

**UAE MOH Guidelines in Good Vigilance Practice (GVP)  
For Marketing Authorization Holders / Pharmaceutical  
Manufacturers  
In UAE**



**وزارة الصحة ووقاية المجتمع**  
**MINISTRY OF HEALTH & PREVENTION**

Drug Department  
Public Health Policies and Licensing Sector  
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## ACRONYMS

MOHaP	Ministry of Health and Prevention
DD	Drug Department
PVMD	Pharmacovigilance and Medical Device Section
EMA	European Medicine Agency
EURD	European Union reference dates
ICH	International Conference for Harmonization
ICSR	Individual Case Safety Report
LSR	Local Safety Responsible
MAH	Marketing Authorization Holder
PASS	Post Authorization Safety Study
PBRER	Periodic Benefit Risk Evaluation Report
PL	Package Leaflet
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person Responsible for Pharmacovigilance
RMM	Risk Minimization Measures
RMP	Risk Minimization Plan
RMS	Risk Management System
SmPC	Summary of Product Characteristics
WHO	World Health Organization

## Introduction

Pharmacovigilance (PV) has been defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.

This guideline was prepared as a result of the discussions and recommendations of the National Pharmacovigilance committee of the Ministry of Health and Prevention and other Local Health Authorities in UAE.

Since the national program for the vigilance of pharmaceutical drug information and poison, seeks to identify the side effects of drug, categorize, analyze, monitor, control, and assess the risks to find solutions to avoid them and to protect members of the community, as well as to identify the adverse interactions between them and chemical medicines or herbal and complementary medicines or food. And the program also seeks to promote continuing education for drug safety and monitoring side effects and educate pharmacists, doctors and community on the medicine safety reporting.

All pharmaceutical companies/ Marketing Authorization Holder (MAH) whose products are registered and marketed in UAE must have a system in place for documenting following Objectives:

- ✓ Pharmacovigilance systems and their quality systems
- ✓ Pharmacovigilance System Master File (PSMF)
- ✓ Pharmacovigilance Inspections
- ✓ Pharmacovigilance audits
- ✓ Risk management systems
- ✓ Management and reporting adverse reactions to medicinal
- ✓ Products Periodic safety update reports (PSURs)
- ✓ Post authorization safety studies
- ✓ Signal management
- ✓ Safety communication
- ✓ Risk minimization measures

**Pharmaceutical Manufacturer/ Marketing Authorization Holder (MAH) and qualified Person Responsible for Pharmacovigilance (QPPV) responsibilities:**

A pharmacovigilance system is defined as a system used by an organization to fulfill its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance.

A pharmacovigilance system, like any system, is characterized by its structures, processes and outcomes. For each specific pharmacovigilance process, including its necessary structures, a dedicated Module is included in GVP.

The MAH should ensure that it has an appropriate Pharmacovigilance System in place in order to assume responsibility and liability for its products on the market and to ensure that appropriate action may be taken when necessary. The MAH should therefore ensure that all information relevant to the risk-benefit balance of a medicinal product is reported to the PV section/ Drug Department/ UAE MOHAP in accordance to these guidelines.

When submitting an application for new Pharmaceutical Product registration, the Applicant, should submit a description of the pharmacovigilance System and submit proof that the services of a Qualified Person Responsible for Pharmacovigilance (QPPV), hereafter referred to as the QPPV, are in place.

The MAH shall have permanently and continuously at its disposal an appropriately QPPV resident in UAE. For multinational MAHs a local safety responsible (LSR) may be accepted Based in UAE. For local MAHs there should be a dedicated QPPV and he/she should be resident in UAE. The names and 24 hours contact details of the nominated QPPV and his alternate during absence should be submitted to PV section /Drug Department.

The MAH shall ensure that the QPPV has acquired adequate theoretical and practical knowledge for the performance of PV activities. The QPPVs should have a minimum of bachelor degree in pharmacy or medicine, a basic training in epidemiology and biostatistics

is desirable.

The QPPV shall be responsible for the establishment and maintenance of the marketing authorization holder's Pharmacovigilance System and therefore shall have sufficient authority to influence the performance of the quality system and the pharmacovigilance activities and to promote, maintain and improve compliance with the legal requirements.

The applicant/MAH should provide the following requirements in order to get QPPV approval:

1. Letter of appointment from the company not the agent
2. Training certificate in PV
3. Experience certificate in PV
4. List of products covered by the company
5. ADR case reports submitted in UAE. (Local companies to report ADR cases of their products to the department within one year of the appointment)
6. SOP of the PV officer.
7. Graduation certificate ( minimum Bachelor Degree in Pharmacy or Medicine)

### Pharmacovigilance System Master File (PSMF)

#### What is PSMF?

The Pharmacovigilance System Master File (PSMF) *is a detailed description of the Pharmacovigilance System used by the marketing authorization holder with respect to one or more authorized medicinal products.*

The content of the pharmacovigilance system master file should reflect global availability of safety information for medicinal products authorized for the MAH, with information on the pharmacovigilance system to the local or regional activities. Despite this fact, pharmacovigilance activities on the national level as described in the PSMF may not be applied to the same extent by all the MAH's national offices/ affiliates, furthermore, some additional national requirements and details may also apply. Accordingly, multinational

MAHs/Applicants should provide clear illustration of the key elements of both global pharmacovigilance system and national pharmacovigilance sub-system, highlighting the role of QPPV, which pharmacovigilance activities are carried out in the KSA, which are carried out in the headquarter/globally and how they integrate together.

For the Multinational MAH/Applicant the following two documents are required to have

1. **The PSMF** (according to European Good Pharmacovigilance Practice) and/ or,
2. **National pharmacovigilance system file (national PVSF)** which describes the key elements of pharmacovigilance activities in the UAE.

**The content of National PVSF is as follow:**

- Roles and Responsibilities of the Marketing Authorization Holder
- Monitoring of Compliance and Pharmacovigilance Inspections
- Qualified Person Responsible for Pharmacovigilance (QPPV)
- Pharmacovigilance Plan
- Organizational chart
- Quality Management System
- Requirements for Risk Management Systems: Clinical & Non-clinical Part of the Safety Specification
- Adverse Events/Adverse Reactions
- Identified and Potential Interactions including Food-Drug and Drug-Drug interactions
- Epidemiology
- The Risk Minimization Plan.
- Requirements for Expedited Reporting of Individual Case Safety Reports
- Requirements for Reporting in Special Situations

- Requirements for Periodic Safety Update Reports
- Training
- Documentation

#### Location of PSMF

The PSMF shall be located (physically) either at the site where the main Pharmacovigilance activities of the marketing authorization holder are performed or at the site where the QPPV operates.

#### PSMF and product registration:

Only a summary of the MAH pharmacovigilance system is required to be included in the marketing authorization application.

#### Changes to PSMF and Variations Applications

There is no requirement for variations for changes in the content of the pharmacovigilance system master file. PSMF will be kept up to date by the MAH, without the need of submitting variation applications. Only a notification letter and the updates should be submitted to PV section/ Drug Department.

### Risk Management System (RMS)

#### What is a Risk Management System (RMS)?

It is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimize risks relating to medicinal products including the assessment of the effectiveness of those activities and interventions.

#### What is a Risk Management Plan (RMP)?

A detailed description of the risk management system.

#### What is Risk minimization activity?



An intervention intended to prevent or reduce the probability of the occurrence of an adverse reaction associated with the exposure to a medicine or to reduce its severity should it occur.

### What are the obligations of MAHs for minimizing risk of medicines?

- Ensuring that they constantly monitor the risks of their medicines in compliance with relevant legislation and report the results of this, as required, to PV & DID.
- Taking all appropriate actions to minimize the risks of their medicines and maximize the benefits including ensuring the accuracy of all information produced by the company in relation to its medicines, and actively updating and communicating it when new information becomes available.

### Overview of the parts and modules of the RMP

The RMP is divided into several parts, with the safety specifications of the RMP organized into modules to increase flexibility.

**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-Authorization Experience

**Module SVII:** Identified and potential risks

**Module SVI:** Additional requirements for the Safety Specification in UAE

**Module SVIII:** Summary of the safety concerns

**Part III** Pharmacovigilance Plan

**Part IV** Plans for post-authorization efficacy studies

**Part V** Risk minimization measures (including evaluation of the effectiveness of risk minimization measures)

**Part VI** Summary of the RMP

**Part VII** Annexes

### Submission and updates for the RMP

- RMP for new molecules should be submitted with the registration application.
- RMP for new innovator, biological, and biosimilar should be submitted with the registration application.
- RMP for other registration status may be requested upon registration application.

### Reporting of adverse reactions to medicinal products

This guide addresses the requirements which are applicable to the PV Section , Drug Department, MOHAP, UAE, as regards the collection, data management and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use authorized in UAE. However, this guide does not address the collection, management and reporting of events or patterns of use, which do not result in suspected adverse reactions (e.g. asymptomatic overdose, abuse, off-label use, and misuse or medication error) or which do not require to be reported as individual case safety report or as Emerging Safety Issues. This information may however need to be collected and presented in periodic safety update reports for the interpretation of safety data or for the benefit risk evaluation of medicinal products.

#### Reporting time frames:

In general, the reporting of serious valid ICSRs is required as soon as possible, but in no case later than 5 working days after initial receipt of the information by any personnel of the marketing authorization holder, including medical representatives and contractors. This applies to initial information while follow-up information should be submitted within 15 calendar days. Where a case initially reported as serious becomes non-serious, based on new follow-up information, this information should still be reported within 15 days; the reporting time frame for non- serious reports should then be applied for the subsequent follow-up reports.

- Reporting of non-serious valid ICSRs is required within 90 days from the date of receipt of the reports marketing authorization holders.
- Direct report of Counterfeit cases is requested.

## Collection of reports:

### **A. Pharmacovigilance & Drug Information Department responsibilities**

Pharmacovigilance & Drug Information Department has in place a system for the collection and recording of unsolicited and solicited reports of suspected adverse reactions that occur in its territory and which are brought to its attention by healthcare professionals, consumers, or MAHs.

In this context, the reporting of suspected adverse drug reactions is possible by all health care providers, consumers and MAH by means of:

- Straightforward paper based reporting forms, reporting to PV @moh.gov.ae
- Online reporting system
- Smart phone application

### **B. Marketing authorization holders' responsibilities:**

1. 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 by healthcare professionals or consumers or occurring in the context of a post-authorization study.
2. MAH shall establish mechanisms enabling the traceability and follow-up of adverse reaction reports while complying with the data protection legislation. Pharmacovigilance data and documents relating to individual authorized medicinal products shall be retained as long as the product is authorized and for at least 10 years after the marketing authorization has ceased to exist.

### **Spontaneous reports**

MAHs shall record all reports of suspected adverse reactions originating from within or outside UAE, which are brought to their attention spontaneously by healthcare professionals, or consumers. This includes reports of suspected adverse reactions received electronically or by any other appropriate means.

### **Solicited reports**

MAHs shall record all reports of suspected adverse reactions originating from within or outside UAE, which occur in post-authorization studies, initiated, managed, or financed by them.

### **Case reports published in the scientific and medical literature**

MAHs should monitor all the active substances for which they hold a marketing authorization by accessing a widely used systematic literature review and reference database.

### **Suspected adverse reactions related to quality defect or falsified medicinal products**

When a report of suspected adverse reactions is associated with a suspected or confirmed counterfeit or falsified medicinal product or quality defect of a medicinal product, a valid ICSR should be reported. The seriousness of the ICSR is linked to the seriousness of the reported suspected adverse reactions.

MAHs should have a system in place to ensure that reports of suspected adverse reactions related to falsified medicinal products or to quality defects of a medicinal product are investigated in a timely fashion and that confirmed quality defects are notified separately to the manufacturer and to PV section, Drug Department, MOHAP, UAE.

### **Suspected transmission via a medicinal product of an infectious agent**

For the purposes of reporting, any suspected transmission of an infectious agent via a medicinal product should be considered as a serious adverse reaction and such cases should be reported within 15 days. If no other criterion is applicable, the seriousness of this ICSR should be considered as important medical event. This also applies to vaccines.

In the case of medicinal products derived from human blood or human plasma,

haemovigilance procedures may also apply. Therefore the MAH should have a system in place to communicate suspected transmission via a medicinal product of an infectious agent to the manufacturer, the relevant blood establishment(s) and PVMD / DD in UAE MOHaP.

### Emerging safety issues

Events may occur, which do not fall within the definition of reportable valid ICSRs, and thus are not subject to the reporting requirements, even though they may lead to changes in the known risk-benefit balance of a medicinal product and/or impact on public health. Therefore, they should be notified as Emerging Safety Issues in writing to the PVMD / DD in UAE MOHaP, where the medicinal product is authorized; this should be done immediately when becoming aware of them.

### Period between the submission of the marketing authorization application and the granting of the marketing authorization:

In the period between the submission of the marketing authorization application and the granting of the marketing authorization, information (quality, non-clinical, clinical) that could impact on the risk-benefit balance of the medicinal product under evaluation may become available to the applicant. It is the responsibility of the applicant to ensure that this information is immediately submitted in accordance with the modalities described to PVMD / DD in UAE MOHaP when the application is under assessment.

### Reporting time frames:

The general rules in relation to the reporting of initial and follow-up reports, including those for defining the clock start are detailed. Reporting timeframes are as follows:

- **Serious domestic valid ICSRs** shall be reported to PVMD / DD in UAE MOHaP, by MAHs **within 15 days** from the date of receipt of the reports;
- **Non-serious domestic valid ICSRs** shall be reported to DPV&DI, DGPA&DC, UAE

by MAHs **within 90 days** from the date of receipt of the reports.

- **Reporting of international cases** is required to be reported through the PSUR/PBRER.

## Periodic Safety Update Reports (PSURs)

### What is Periodic Safety Update Reports (PSURs)

Periodic safety update reports (PSURs) are PV documents intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission by MAHs at defined time points during the post-authorization phase.

The PSUR should focus on summary information, scientific safety assessment and integrated benefit-risk evaluation.

The obligations imposed in respect of PSURs should be proportionate to the risks posed by medicinal products. PSUR reporting should therefore be linked to the risk management systems of a medicinal product. As part of the assessment, it should be considered whether further investigations need to be carried out and whether any action concerning the marketing authorizations of products containing the same active substance or the same combination of active substances, and their product information is necessary.

The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the risk-benefit balance of the medicinal product taking into account new or emerging information in the context of cumulative information on risks and benefits. The PSUR is therefore a tool for post-authorization evaluation at defined time points in the lifecycle of a product. For the purposes of lifecycle benefit-risk management, it is necessary to continue evaluating the risks and benefits of a medicine in everyday medical practice and long-term use in the post-authorization phase.



### Format and contents of the PSUR:

The required format and content of PSURs 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. The PBRER format replaces the PSUR format previously described in the ICH-E2C (R1). **In UAE, the report shall be described and named as either as PSUR or PBRER.**

### Timelines for PSUR submission:

- 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; ad hoc PSURs** should be submitted **within 90 calendar days** of the data lockpoint.
- PSUR Frequencies to be harmonized with **EURD** calendar.

### Training of staff members related to the PSUR process:

For all organizations, it is the responsibility of the person responsible for the pharmacovigilance system to ensure that the personnel, including pharmacovigilance, quality personnel involved in the preparation, review, quality control, submission and assessment of PSURs are adequately qualified, experienced and trained according to the applicable guidelines.

## Post-authorization Safety Study (PASS)

### What is PASS?

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

A PASS may be initiated, managed or financed by a MAH voluntarily, or pursuant to an obligation imposed by PVMD / DD in UAE MOHAP.

- The Module concerns PASS which are clinical trials or non-interventional studies and does not address non-clinical safety studies. A PASS is non-interventional if the following requirements are cumulatively fulfilled:
- the medicinal product is prescribed in the usual manner in accordance with the terms of the marketing authorizations;
- the assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study; and
- No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

Non-interventional studies are defined by the methodological approach used and not by its scientific objectives. Non-interventional studies include database research or review of records where all the events of interest have already happened (this may include case-control, cross-sectional, cohort or other study designs making secondary use of data). Non-interventional studies also include those involving primary data collection (e.g. prospective observational studies and registries in which the data collected derive from routine clinical care), provided that the conditions set out above are met. In these studies, interviews, questionnaires and blood samples may be performed as part of normal clinical practice.

## Signal Management

A *signal* is defined as 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 an action.

The signal management process can be defined as 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.

The signal management process concerns all stakeholders involved in the safety monitoring of medicinal products including patients, healthcare professionals, MAHs, regulatory authorities, scientific committees. Whereas the ADRs database will be a major source of pharmacovigilance information, the signal management process covers signals arising from any source, only signals related to an adverse reaction shall be considered.

The signal management process covers all steps from detecting signals to recommending action(s) as follows:

- signal detection;
- signal validation;
- signal analysis and prioritization;
- signal assessment;
- recommendation for action;
- Exchange of information.

## Safety communication

Safety communication module provides guidance to MAH), national medicines authorities on how to communicate and coordinate safety information. Communicating safety information to patients and healthcare professionals is a public health responsibility and is essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicines, preventing harm from adverse reactions and contributing to the protection of patients' and public health. Safety communication is a broad term covering different types of information on medicines, including statutory information as contained in the product information (i.e. the Summary of Product Characteristics (SmPC), Package Leaflet (PL) and the labeling of the packaging).

The primary target audiences for safety communication issued by regulatory authorities and marketing authorization holders should be patients and healthcare professionals who use (i.e. prescribe, handle, dispense, administer or take) medicinal products

As primary target audiences, healthcare professionals play an essential role. Effective safety communication enables them to give clear and useful information to their patients, thereby promoting patient safety and confidence in the regulatory system. Both healthcare professionals in clinical practice and those involved in clinical trials should be provided with appropriate information on any safety concern at the same time.

Patient, consumer and healthcare professional organizations can play a role as multipliers as they can disseminate important safety information to target audiences. The media is also a target audience for safety communication. The capacity of the media to reach out to patients, healthcare professionals and the general public is a critical element for amplifying new and important information on medicines. The way safety information is communicated through the media will influence the public perception and it is therefore important that the media receives safety information directly from the national medicines authorities in addition to the information they receive from other

sources, such as from the MAHs.

### Means of Safety Communication

- Direct healthcare professional communication (DHPC)
- Documents in lay language
- Press communication
- Website
- Other web based communications
- Bulletins and newsletter
- Inter authorities communication
- Responding to enquiries from the public

## Risk Minimization Measures (RMM)

### What is RMM?

Risk Since the national program for the vigilance of pharmaceutical drug information and poison, and seeks to identify the side effects of drug and categorized and analyzed, and ways to monitor and control, as well as pharmaceutical and error how to assess the risks and find solutions to avoid them and to protect members of the community solutions and sick of the negative effects, as well as to identify the adverse interactions between them and chemical medicines or herbal and complementary medicines or food. And the program also seeks to promote continuing education for drug safety and monitoring side effects to him and educate pharmacists, doctors, community awareness of the reports of the safety of medicines measures are interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient should adverse reactions occur. Planning and implementing risk minimization measures and assessing their effectiveness are key elements of risk management. Risk minimization measures may consist of routine risk minimization or additional risk minimization measures. Routine risk minimization is applicable to all medicinal products, and involves the use of the following tools.

- the Summary of Product Characteristics (SmPC);
- the Package Leaflet (PL);
- the labeling;
- the pack size and design;
- The legal (prescription) status of the product.

Risk minimization measures aim to optimize the safe and effective use of a medicinal product throughout its life cycle. The risk-benefit balance of a medicinal product can be improved by reducing the burden of adverse reactions or by optimizing benefit, through targeted patient selection and/or exclusion and through treatment management (e.g. specific dosing regimen, relevant testing, patient follow-up). Risk minimization measures should therefore guide optimal use of a medicinal product in medical practice with the

goal of supporting the provision of the right medicine, at the right dose, at the right time, to the right patient and with the right information and monitoring. Additional risk minimization activities should only be introduced when they are deemed to be essential for the safe and effective use of the medicinal product and should be developed and provided by suitably qualified people.

## Educational programs

Are based on targeted communication with the aim to supplement the information in the summary product characteristics (SmPC) and package leaflet. Any educational material should focus on actionable goals and should provide clear and concise messages describing actions to be taken in order to prevent and minimize selected safety concerns.

### The aim of an educational program

Is to improve the use of a medicine by positively influencing the actions of healthcare professionals and patients towards minimizing risk. Educational materials should therefore be built on the premise that there is an actionable recommendation for targeted education and that applying this measure is considered essential for minimizing an important risk and/or for optimization of the risk-benefit balance. Ideally, educational materials should be available in a range of formats so as to ensure that access is not limited by disability or access to the internet. When feasible the appropriateness of the tool and media for the target audience (e.g. suitable language, pictures, diagrams, or other graphical support) should be user tested in advance, in order to optimize the success of the implementation phase.

### The content of any educational material

Should be fully aligned with the currently approved product information for a medicinal product, such as the SmPC and package leaflet, and should add rather than duplicate SmPC and package leaflet information. Promotional elements, either direct or veiled (e.g. logos, product brand colors, suggestive images and pictures), should not be included and the focus of the educational material should be on the risk(s) related to the product and the management of those risk(s) requiring additional risk minimization.

## Educational tools

Should focus on clearly defined actions related to specific safety concerns described in the RMP and should not be unnecessarily diluted by including information that is not



immediately relevant to the safety concern and that is adequately presented in the SmPC or package leaflet. Educational tools should refer the reader to the SmPC and the package leaflet. In addition to an introductory statement that the educational material is essential to ensure the safe and effective use and appropriately manage important selected risks, elements for inclusion in an educational tool could provide:

- guidance on prescribing, including patient selection, testing and monitoring;
- guidance on the management of such risks (to healthcare professionals and patients or carers);
- Guidance on how and where to report adverse reaction of special interest.

#### Educational tools targeting healthcare professionals:

The aim of any educational tool targeting a healthcare professional should be to deliver specific recommendation(s) on the use (what to do) and/or contraindication(s) (what not to do) and/or warnings (how to manage adverse reactions) associated with the medicine and the specific important risks needing additional risk minimization measures, including:

- selection of patients;
- treatment management such as dosage, testing and monitoring;
- special administration procedures, or the dispensing of a medicinal product;
- Details of information which needs to be given to patients.

The format of a particular tool will depend upon the message to be delivered. For example, where a number of actions are needed before writing a prescription for an individual patient, a checklist may be the most suitable format. A brochure may be more appropriate to enhance awareness of specific important risks with a focus on the early recognition and management of adverse reactions, while posters for display in certain clinical environments can include helpful treatment or dosage reference guides. Other formats may be preferable, depending on the scope of the tool.

#### Educational tools targeting patients and/or carers:

The aim of tools targeting patients should be to enhance the awareness of patients or their carers on the early signs and symptoms of specific adverse reactions causing the need for additional risk minimization measures and on the best course of action to be taken should any of those symptoms occur. If appropriate, a patient's educational tool could be used to provide information on the correct administration of the product and to remind the patient about an important activity, for example a diary for posology or diagnostic procedures that need to be carried out and recorded by the patient and eventually discussed with healthcare professionals, to ensure that any steps required for the effective use of the product are adhered to.

#### Patient alert card

The aim of this tool should be to ensure that special information regarding the patient's current therapy and its important risks (e.g. potential life-threatening interactions with other therapies) is held by the patient at all times and reaches the relevant healthcare professional as appropriate. The information should be kept to the minimum necessary to convey the key minimization message(s) and the required mitigating action, in any circumstances, including emergency. Ability to carry with ease (e.g. can be fitted in a wallet) should be a key feature of this tool.

## References

- 1. Pharmacovigilance Practice (GVP) for Arab Countries for Medicinal Products for Human Use (Version 3),**
- 2. International Conference for Harmonization (ICH)**
- 3. European Medicine Agency (EMA) guidelines.**