Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control

Department of Pharmacovigilance and Drug Information

Guideline on Good Pharmacovigilance Practices in Oman For MAHs/ Pharmaceutical Companies

Version 1, 2017

Contents

1. 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 has been developed to bring guidance on the requirements, procedures, roles and activities in the field of PV, for Marketing Authorization Holders (MAH) of medicinal products for human use in Oman. Pharmacovigilance obligations apply to all products available in Oman, including the registered and non-registered products.

All pharmaceutical companies/ Marketing Authorization Holder (MAH) whose products are registered and marketed in Oman have to have a system in place for documenting the objectives laid down in the GVP modules viz.,

1- Pharmacovigilance systems and their quality systems
2- Pharmacovigilance System Master File (PSMF)
3- Pharmacovigilance Inspections
4- Pharmacovigilance audits
5- Risk management systems
6- Management and reporting adverse reactions to medicinal products
7- Periodic safety update reports (PSURs)/ Periodic Benefit Risk Evaluation Report (PBRER)
8- Post authorization safety studies
9- Signal management
10- Safety communication
11- Risk minimization measures.

The requirements explained in this guideline are based on the Guideline on Good Pharmacovigilance Practice (GVP) for Arab Countries for Medicinal Products for Human Use (Version 2), International Conference for Harmonization (ICH) and the European Medicine Agency (EMA) guidelines.

2. Responsibilities of Marketing Authorization Holder (MAH) Pharmaceutical Companies/ and Qualified Person Responsible for Pharmacovigilance (QPPV):

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 Department of Pharmacovigilance & Drug Information (DPV & DI) fully and on time in accordance with the guideline.

When submitting an application for a marketing authorisation, the Applicant, in preparation for the role and responsibilities as MAH, 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 Oman or any other Gulf Cooperation Council (GCC) country. For multinational MAHs, who do not have a scientific office in any of the GCC countries can designate a local safety responsible (LSR), on behalf of the local agent in Oman. For local MAHs, there should be a dedicated QPPV and he/she should be resident in Oman. The names and 24 hours contact details of the nominated QPPV and his alternate during absence should be submitted to DPV&DI.

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.

3. 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.*

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.

Summary of the PSMF

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

Contents of PSMF

The PSMF contents and format shall be according to the current version of Arab GVP.

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 for changes to the 'PSMF Summary', Variation Applications should be submitted.

4. Pharmacovigilance Inspection

In order to determine that marketing authorisation holders comply with pharmacovigilance obligations, and to facilitate compliance, the DPV & DI will conduct, pharmacovigilance inspections of MAHs or any firms employed to fulfil marketing authorisation holder's pharmacovigilance obligations.

Pharmacovigilance Inspections will be routine as well as targeted to MAHs suspected of being non-compliant. The results of an inspection will be provided to the inspected MAH who will be given the opportunity to comment on the any non-compliance identified. In case that the outcome of the inspection of the marketing authorization holder does not comply with the pharmacovigilance obligations, the DGPA & DC shall take the necessary measures to ensure that a marketing authorization holder is subject to effective, proportionate and dissuasive penalties.

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;
- to identify, record and address non-compliance which may pose a risk to public health;
- To use the inspection results as a basis for enforcement action, where considered necessary.

For the structure and process of Pharmacovigilance Inspection, refer to the current version of Arab GVP.

What routine PV inspection may include

- Individual Case Safety Reports (ICSRs)
- Periodic safety update reports (PSURs)
- Ongoing safety evaluation
- Interventional (where appropriate) and non-interventional clinical trials
- Pharmacovigilance system

The inspection may also include the system for the fulfillment of conditions of a marketing authorization and the implementation of risk–minimization activities, as they relate to any of the above safety topics.

Obligations of MAH

Marketing authorization holders with authorized products and applicants who have submitted new applications are subject to pharmacovigilance inspections. Therefore, both have responsibilities in relation to inspections, including but not limited to the following:

- Always to be inspection-ready as inspections may be unannounced or in short notice.
- To maintain and make available to the inspectors on request, no later than 14 calendar days after the receipt of a request, the pharmacovigilance system master file.
- To ensure that the sites viz., the manufacturing site/the-scientific office responsible for PV activities/Local agent in the country, selected for inspection, which may include firms employed by the marketing authorization holder to perform pharmacovigilance activities, agree to be inspected before the inspection is performed.
- To make available to the inspectors any information and/or documentation required for the preparation of the inspection within the deadline given or during the conduct of the inspection.
- To ensure that relevant staff/ designated person involved in pharmacovigilance activities or related activities are present and available during the inspection for interviews or clarification of issues identified.
- To ensure that relevant pharmacovigilance data is accessible from one point.
- To ensure that appropriate and timely corrective and preventive action plans are implemented to address findings observed during an inspection, with appropriate prioritization of critical and/or major findings.

5. 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 minimise risks relating to medicinal products including the assessment of the effectiveness of those activities and interventions.

The MAHs shall submit global/EU or Core RMP as part of the risk management system.

What is a Risk Management Plan (RMP)?

A detailed description of the risk management system.

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 DPV & DI.

- 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 Oman (on request)

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

Note:

Generic products are exempted from submission of RMPs, however on request they need to adhere to any new safety measures as part of the RMP on request from the DPV & DI.

During New Registration of medicinal products, RMP shall be submitted along with eCTD dossier. Any RMP updates need shall be submitted to DPV & DI with a copy to Registration Section in Drug control department. The MAH is obliged to submit RMP on an emerging safety issue in situations that has particular reference to a region as well, on request from the DPV & DI.

RMP shall be submitted as EU/ Core or Global.

6. Management and reporting of adverse reactions to medicinal products

This guide addresses the requirements, which are applicable to the DPV & DI, 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 Oman. 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 all domestic serious valid ICSRs is required as soon as possible, but in no case later than **15** calendar days after initial receipt of the information by any personnel of the marketing authorization holder, including medical representatives and contractors. This applies to initial and follow-up information. 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 all domestic non-serious valid ICSRs is required within **90** calendar days from the date of receipt of the reports marketing authorization holders.

Collection of reports:

A. Department of Pharmacovigilance & Drug Information responsibilities

Department of Pharmacovigilance & Drug Information 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,
- Web-based formats (www.moh.gov.om).
- Mobile Smart Application: Esehaty.

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 that 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 Oman, 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 Oman, 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 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 DPV & DI.

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) to DPV & DI, DGPA & DC, Oman.

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 DPV & DI, DGPA & DC, Oman where the medicinal product is authorized or available; this should be done immediately on 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 DPV & DI, DGPA & DC, Oman, when the application is under assessment.

During this period, the MAH is not mandated to follow any reporting modality unless there is any emerging safety issue that need to be communicated to DPV & DI either manually or through the MOH website.

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 DPV & DI, DGPA & DC, Oman, 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, Oman by MAHs **within 90 days** from the date of receipt of the reports.
- Reporting of foreign / international cases is not required.

7. Periodic Safety Update Reports (PSURs)/ PBRER

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 scope, objectives, format and content of the PSUR are described in current GVP for Arab countries. The required format and content of PSURs are based on those 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). The primary objective of the PSUR was to provide a comprehensive picture of the safety of approved medicinal products. With recognition that the assessment of the risk of a medicinal product is most meaningful when considered in light of its benefits, the proposed report would provide greater emphasis on benefit than the PSUR, particularly when risk estimates change importantly. In such cases there will need to be an overall explicit evaluation of benefit- risk. Consequently, the name of the proposed report is the "Periodic Benefit -Risk Evaluation Report" (PBRER). The PBRER would also provide greater emphasis on the cumulative knowledge regarding a medicinal product, while retaining a focus on new information.

In Oman, the report shall be described / named and submitted as either PSUR or PBRER, which is based on the EU/ICH guideline.

Timelines for PSUR /PBRER 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 lock point.
- PBRER submissions for newly approved products shall be based on the EURD reference list.

Training of staff members related to the PSUR/ PBRER 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.

8. 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, characterising 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 DPV & DI.

- The Module concerns of PASS 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.

9. 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.

10. 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 labelling of the packaging).

The primary target audiences for safety communication issued by regulatory authorities and marketing authorisation 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 receive safety information directly from the national medicines authorities in addition to the information they receive from other sources, such as from the MAHs.

Content of safety communication:

Refer to current GVP for Arab countries.

Means of Safety Communication

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

Note:
Any safety update in any format, which need to be communicated to healthcare professionals or public, the same text format, should be approved by DPV & DI before it is communicated.

11. Risk Minimisation Measures (RMM)

What is RMM?

Risk minimisation 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 minimisation measures and assessing their effectiveness are key elements of risk management. Risk minimisation measures may consist of routine risk minimisation or additional risk minimisation measures. Routine risk minimisation 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 labelling;
- the pack size and design;
- the legal (prescription) status of the product.

Risk minimisation measures aim to optimise 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 optimising benefit, through targeted patient selection and/or exclusion and through treatment management (e.g. specific dosing regimen, relevant testing, and patient follow-up). Risk minimisation 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 minimisation 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 programmes

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 programme

Is to improve the use of a medicine by positively influencing the actions of healthcare professionals and patients towards minimising 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 minimising an important risk and/or for optimisation of the risk-benefit balance. Ideally, educational materials should be available in a range of formats 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 optimise 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 colours, 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 minimisation.

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 minimisation 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 that 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 minimisation 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 minimisation 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.

Other risk minimisation measures:

Controlled distribution systems

A controlled distribution system refers to the set of measures implemented to ensure that the stages of the distribution chain of a medicinal product are tracked up to the prescription and/or pharmacy dispensing the product.

Pregnancy prevention programme (PPP) is a set of interventions aiming to minimise pregnancy exposure during treatment with a medicinal product with known or potential

teratogenic effects. The scope of such a programme is to ensure that female patients are not pregnant when starting therapy or do not become pregnant during the course and/or soon after stopping the therapy. It could also target male patients when use of a medicinal product by the biological father might have a negative effect on pregnancy outcome.

Any additional risk minimization measures introduced on a product should be made known to the DPV& DI, DGPA & DC, Oman, and the proposal of the plan need to be submitted and prior approval need to be taken before implementing any such strategy.

ACRONYMS

DGPA & DC	Directorate General of Pharmaceutical Affairs and Drug Information
EMA	European Medicine Agency
GCC	Gulf Cooperation Council
GVP	Good Pharmacovigilance Practice
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
DPV & DI	Pharmacovigilance & Drug Information Department
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

References

1. Pharmacovigilance Practice (GVP) for Arab Countries for Medicinal Products for Human Use (Version 2),

2. International Conference for Harmonization (ICH)

3. European Medicine Agency (EMA) guidelines.