by the Marketing Authorization Holder (MAH), and makes sure that the MAH has a functioning pharmacovigilance system globally and locally and asks Marketing Authorization Holders (MAHs) to perform additional activities and risk minimization measures tailored to the national context, if required.

VII. References:

- WHO Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations
- EDA Chairman Decree 184 for the year 2023
- EDA Chairman Decree 450 for the year 2023
- Ministerial decree 820 for the year 2016

- Ministerial decree 425 for the year 2015, article number 4
- EDA Chairman Decree 343 for the year 2021
- Ministerial decree 368 for the year 2012
- Technical Committee decision 18/1/2024