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GOOD PHARMACOVIGILANCE PRACTICES: A GENERAL REVIEW

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ABSTRACT
This review article primarily focuses on pharmacovigilance activities in the European Economic Area (EEA), which recently launched a new operational plan for the development of operational activity with anticipated timelines. It also focuses on Good Pharmacovigilance Practices (GVP), which analyze safety data from unrestricted reporting systems and have been shown to be valuable for identifying risks associated with marketed medicines. GVP also includes more modules of implemented guidelines. The EV system outlines the major initiatives and events that will affect or be related to it and its stakeholders during the course of the following three years, from 2018 to 2020. Protecting public health and supporting EU pharmacovigilance efforts are the primary goals of ensuring the sustainability of EV and related operations. In terms of dates and new initiatives/developments, the operation plan will be revised on a regular basis. A platform for learning, collaboration, and alignment throughout the development and operation of EV is also ensured by covering system contact with the stakeholders as part of training and communication engagement. Maintaining effective reporting standards to prevent adverse reactions and increasing the beneficial effects of drugs on the population are covered by GVP. The guidelines are based on pharmacovigilance processes and population or product specific considerations.

KEYWORDS: Good Pharmacovigilance Practice, Pharmacovigilance, World Health Organisation, Modules, European Medicine Agency.

INTRODUCTION
Pharmacovigilance (PV) is a crucial public health tool because of its ultimate goal of limiting risks and optimizing the benefits of pharmaceutical goods.[1][2] "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" is how the World Health Organization (WHO) defines PV.[3] Drug products must pass stringent examination and testing during clinical trials to prove their safety and efficacy before being approved by regulatory bodies.[4][5] The desire to lessen the drawbacks of pre-marketing/registration clinical trials, such as their limited sample sizes, short durations, and exclusion of certain population groups (such as minors and pregnant women), is the foundation for post-marketing PV.[6][7] Thus, it is common for unexpected or severe adverse drug reactions (ADRs) to go unnoticed prior to regulatory approval, increasing the risk of illness, death, and financial loss.[8][9] PV makes it possible to gather data on the safety and effectiveness of drugs after they are marketed, or in the real world, which lowers patient morbidity and death rates associated with drugs.[10] Additionally, PV lowers the financial burden of providing care for people who have these issues.[11][12] This is accomplished by sharing the advantages and hazards of medications, improving pharmaceutical safety throughout the healthcare system[13], as well as by offering data and expertise to support regulatory actions.[14][15][16]

It is crucial to remember that patient safety (PV) activities encompass the whole lifecycle of a drug product and are an extension and culmination of the analysis carried out on medications from pre-registration clinical trials.[17] They are also not restricted to safeguarding patient safety during the post-marketing period. PV also helps pharmaceutical companies with patient outreach by informing patients on the risk-benefit profile of their drugs, which helps them become more informed and increases their faith in the sector.[18] Insurance companies, who pay for pharmaceuticals collectively, use PV data to gauge the proven worth of pharmaceuticals to patients when determining whether to reimburse.[19]

The local contextual factors including healthcare spending, disease types and prevalence, and political climate impact the variations in PV systems in developing nations.[20] It is crucial that each nation create its own PV system since these variations can cause variations in the way that medications are used and the types of side effects that patients experience.[21] Following the thalidomide tragedy in the 1960s, the majority of wealthy nations began their PV endeavors by installing PV systems and enlisting in the WHO Programme for International Drug Monitoring (PIDM) Developing nations did not sign up for the WHO PIDM until the 1990s or later[22], but ever since then, the number of developing nations adopting PV and signing up for the program has risen consistently.[23][24]

National medicines regulatory authorities (NMRAs), as well as national and international legislative organizations, have released a significant quantity of legislation and guidance over the past few decades to give nations a legal framework and useful implementation guidelines for their national PV systems.[25] The European Medicines Agency (EMA) introduced the Guidelines on Good Pharmacovigilance Practices (GVP) in 2012 with the goal of facilitating PV in the European Union (EU).[26] The EMA's GVP recommendations are widely used by developing nations to establish their national photovoltaic systems, with the goal of bringing them into compliance with international standards.[25][27]

Objectives of Pharmacovigilance

The World Health Organization (WHO) defines pharmacovigilance as the study and practice of identifying, evaluating, comprehending, and averting side effects or any other medication-related issue. The underlying goals of the applicable legislation for pharmacovigilance, as per this general definition, are.

- Preventing harm from adverse reactions in humans resulting from the use of authorized medicinal products within or outside the terms of marketing authorization or from occupational exposure
- Promoting the safe and effective use of medicinal products, particularly by promptly informing patients, healthcare professionals, and the public about the safety of medicinal products. Thus, one activity that supports patient safety and public health is pharmacovigilance.

Structure of GVP

One main pharmacovigilance process is presented in each GVP Module. Pharmacovigilance activities are arranged by discrete yet interconnected processes. Furthermore, GVP offers instructions on how to carry out pharmacovigilance for particular product categories or populations (P parts) that consume medications. These GVP Considerations are applicable in addition to the Modules' process-related guidelines. While GVP is still being developed, certain other guidelines created by the European Medicines Agency (EMA) under earlier EU regulations are still recognized from a scientific standpoint in the Arab countries and are still in effect in theory (unless there are circumstances that make them incompatible with this guideline). Furthermore, those additional guidelines—which are mentioned under GVP for Arab Countries—may be changed at a later date.

- ♣ GVP Modules
- ♣ GVP P-parts
- ♣ GVP Annexes

Region's and countries' Pharmacovigilance Performance

All countries had average scores of 14.86 and median scores of 15.0/63. None of the nations met more than 40% of the WHO parameters, despite the fact that 51% of them had a total score that was higher than average and 49% had a score that was above the median. With an average total score of 15.89, the Middle East and North Africa had the greatest score, while Latin America and the Caribbean had the lowest (10.5). By contrast, the Middle East and North Africa had the highest median score (18.0), while South Asia had the lowest (10.0). Tanzania achieved the highest score (26.0). Djibouti, Syria, Myanmar, and Bahrain all received zero points. Performance of Key Indicators The average and median scores for the "Core" indications were 9.27 and 9.0, respectively, out of a possible score of 27. South Asia had the lowest average score (7.3), while East Asia and the Pacific had the highest (10.17). Conversely, Sub-Saharan Africa had the highest median score (11.5) among all regions. South Asia had the lowest (7.0). Nigeria, Indonesia, and Malaysia got the most (15.0) out of all the regions, while Bahrain, Syria, Djibouti, and Myanmar received zero points.It was reported that 80% of countries have PV rules in place, and 92% of countries had facilities for conducting PV operations. The information that was reported on the PV rules in Yemen, Cambodia, and Oman was inconsistent. Two studies[28, 30] in Oman found such laws to be in place, whereas a third study[29] found none at all. Regulations are in place in Yemen, according to Qato[29], however Alshammari et al.[28] suggested otherwise. Suwankesawong et al. and Chan et al. presented contradicting information for Cambodia. All of these instances used the most recent results that had been released.Regarding finances, just 35 percent of countries reported having regular financial resources available for PV operations, the majority of which were among the highest achieving nations overall. The data pertaining to this indication in Oman and the United Arab Emirates (UAE) was inconsistent; two research[28][30] claimed it was there, while another[29] said it wasn't. Regarding human resources, it was discovered that 75% of the countries had committed employees performing PV operations.

It was discovered that the majority of nations (86%) have a uniform form for reporting ADRs. Nevertheless, whether the form contained reporting by the general public, pharmaceutical errors, therapeutic ineffectiveness, misuse, abuse, or reliance on

medications, or counterfeit/substandard medicines, it was only noted in 16 nations.

Only four nations—China, Egypt, Ethiopia, and Uganda—were noted to have included PV in their national HCP curricula. There was either no mechanism in place or no knowledge of the existence of a PV information dissemination mechanism in 22 countries (43%). There were PV advisory committees in 63% of the nations. Qato[29] and Alshammari et al.[28] provided contradicting information about this indicator; the former said that Jordan and Tunisia had advisory committees, while the latter stated the opposite.

GVP: MODULES

Modules	Title	Last update	Legal effective date
I	Pharmacovigilance systems and their quality systems	25th June 2012	2nd July 2012
II	Pharmacovigilance system master file	30th March 2017	31st March 2017
III	Pharmacovigilance inspections	15th September 2014	16th September 2014
IV	Pharmacovigilance audits	11th august 2015	-
V	Risk management systems	30th march 2017	31st march 2017
VI	Collection, management and submission of reports of suspected adverse reactions to medicinal products	2nd august 2017	22nd November 2017
VI	Addendum I-duplicate management of suspected adverse reaction reports	2nd august 2017	22nd November 2017
VII	Periodic safety update report (PSUR)	12th December 2013	13th December 2013
VIII	Post authorization safety studies	12th Oct 2017	13th Oct 2017
VIII	Addendum I-Requirements and recommendations for the submission for the information on non-interventional post authorization safety studies	8th august 2016	9th august 2016
IX	Signal management	12th Oct 2017	22nd November 2017
IX	Addendum I-Methodological aspects of signal detection from spontaneous reports of suspected adverse reactions	12th Oct 2017	22nd November 2017
X	Additional monitoring	25th April 2013	25th April 2013
XV	Safety communication	12th Oct 2017	13th Oct 2017
XVI	Risk minimization measures: selection of tools and effectiveness indicators	30th march 2017	31st march 2017
XVI	Addendum I-Educational materials	15th December 2015	16th December 2015

Module I– Pharmacovigilance systems and their quality systems

I.A. Introduction

This module provides marketing authorization holders and medication authorities with guidelines for creating and maintaining quality-assured pharmacovigilance systems. Each Module of GVP describes how these organizations' systems work together to carry out particular pharmacovigilance procedures. A pharmacovigilance system is defined as one that is intended to monitor the safety of approved pharmaceutical products and identify any alterations to their risk-benefit balance. It is utilized by the holders of marketing authorizations and by the medicines authorities to carry out their duties. To carry out its pharmacovigilance duties, the pharmaceuticals authorities also uphold a pharmacovigilance system. Marketing authorization holders and medication authorities must set up and employ quality systems that are sufficient and efficient for carrying out their pharmacovigilance tasks.

Applying the quality system should be adjusted to the degree to which each pharmacovigilance task is essential to achieving the quality objectives for each medicinal product covered by a quality system by adhering to the overall quality objectives in I.B.4 and the guiding principle in I.B.5, which aim to meet the needs of patients, healthcare providers, and the public with regard to the safety of medicines. Generally speaking, the modal verb "shall" designate all applicable legal requirements in this module. The modal verb "should" be used to provide instructions for carrying out legal requirements.

I.B. Structures and processes

I.B.1. Pharmacovigilance system
I.B.2. Quality, quality objectives, quality requirements and quality system
I.B.3. Quality cycle
I.B.4. Overall quality objectives for pharmacovigilance
I.B.5. Principles for good pharmacovigilance practices
I.B.6. Responsibilities for the quality system within an organization
I.B.7. Training of personnel for pharmacovigilance
I.B.8. Facilities and equipment for pharmacovigilance
I.B.9. Specific quality system procedures and processes
I.B.10. Record management
I.B.11. Documentation of the quality system
I.B.12.Monitoring the pharmacovigilance system's and its quality system's efficacy and performance
I.B.13. Pharmacovigilance emergency preparedness planning in public health emergencies

Module II- Pharmacovigilance system master file

II.A. Introduction

The marketing authorization holder's pharmacovigilance system for one or more authorized medical goods is described in full in the pharmacovigilance system master file definition. The primary location of the marketing authorization holder's primary pharmacovigilance activities or the site of the qualified individual in charge of pharmacovigilance operations shall house the pharmacovigilance system master file. The pharmacovigilance system master file requirements, including upkeep, content, and related filings to national pharmaceuticals agencies, are covered in full by this module.

II.B. Structures and processes

II.B.1. Objectives
II.B.2. Registration and maintenance
II.B.3. The representation of pharmacovigilance systems
II.B.4. Details that will be included in the PSMF
II.B.5 Change control, logbook, versions and archiving
II.B.6. Pharmacovigilance system master file presentation

Module III – Pharmacovigilance inspections

III.A. Introduction

This module defines the roles of the various stakeholders and provides guidance on the organization, execution, reporting, and follow-up of pharmacovigilance inspections in the Arab countries. While III.C. addresses the general management of pharmacovigilance inspections in the Arab Countries, III.B. offers general guidelines. Pharmacovigilance inspections of marketing authorization holders or any companies hired to carry out marketing authorization holders' pharmacovigilance obligations shall be conducted by the national medicine's authorities in question in order to ascertain that marketing authorization holders comply with pharmacovigilance obligations established within an Arab Country and to facilitate compliance.

The pharmacovigilance system master file (PSMF), headquarters, records, documents, and any businesses that the marketing authorization holder employs to carry out pharmacovigilance activities may all be inspected by inspectors designated by the national medicines authority. The pharmacovigilance system master file, which will be used to guide inspection conduct, is specifically needed to be provided, upon request, by holders of marketing authorizations (see Module II).

The objectives of pharmacovigilance inspections are.

1. To ascertain if the holder of the marketing authorization has the facilities, processes, and staff necessary to fulfill their pharmacovigilance duties.
2. The objective is to detect, document, and manage instances of non-adherence that could jeopardize public health.
3. If enforcement action is deemed necessary, to base it on the findings of the inspection.

In the case of an Arab nation, the national medicines authority bears the task of confirming that the holder of the marketing authorization for a medical product meets the national pharmacovigilance standards. The primary site of the marketing authorization holder's pharmacovigilance activities or the office of the qualified individual in charge of pharmacovigilance is where the pharmacovigilance system master file should be kept. Pre-authorization inspections may be carried out by the national pharmaceuticals authority to confirm the precision and effective operation of the current or suggested pharmacovigilance system.

Inspection programmes for pharmacovigilance will be put into place. These will comprise of routine inspections scheduled based on risk assessments and ―for cause‖ inspections, which are initiated to investigate suspected non-compliance or possible hazards, typically affecting a particular product or products. The inspected entity shall receive the results of the inspection and have the right to comment on any non-compliance found. A corrective and preventive action plan should be implemented promptly by the holder of the marketing authorization to address any non-compliance.

III.B. Structures and processes

III.B.1. Inspection types
III.B.2. Inspection planning
III.B.3. Sites to be inspected
III.B.4. Inspection scope
III.B.5. Inspection process
III.B.6. Inspection follow-up
III.B.7. Regulatory actions and sanctions
III.B.8. Record management and archiving
III.B.9. Qualification and training of inspectors
III.B.10. Quality management of pharmacovigilance inspection process

Module IV – Pharmacovigilance audits

IV.A. Introduction

Regarding the pharmacovigilance system audits and the audit(s) of the quality system for pharmacovigilance activities, references to pharmacovigilance audit(s) and pharmacovigilance audit activities are considered to cover both. Module I pertain to the general overview and goals of pharmacovigilance systems and quality systems for pharmacovigilance activities, whereas each Module of GVP describes the particular pharmacovigilance processes. Throughout this Module, the modal verb "shall" refer to all applicable legal duties. The modal verb should is used to offer guidance for the application of legal obligations. Guidance on the function, context, and management of pharmacovigilance audit activity, as well as planning and carrying out legally mandated audits, are provided in this module.

This module aims to simplify and promote harmonization while making the pharmacovigilance audit process easier to conduct. It also encourages consistency and simplification of the audit procedure. A

risk-based approach to pharmacovigilance audits is supported by the principles in this module, which are in line with globally recognized auditing standards published by pertinent international auditing standardization organizations. The steps that marketing authorization holders can take to plan, carry out, and report on a single pharmacovigilance audit engagement are described in Section IV.B., along with the general structures and procedures that should be followed to determine which pharmacovigilance audit engagements are the most appropriate. The basic quality system and record management procedures for the pharmacovigilance audit procedures are also outlined in this section.

IV.B. Structures and processes

IV.B.1. Pharmacovigilance audit and its objective
IV.B.2. The risk-based approach to pharmacovigilance audits
IV.B.3. Quality system and record management practices

Module V – Risk Management Systems (Rev 1)

V.A. Introduction

It is acknowledged that there isn't much information available about a medicine's safety at the time of authorization. The small number of clinical trial participants compared to the intended treatment population, the restricted demographic in terms of age, gender, and ethnicity, the restricted co-morbidity, the restricted co-medication, the restricted conditions of use, the relatively short exposure and follow-up periods, and the statistical issues related to examining multiple outcomes are some of the factors contributing to this. A medicine is approved if, at the time of approval, it is determined that, for the designated indication(s), the risk-benefit ratio is favorable for the intended audience.

Almost every pharmaceutical medication carries a number of dangers, and each risk has a different level of severity, influence on specific patients, and potential consequences for public health. To be sure, not every risk—actual or potential—will have been recognized at the time an initial authorization is requested, and many dangers related to the use of a medication will only come to light and be defined after that. If specific issues found in pre- or post-authorization data and pharmacological principles are more closely considered when planning the pharmacovigilance activities required to characterize the safety profile of the medicinal product, the planning will be better. However, risk minimization or mitigation should always be achievable as a result of risk identification and characterization.

1. characterization of the medicinal product's safety profile, considering both known and unknown risks;
2. planning of pharmacovigilance activities to identify new risks, characterize existing risks, and broaden our understanding of the product's safety profile;
3. planning and carrying out risk mitigation and minimization strategies, as well as evaluating their efficacy.

Medicinal products might be subject to risk management at any stage of their development. On the other hand, the focus of this module is risk management during and after authorization. This guideline addresses concerns associated with both clinical and non-clinical safety. Furthermore, if a quality issue affects the product's effectiveness or safety, it can be relevant. Addressing situations where the product's disposal could present a specific risk due to residual active ingredient (such as patches) is also necessary. The concepts of risk minimization and the specifics of routine risk minimization procedures are covered in this module, but Module XVI goes into greater detail about specific extra risk minimization tools and how to monitor the efficacy of risk management.

V.B. Structures and processes

V.B.1. Terminology
V.B.2. Principles of risk management
V.B.3. Responsibilities for risk management within an organisation
V.B.4. Objectives of a risk management plan
V.B.5. Structure of the risk management plan
V.B.6. A thorough explanation of every component of the risk management strategy
V.B.7. RMP part I “Product overview”
V.B.8. RMP part II “Safety specification”
V.B.9. RMP Part III “Pharmacovigilance plan”
V.B.10. Plans for post-authorization efficacy studies" is component IV of the RMP.
V.B.11. RMP Part V “Risk minimisation measures”
V.B.12. RMP part VI “Summary of activities in the risk management plan by medicinal product”
V.B.13. "Annexes to the risk management," Part VII of the RMP
V.B.14. How the periodic safety update report and the risk management strategy relate to each other
V.B.15: Risk management plan evaluation guidelines
V.B.16. Quality systems and record management

Module VI –Handling and documenting side effects from pharmaceuticals

VI.A. Introduction

This module covers the requirements that apply to marketing authorization holders and national medicine authorities in Arab countries regarding the gathering, data management, and reporting of suspected adverse reactions (both serious and non-serious) connected to human use pharmaceuticals that are authorized in Arab countries. This module also includes recommendations for reporting newly discovered safety concerns or suspected adverse responses that arise under unique circumstances.

With regard to this Module, the definitions that follow will be used. This chapter also includes certain general guidelines that should be followed, which are stated in the ICH-E2A and ICH-E2D guidelines16.

- Unfavourable response
- The relationship between

- Overdosing, off-label usage, abuse, and exposure at work
- Pharmaceutical item• Individual Case Safety Report (ICSR)

VI.B. Structures and Processes
VI.B.1. Collection of reports
VI.B.2. Validation of reports
VI.B.3. Follow-up of reports
VI.B.4. Data management
VI.B.5. Quality management
VI.B.6. Special situations
VI.B.7. Reporting of ICSRs
VI.B.8. Reporting modalities

Module VII - Periodic safety update report (PSUR)
VII.A. Introduction
In the post-authorization phase, marketing authorization holders are required to provide periodic safety update reports (PSURs), which are pharmacovigilance documents designed to offer an assessment of the risk-benefit balance of a medical product at predetermined intervals. The national rule lays out the legal conditions for PSUR submission. The modal verb "must" in this Module refers to all applicable legal requirements. The modal verb "should" is used to provide guidance on how to implement legal requirements. This module offers instructions on how to prepare, submit, and evaluate PSURs. The following deadlines must be followed by each marketing authorization holder in order to submit PSURs for its own products to the national medicine authorities in the Arab countries.

1. The PSURs covering intervals up to 12 months (including exactly 12 months) must be submitted within 70 calendar days of the data lock point (day 0);
2. For PSURs covering intervals over 12 months, they must be submitted within 90 calendar days of the data lock point (day 0); the national medicines authorities' request will typically
3. Specify the timeline for submitting ad hoc PSURs; if not, they must be submitted within 90 calendar days of the data lock point.

VII.B. Structures and processes
VII.B.1. Objectives of the periodic update safety report (PSUR)
VII.B.2. Guidelines for assessing the risk-benefit ratio in PSURs and the range of data that must be disclosed
VII.B.3. Principles for the preparation of PSURs
VII.B.4. Reference information
Company core data sheet (CCDS)Other options for the reference product informationchanges to contraindications, warnings/precautions sections;addition to adverse reactions and interactions;addition of important new information on use in overdose.
VII.B.5. Format and contents of the PSUR
VII.B.6. PSUR quality systems at the marketing authorization holder level
VII.B.7. Employee education regarding the PSUR procedure

Module VIII – Post authorization safety studies
VIII.A. Introduction
A post-authorization safety study (PASS) is any study related to an approved medication that is carried out to determine the existence, nature, or extent of a safety hazard, validate the medication's safety profile, or assess the efficacy of risk control strategies. A PASS may be started, run, or funded by the holder of a marketing authorization voluntarily or in response to a mandate from the regulatory body for a drug. This module does not cover non-clinical safety studies and instead focuses on PASS, which are clinical trials or non-interventional studies. If all of the following conditions are met cumulatively, a PASS is non-interventional.
the prescription drug is given in the customary way in compliance with the marketing authorization terms;

- the medication is prescribed in compliance with the marketing authorization terms and conditions, as normal;
- The patient is assigned to a specific therapeutic strategy based on current practice rather than a trial protocol, and the choice to engage the patient in the study is explicitly separated from the prescription of medication;
- The patients receive no extra diagnostic or monitoring treatments, and the data is analyzed using epidemiological techniques. Studies classified as non-interventional are determined by the methodological strategy employed, not by their goals in terms of science. Database research and record reviews in which all relevant events have already occurred are examples of non-interventional studies (which may include case-control, cross-sectional, cohort, or other study designs that make secondary use of data). As long as the prerequisites outlined above are satisfied, non-interventional studies can also incorporate primary data collection (e.g., registries and prospective observational studies where the data come from standard clinical care). Blood samples, questionnaires, and interviews may be conducted for these research as routine clinical procedures.

In the event that a PASS qualifies as a clinical trial (also known as an interventional study), all national regulations in each Arab country pertaining to the pharmacovigilance of clinical trials and the interventional clinical trials of pharmaceuticals must be adhered to. This Module's objectives are to.

- Provide broad guidelines regarding the openness, scientific criteria, and quality requirements of non-interventional PASS carried out by holders of marketing authorizations either voluntarily or in response to a mandate from the regulatory body for medicines (VIII.B.);
- Describe the processes by which a holder of a marketing authorization may be required by

medicine authorities to carry out a clinical trial or a non-interventional study (VIII.C.2), and the effect that this requirement will have on the risk management system (VIII.C.3);

- Describe the steps that must be followed for non-interventional PASS in order to comply with VIII.C.4. requirements for protocol oversight and results reporting, and VIII.C.5. requirements for modifications to the marketing authorization after results.

VIII.B. Structures and processes
VIII.B.1. Scope
VIII.B.2. Terminology
VIII.B.3. Principles
VIII.B.4. Study registration
VIII.B.5. Study protocol
VIII.B.6. Data reporting on pharmacovigilance to pharmaceutical regulatory bodies
VIII.B.7. Publication of study results
VIII.B.8. Data protection
VIII.B.9. Quality systems, audits and inspections
VIII.B.10. Impact on the risk management system

Module IX – Signal management
This module's Section IX.B. attempts to give broad guidelines and specifications on the organizations and procedures related to signal management.

Section IX.C. of the module describes how these structures and processes are applied in the context of the regulatory bodies and pharmacovigilance departments of the Arab Countries.

IX.B. Structures and processes
IX.B.1. Sources of data and information
IX.B.2. Methodology for signal detection
IX.B.3. The signal management process
IX.B.4. Quality requirements

Module X– Additional monitoring
X.A. Introduction
The goal of pharmacovigilance, a crucial public health role, is to quickly identify and address any potential safety risks related to the use of pharmaceuticals. A medication is authorized if, at that point in time, its benefit-risk balance is deemed to be positive for a designated target group falling within the parameters of its approved indication (s).

But not every danger can be recognized at the time of first authorization, and some concerns related to using a medication surface or become more distinct throughout the post-authorization stage of the product's lifecycle. This guideline has strengthened the safety monitoring of pharmaceuticals by introducing a framework for increased risk proportionate post-authorization data collecting, which includes the idea of supplementary monitoring for specific pharmaceuticals.

There are two sections in this module.
X.B. offers broad guidelines on communication and transparency issues as well as how to allocate extra monitoring status to pharmaceuticals.

X.C. outlines the operation in the Arab countries with reference to the communication plan, the supervision of extra monitoring status, and the effect on pharmacovigilance efforts.

X.B. Structures and processes
X.B.1. Guidelines for giving a medication product additional monitoring status
X.B.2. Communication and transparency

Module XI - Public participation in pharmacovigilance.

Module XII: Ongoing benefit-risk assessment, regulatory action, public communication planning, and continuous pharmacovigilance.

Module XIII is no longer being worked on. Module XII will now cover all of the subjects that were initially planned to be addressed in this module.

Module XIV - International cooperation

Module XV – Safety communication

XV.A. Introduction
This module offers national medical authorities and marketing authorization holders (MAHs) guidelines on how to coordinate and exchange safety information across the Arab world. In order to achieve the goals of pharmacovigilance, which include encouraging the sensible, safe, and effective use of medications, preventing harm from adverse reactions, and supporting patient and public health protection, it is imperative that safety information be communicated to patients and healthcare professionals. The term "safety communication" refers to a broad range of information about medications, including legally required information found in product information such as the package leaflet (PL), summary of product characteristics (SmPC), and packaging label. Despite the fact that several concepts in this Module (such as Sections XV.B.1 and B.2).

apply to all forms of safety communication, the module itself concentrates on the dissemination of new or emerging safety information, which is defined as fresh information regarding a medication's risk that was previously unknown or has the potential to affect the benefit-risk ratio and usage guidelines. In this module, the word "safety communication" refers to new safety information unless otherwise indicated. When releasing significant new safety information on pharmaceuticals, it is vital to consider the expectations and opinions of all

relevant parties, including patients and medical professionals, as well as the applicable laws.

This Module addresses some aspects of the interaction with concerned parties and supplements the specific guidance will be given in Module XI on public participation as well as the guidance on communication planning will be given in Module XII.

XV.B. Structures and processes

XV.B.1. Objectives of safety communication
XV.B.2. Principles of safety communication
XV.B.3. Target audiences
XV.B.4. Content of safety communication
XV.B.5. Means of safety communication
XV.B.6. Effectiveness of safety communication
XV.B.7. Quality system requirements for safety communication

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