The Common Arab Guidelines in PV

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Outlines

Old Egyptian Guidelines

Current Situation in Arab World

The new Common Arab Guidelines in Pharmacovigilance
Old Egyptian Guidelines
Cascade of Released regulations and legal framework

Egyptian Guideline for Marketing Authorization Holders
Guidelines on Pharmacovigilance for Medicinal Products for Human Use

-Draft 01 /August 2011-

The Egyptian Pharmacovigilance Center (EPVC)
http://epvc.gov.eg/
EPVC Guidelines for MAHs

1. Requirements for Qualified Person for Pharmacovigilance (QPPV)
2. Detailed Description of the Pharmacovigilance System (DDSP)
3. Requirements for Risk Management Systems
4. Requirements for Reporting of Individual Case Safety Reports (ICSRs)
5. Requirements for Periodic Safety Update Reports
7. Overall Pharmacovigilance Evaluation and Safety-Related Regulatory Action
8. Guidelines for Marketing Authorization Holders and Competent Authorities on Pharmacovigilance Communication
Routine Pharmacovigilance

Activities ➔ 5
Additional Pharmacovigilance
Activities → 3
Current Situation in Arab World
Assessing the need

• With the increasing and ever-more stringent regulations in pharmacovigilance, the regulatory authorities face greater demands for patient welfare and safety.

• These in turn necessitate standard levels of monitoring and data analysis that ensure safe drug delivery.

• This can be only attained by well-structured pharmacovigilance centres backed-up with a robust legal framework and clear guidelines.
Situation in the Arab region ‘regulatory pharmacovigilance’

- Egypt, Saudi Arabia and Jordan already have very strong regulations in pharmacovigilance based in their drug regulatory authorities.
- Morocco has a collaborating PV center with the WHO.
- Tunisia has pharmacovigilance centres located outside drug regulatory authorities.
- United Arab Emirates, Oman, Kuwait, Iraq, Sudan and Syria has pharmacovigilance centres located within drug regulatory authorities.
Recent developments → Change in ideology

• **From** assessment of whether MAHs have infrastructures or not (described in Detailed Description of Pharmacovigilance System (DDPS)) **to** the concept of assessing the intelligence of such infrastructures (described now in Pharmacovigilance system master file (PSMF)).

• **From** assessing only Periodic Safety (described in PSURs) **to** assessing Benefit/Risk ratio (described in Periodic Benefit Risk Evaluation reports (PBRER)).
Recent developments ➔ Change in ideology

• **From** assessing only submitted documents **to** performing pharmacovigilance audits and inspections.

• **From** relying on Standard Operating Procedure (SOPs) of performance, **to** assessing quality systems as a whole.

• **From** depending only on DDL for urgent safety evaluation **to** make use of recent revolution of internet connection.

• **From** acting reactively **to** acting proactively by adding more weight to RMPs and risk minimization activities.

• **Adding** more weight on Public participation and international cooperation.
Moves by the Arab League

• Arab ministers of health came to a common decree (number 7) in their 37th regular meeting in March 2012 → ‘The Higher Technical Committee for Medicines’ was established with representatives from all Arab countries → create common Arab guidelines in pharmacovigilance, and in bioequivalence.

• This committee elected Dr. Amr Saad, head of the Egyptian centre, to lead the committee across all its rounds.

• The committee finished the final drafts of the two common guidelines which were submitted to the 41st regular ministers meeting March 2014 (decree number 9).
Guidelines adopted

• The new guidelines is mainly adapted from the newly-established international Good Pharmacovigilance Practice.
• Composed of 16 different modules.
• Together with some product/population specific considerations, as well as annexes and templates of submission.
• The Guidelines were published in March 2014 and the effective date will be 1st July 2015.
The new common Arab Guidelines in PV
Guideline on good pharmacovigilance practices (GVP)
For Arab Countries
Concept

With the strategic objectives to:

1. **Not reinvent the wheel**

2. **Harmonize with the new development in pharmacovigilance practices & regulations**

→ These guideline is greatly adopted from the European Good Pharmacovigilance Practices (EU GVP).

• which considered the most compatible ICH pharmacovigilance guideline thus the most widely applied pharmacovigilance practices in the developed European Countries.
Guideline on good pharmacovigilance practices (GVP) for Arab Countries - Overview

GVP: Modules

- Module I - Pharmacovigilance systems and their quality systems
- Module II - Pharmacovigilance system master file
- Module III - Pharmacovigilance inspections
- Module IV - Pharmacovigilance audits
- Module V - Risk Management Systems
- Module VI - Management and reporting of adverse reactions to medicinal products
- Module VII - Periodic safety update report (PSUR)
- Module VIII - Post authorization safety studies
- Module IX - Signal management
- Module X - Additional monitoring
- Module XI - Public participation in pharmacovigilance
- Module XII - Continuous pharmacovigilance, on-going benefit-risk evaluation, regulatory action and planning of public communication
- Module XIV - International cooperation
- Module XV - Safety communication
- Module XVI - Risk minimization measures: selection tools and effectiveness indicators
“Guideline on good pharmacovigilance practices (GVP) for Arab Countries” - Overview

• GVP: Modules

• GVP: P parts (Product- or population-specific specific considerations)

• GVP: Annexes
  • Annex I – Definitions
  • Annex II – Templates
  • Annex III – Other pharmacovigilance guidance
  • Annex IV – International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for pharmacovigilance
  • Annex V- Abbreviations
Structure of GVP

- Each GVP Module presents one major pharmacovigilance process.
- In addition, GVP provides guidance on the conduct of pharmacovigilance for specific product types or specific populations in which medicines are used (GVP P-parts).
- Within each chapters,
  - Section A provides introduction to the legal, technical and scientific context of the respective process.
  - Section B gives guidance which reflects scientific and regulatory approaches, formats and standards agreed internationally, Section B describes approaches which are considered in line with general current thinking in the field.
  - Section C focuses on the specifics of applying the approaches, formats and standards in the Arab Countries and other aspects of operating the respective process in the Arab Countries.
Module I– Pharmacovigilance systems and their quality systems
Module I– Pharmacovigilance systems and their quality systems

• For performing their pharmacovigilance activities, marketing authorization holders, medicines authorities shall establish and use quality systems that are adequate and effective for this performance.

• A pharmacovigilance system, like any system, is characterised by its structures, processes and outcomes.

• Each Pharmacovigilance system can have only one QPPV. A QPPV may be employed by more than one marketing authorisation holder (i.e. only in case of subcontracting to a third party organisation).
Responsibilities for the quality system within an organization

- Ensuring that the organisation documents the quality system;
- Ensuring that the documents describing the quality system are subject to document control in relation to their creation, revision, approval and implementation;
- Ensuring that adequate resources are available and that training is provided;
- Ensuring that suitable and sufficient premises, facilities and equipment are available;
- Ensuring adequate compliance management;
- Ensuring adequate record management;
- Auditing: reviewing the pharmacovigilance system including its quality system at regular intervals in risk-based manner to verify its effectiveness & introducing corrective and preventive measures where necessary;
- Ensuring that mechanisms exist for timely and effective communication, including escalation the non-adherence to the requirements of the quality and pharmacovigilance systems and taking corrective, preventive and escalation action as necessary;
• Critical pharmacovigilance processes and business continuity
  – Continuous safety profile monitoring and benefit-risk evaluation of medicinal products;
  – Establishing, assessing and implementing risk management systems and evaluating their effectiveness;
  – Collection, processing, management, quality control, follow-up for missing information, coding, classification, duplicate detection, evaluation and timely electronic transmission of individual case safety reports (ICSRs) from any source;
  – Signal management;
  – Scheduling, preparation (including data evaluation and quality control), submission and assessment of periodic safety update reports;
  – Meeting commitments and responding to requests from national medicines authorities, including provision of correct and complete information;
  – Interaction between the PV and product quality defect systems;
• Critical pharmacovigilance processes and business continuity- Cont.

– Communication about safety concerns between marketing authorization holders and national medicines authorities, in particular notifying changes to the risk-benefit balance of medicinal products;

– Communicating information to patients and healthcare professionals about changes to the risk-benefit balance of products for the aim of safe and effective use of medicinal products;

– Keeping product information up-to-date with the current scientific knowledge, including the conclusions of the assessment and recommendations from the applicable medicines authority.

– Implementation of variations to marketing authorizations for safety reasons according to the urgency required.
Module II- Pharmacovigilance system master file (PSMF)
Module II- Pharmacovigilance system master file (PSMF)

- The PSMF is a detailed description of the pharmacovigilance system used by the MAH with respect to one or more authorized medicinal products.

- Location
  - PSMF shall be located either at the site where the main pharmacovigilance activities of the marketing authorisation holder are performed or at the site where the qualified person responsible for pharmacovigilance operates.
  - Details about the location of the PSMF are required to be notified to the national medicines authority, and any change to the location shall be notified immediately to the national medicines authority.

- There is no requirement for variations for changes in the content of the pharmacovigilance system master file.

- The PSMF shall be maintained in a current state and be permanently available to the QPPV.
Module II- Pharmacovigilance system master file (PSMF) - Cont.

• PSMF Registration:

Each national medicines authority in the Arab Countries should manage a national list/database which provides a practical mechanism for maintaining up-to-date information about:

– the MAH's (or contractual partner) PSMF,
– its status,
– its location,
– the QPPV&/or LSR contact information and
– the products relevant to the pharmacovigilance system described in the PSMF
• Change control, logbook, versions and archiving:

Changes to the PSMF should be recorded, such that a history of changes is available (specifying the date and the nature of the change), descriptive changes to the PSMF must be recorded in a logbook.
Module II- Pharmacovigilance system master file (PSMF)- Cont.

- Information to be contained in the PSMF
  1. PSMF section on qualified person responsible for pharmacovigilance (QPPV)
  2. PSMF section on the organisational structure of the marketing authorisation holder
  3. PSMF section on the sources of safety data
  4. PSMF section on computerised systems and databases
  5. PSMF section on pharmacovigilance processes
  6. PSMF section on pharmacovigilance system performance
  7. PSMF section on quality system
  8. Annex to the PSMF
• Special considerations for the multinational MAHs/applicants
  two documents are required:

  – The PSMF (according to European Good Pharmacovigilance
    Practice which is the base for this guideline) and,

  – National pharmacovigilance sub-system file (national PSSF)
    which describes the key elements of pharmacovigilance activities in
    the Arab County concerned.
Module III – Pharmacovigilance inspections
The objectives of pharmacovigilance inspections are to:

- Determine that the marketing authorization holder has personnel, systems and facilities in place to meet their pharmacovigilance obligations;
- Identify, record and address non-compliance which may pose a risk to public health;
- Use the inspection results as a basis for enforcement action, where considered necessary.

Inspection types

- System and product-related inspections
- Routine and “for cause” pharmacovigilance inspections
- Pre-authorisation inspections
- Post-authorisation inspections
- Announced and unannounced inspections
- Re-inspections
- Remote inspections (This approach may also be taken where there are logistical challenges to an on-site inspection (e.g. a pandemic outbreak))
• When non-compliance with pharmacovigilance obligations is detected the medicines authority shall take the necessary regulatory action. What action is taken will depend on the potential negative public health impact of the non-compliance(s).

• Cooperation and Sharing of information:
The national medicines authorities in Arab Countries are encouraged to cooperate regarding pharmacovigilance inspections and in particular the following as applicable:
  – Training
  – Joint pharmacovigilance inspection
  – Exchange of information
Module IV – Pharmacovigilance audits
Module IV – Pharmacovigilance audits

- The MAH in the Arab Countries is required to perform regular risk-based audit(s) of their pharmacovigilance system, including audit(s) of its quality system to ensure that the quality system complies with the quality system requirements.

- The MAH shall place a note concerning critical and major audit findings of any audit relating to the pharmacovigilance system in the PSMF.

- Based on the audit findings, the MAH shall ensure that an appropriate plan detailing corrective and preventative action is prepared and implemented.
Module V – Risk Management Systems
• It is recognised that at the time of authorisation, information on the safety of a medicinal product is relatively limited.

• A medicinal product is authorised on the basis that in the specified indication(s), at the time of authorisation, the benefit-risk balance is judged to be positive for the target population.
Module V – Risk Management Systems

- Risk management has three stages which are inter-related and re-iterative:
  - Characterization of the safety profile of the medicinal product including what is known and not known.
  - Planning of pharmacovigilance activities to characterise risks and identify new risks and increase the knowledge in general about the safety profile of the medicinal product.
  - Planning and implementation of risk minimisation and mitigation and assessment of the effectiveness of these activities.
• Historically, risk management systems for medicinal products for human use was based solely on managing risks. However, when considering how to maximise, or indeed assess, the risk-benefit balance, risks need to be understood in the context of benefit.

• Both post-authorisation safety studies and post-authorisation efficacy studies may be a condition of the marketing authorisation in certain circumstances and for these studies they shall be included in the risk management plan (RMP).
• Risk management is a global activity. However, because of differences in indication and healthcare systems, target populations may be different across the world and risk minimisation activities will need to be tailored to the system in place in a particular country.

• Risk management, is applicable to medicinal products at any point in their lifecycle.
Module V – Risk Management Systems

Cont.

• Structure of the risk management plan
  – Part I  Product(s) overview
  – Part II  Safety specification
    • Module SI  Epidemiology of the indication(s) and target population(s)
    • Module SII  Non-clinical part of the safety specification
    • Module SIII  Clinical trial exposure
    • Module SIV  Populations not studied in clinical trials
    • Module SV  Post-authorisation experience
    • Module SVI  Additional requirements for the safety specification
    • Module SVII  Identified and potential risks
    • Module SVIII  Summary of the safety concerns
  – Part III  Pharmacovigilance plan
  – Part IV  Plans for post-authorisation efficacy studies
  – Part V  Risk minimisation measures (including evaluation of the effectiveness of risk minimisation measures)
  – Part VI  Summary of the risk management plan
  – Part VII  Annexes
• Formats for risk-management plans
  – **Integrated RMP** with all of the modules in one document (e.g. for innovators not having EU RMP, biosimilars….etc.);
  – **Abridged format** suitable for use for generic medicines;
  – **National Display of RMP** format suitable for any MAH/Applicants having EU RMP in place (whether innovators, generics or importers), submitted altogether with most updated version EU RMP.
Module VI – Management and reporting of adverse reactions to medicinal products
Module VI – Management and reporting of adverse reactions to medicinal products

• Scope: collection, data management and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use

• Only valid ICSRs should be reported

• Reporting time frames
  – Serious domestic valid ICSRs shall be reported to medicines authority in the Arab Country concerned by MAH within 15 days from the date of receipt of the reports;
  – Non-serious domestic valid ICSRs shall be reported to medicines authority in the Arab Country concerned by MAH within 90 days from the date of receipt of the reports.
  – Reporting of serious international valid ICSRs by MAHs may be required in some Arab Countries; consult with the national medicines authority for national requirements for these ICSRs.
Module VI – Management and reporting of adverse reactions to medicinal products

- Marketing authorisation holders responsibilities
  - Each MAH shall have in place a system for the collection and recording of all reports of suspected adverse reactions which are brought to its attention, whether reported spontaneously or occurring in the context of a post-authorisation study.
  - MAH shall establish mechanisms enabling the traceability and follow-up of adverse reaction reports. Pharmacovigilance data and documents shall be retained as long as the product is authorised and for at least 10 years after the marketing authorisation has ceased to exist.
Module VI – Management and reporting of adverse reactions to medicinal products

- Marketing authorisation holders responsibilities
  - MAH responsibilities apply to reports related to medicinal products for which ownership cannot be excluded on the basis of one of the following criteria: medicinal product name, active substance name, pharmaceutical form, batch number or route of administration.
  - MAH shall ensure that any information on adverse reactions, suspected to be related to at least one of the active substances of its medicinal products authorised in the Arab Country concerned, is brought to its attention by any company outside this Arab country belonging to the same mother company (or group of companies).
Module VI – Management and reporting of adverse reactions to medicinal products

• Reporting models of ICSRs
  – **Full electronic reporting:** the national medicines authority has an electronic regulatory submission environment, **Gateway**. To be compatible, the MAH must have a fully ICH E2B (R2) compliant pharmacovigilance system and ICH M2 ESTRI gateway; (i.e. MAH submit the valid ICSRs through ESTRI gateway);
  – **Partial electronic reporting:** The MAH submit the valid ICSRs as an XML file (e.g. through secured email or on CD…etc.; check the national requirements) to the pharmacovigilance department at the national medicines authority who will then import this submitted XML file into the “National Pharmacovigilance and Safety reports database” i.e. no gateway;
  – **Web-based reporting tool:** the national medicines authority provides such tool which has online functions enable the MAH to **generate and submit** a fully ICH E2B and M2 compliant Safety Messages (ICSRs). This is most beneficial for Small and Medium Size Enterprises (SMEs), which do not have the necessary IT in-house tools available (i.e. do not have a fully ICH E2B (R2) compliant pharmacovigilance system and/or ESTRI gateway in place).
  – **None electronic reporting:** MAH submit the valid ICSRs on CIOMs form (whether hard or soft copy);
Module VII - Periodic safety update report (PSUR)
• Periodic safety update reports (PSURs) are pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission by marketing authorisation holders at defined time points during the post-authorisation phase.
• The required format and content of PSURs in the Arab Countries are based on those for PSUR described in the European Good Pharmacovigilance Practice as well as for the Periodic Benefit Risk Evaluation Report (PBRER) described in the ICH-E2C(R2) guideline. In line with the national legislation, the report is described as PSUR in the GVP Modules in the Arab Countries.

• The “modular approach” of PSUR enables the common content of particular sections to be utilised interchangeably in PSURs and RMPs, hence, minimises duplication during the preparation.
Module VII - Periodic safety update report (PSUR)- Cont.

• Dates and frequency of PSUR submission:
  – According to the "list of EU reference dates“ which is adopted in the guideline.

• PSUR submission timelines:
  – within 70 calendar days of the data lock point (day 0) for PSURs covering intervals up to 12 months (including intervals of exactly 12 months); and
  – within 90 calendar days of the data lock point (day 0) for PSURs covering intervals in excess of 12 months;
  – the timeline for the submission of ad hoc PSURs requested by national medicines authorities will normally be specified in the request, otherwise the ad hoc PSURs should be submitted within 90 calendar days of the data lock point.

• To avoid duplication of efforts a single assessment of PSURs for different authorised medicinal products containing the same active substance should be performed in each Arab Country.
• Contents of the PSUR:
  – Part I: Title page including signature
  – Part II: Executive Summary
  – Part III: Table of Contents
  1. Introduction
  2. Worldwide marketing authorisation status
  3. Actions taken in the reporting interval for safety reasons
     – Actions related to investigational uses *(not applicable for generics)*
     – Actions related to marketing experience
  4. Changes to reference safety information
5. Estimated exposure and use patterns
   - Cumulative subject exposure in clinical trials (*not applicable for generics*)
   - Cumulative & interval patient exposure from marketing experience

6. Data in summary tabulations
   - Reference information
   - Cumulative summary tabulations of serious adverse events from clinical trials (*not applicable for generics*)
   - Cumulative and interval summary tabulations from post-marketing data sources
   - 7. Summaries of significant findings from clinical trials during the reporting interval (*not applicable for generics*)
8. Findings from non-interventional studies
9. Information from other clinical trials and sources
10. Non-clinical Data (not applicable for generics)
11. Literature
12. Other periodic reports
13. Lack of efficacy in controlled clinical trials (not applicable for generics)
14. Late-breaking information
15. Overview of signals: new, ongoing or closed
16. Signal and risk evaluation
17. Benefit evaluation
18. Integrated benefit-risk analysis for authorised indications
19. Conclusions and actions
20. Appendices to the PSUR
Module VIII – Post authorization safety studies
Module VIII – Post authorization safety studies

- A post-authorisation safety study (PASS) is defined as any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

- This guidance applies to non-interventional PASS which are initiated, managed or financed by a marketing authorisation holder and conducted in the Arab Country concerned.
Module VIII – Post authorization safety studies

• Roles and responsibilities of the MAH, for imposed non-interventional PASS as a condition to the marketing authorisation:
  – Develop a study protocol and submit it to the national medicines authority
  – Ensure the fulfilment of its pharmacovigilance obligations in relation to the study and that this can be audited, inspected and verified. (Adverse reactions/adverse events should be reported to medicines authorities in accordance with the provisions of Module VI. Procedures for the collection, management (including a review by the marketing authorisation holder if appropriate) and reporting of suspected adverse reactions/adverse events should be put in place and summarised in the study protocol.
  – Submit any substantial amendments to the protocol, before their implementation, to the national medicines authority/national scientific research ethics committee
  – MAH may be requested to submit the study progress reports to the medicines authorities
  – Submit a final study report, including a public abstract, to the national medicines authority/national scientific research ethics committee as soon as possible and not later than 12 months after the end of data collection
  – Evaluate whether the study results have an impact on the marketing authorisation and if necessary, submit to the national medicines authorities an application to vary the MA
Module VIII – Post authorization safety studies

• Following the review of the final study report, the national medicines authority may decide:
  ✔ Variation
  ✔ Suspension
  ✔ Revocation of the marketing authorisation

• The decision shall mention any divergent positions and the grounds on which they are based and include a timetable for the implementation of this agreed action.
Module IX – Signal management
Module IX – Signal management

• Signal defined: information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action. *For the purpose of GVP, only new information related to adverse effects will be considered.*
Module IX – Signal management

• Signal management process can be defined:
The set of activities performed to determine whether, based on an examination of individual case safety reports (ICSRs), aggregated data from active surveillance systems or studies, literature information or other data sources, there are new risks associated with an active substance or a medicinal product or whether known risks have changed.
Module IX – Signal management

• Signal management process steps:

✓ signal detection
✓ signal validation
✓ signal analysis & prioritisation
✓ signal assessment
✓ recommendation of action
✓ exchange of information
Module IX – Signal management

- Roles and responsibilities of MAH
  - Shall monitor the data in its ADRs database; as well as monitor the data in “National Pharmacovigilance and Safety reports database” to the extent of their accessibility (accessible in only some Arab Countries).
  - Shall validate any signal detected and shall forthwith inform the responsible medicines authority for signal detection with special attention to those in the list as published by the national medicines authority.
  - Should notify in writing as an Emerging Safety Issue to the medicines authorities in Arab Countries where the medicinal product is authorised, any safety issue arising from its signal detection activity which could have a significant impact on the benefit-risk balance for a medicinal product and/or have implications for public health.
Module IX – Signal management

• Roles and responsibilities of MAH
  – Should collaborate with the national medicines authority for the assessment of the signals by providing additional information upon request.
  – Should keep an audit trail of its signal detection activities.
Module X – Additional monitoring
Module X– Additional monitoring

- National Medicines Authorities, shall set up, maintain and make public a list of medicinal products that are subject to additional monitoring. European list is adopted.
- These medicinal products will be readily identifiable by an inverted equilateral black triangle ▼. That triangle will be followed by an explanatory statement in the summary of product characteristics (SmPC) as follows:

“This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section ....... for how to report adverse reactions.”

- A similar statement will also be included in the package leaflet.
- This explanatory statement should encourage healthcare professionals and patients to report all suspected adverse reactions.
Module XV – Safety communication
Module XV – Safety communication

- Objectives of safety communication
  - providing timely, evidence-based information on the safe and effective use of medicines;
  - facilitating changes to healthcare practices (including self-medication practices) where necessary;
  - changing attitudes, decisions and behaviours in relation to the use of medicines;
  - supporting risk minimisation behaviour;
  - facilitating informed decisions on the rational use of medicines.
Module XV – Safety communication

- Means of safety communication
  - Direct healthcare professional communication (DHPC)
  - Documents in lay language
  - Press communication
  - Website
  - Other web-based communications
  - Bulletins and newsletters
  - Responding to enquiries from the public
Module XV – Safety communication

- Processing of DHPCs, MAH should submit the following to the medicines authority (s) in the Arab Country (s) where the products are authorised:
  - Draft DHPC; and
  - The dissemination list
  - Timetable for disseminating the DHPC
  - Dissemination mechanism
Modules Underdevelopment

- Module XI - Public participation in pharmacovigilance
- Module XII - Continuous pharmacovigilance, ongoing benefit-risk evaluation, regulatory action and planning of public communication
- Module XIV - International cooperation
- Module XVI – Risk minimization measures: selection tools and effectiveness indicators
Thank you