الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guideline on Good Pharmacovigilance Practices (GVP)

Draft

This document is a draft SFDA guideline published for comments and suggestions purposes. It is, therefore, subject to alteration and modification and may not be referred to as SFDA guideline until approved by SFDA

Guideline on Good Pharmacovigilance Practices (GVP)

Draft

Saudi Food & Drug Authority

Drug Sector

Please visit SFDA's website for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

- **What is new in version no. 3.2?**

The following table shows the update to the previous version:

Section	Description of change
VII.C.1. Standard submission schedule of PSUR/PBRERs	**Add (new)** The MAH should submit the PSUR/PBRER in CD or via DS@sfda.gov.sa for Medicinal product authorized in Saudi Arabia that contains a new chemical entity, Biological/Biosimilar medicinal products and first registered generics The MAH should submit the PSUR/PBRER submission plan annually via DS@sfda.gov.sa for Medicinal product authorized in Saudi Arabia that contains a new chemical entity, Biological/Biosimilar medicinal products and first registered generics
VII.B.5.3. PSUR/PBRER section "Actions taken in the reporting interval for safety reasons"	**Delete:** Submission of comprehensive signal evaluation report of potential signal based on SFDA request.
V.B.10.9. RMP annex 9: Saudi-Specific Annex (SSA)	**Update:** **Before**: The MAH must submit a SSA whenever an EU RMP (or alternative RMP where no current EU RMP exists) is submitted. **After**: The MAH must submit the SSA whenever an EU RMP (or alternative RMP where no current EU RMP exists) is submitted in pre-marketing during registration and post marketing phase where the RMP is updated or required for submission.
V.C.1. Requirements for the applicant/MAH in the KSA	**Update:** **Before:** For all new marketing applications, the applicant shall submit the RMP describing the risk management system, together with a summary. A SSA must be submitted with the RMP whenever an EU RMP (or alternative RMP where no current EU RMP exists) is submitted. **After:** For all new marketing applications, the applicant shall submit the RMP describing the risk management system, together with a summary. SSA must be submitted with the RMP in pre-marketing during registration and post marketing phase where the RMP is updated or required for submission (see V.B.10.9.).

V.C.1. Requirements for the applicant/MAH in the KSA	**Update** **Before:** With an application involving a change to an existing marketing authorization when the data included leads to a change in the list of the safety concerns, or when a new additional pharmacovigilance activity or a new risk minimization activity is needed or is proposed to be removed. The RMP update may be warranted as a result of data submitted with applications such as new or significant change to the indication, a new dosage form, a new route of administration, a new manufacturing process of a biotechnologically-derived product. **After:** - With an application involving a change to an existing marketing authorization when the data included leads to a change in the list of safety concerns, The RMP update may be warranted as a result of data submitted with applications such as a new or significant change to the indication, a new dosage form, a new route of administration, a new manufacturing process of a biotechnologically-derived product. - or when a new additional pharmacovigilance activity or a risk minimization activity is needed or is proposed to be removed. and after the approval of the new additional risk minimization activity.
V.C.1. Requirements for the applicant/MAH in the KSA	**Update:** **Before:** Post-authorization RMPs can be submitted through e-mail (NPC.Drug@sfda.gov.sa). **After:** Post-authorization RMPs can be submitted through e-mail (RM.drug@sfda.gov.sa).
V.C.1.1. Risk management plans with initial marketing authorization applications	**Add:** In the case of initial marketing authorization application of a new generic product of a non-SFDA registered reference product, all parts of an RMP should be submitted.

XV.B.5.1. Direct healthcare professional communication (DHPC)	**Update:** Before: Where there are several MAHs of the same active substance for which a DHPC is to be issued, a single consistent message should normally be delivered. **After:** Where there are several marketing authorization holders of the same active substance and/or a class of products for which a DHPC is to be issued, a single consistent message should be delivered (see XV.C.2.1.).
XV.C.2.1. Processing of DHPCs	**Add:** The SFDA may publish the final DHPC. Also, The SFDA may issue an additional safety announcement, and disseminate the DHPC to relevant healthcare professionals' organizations as appropriate. When several marketing authorization holders are concerned (i.e. when the DHPC covers several products with the same active substance or products of the same therapeutic class), marketing authorization holders are strongly encouraged to arrange for one marketing authorization holder to act on behalf of all concerned marketing authorization holders as the contact point for SFDA. Where generics are involved, the contact point should normally be the marketing authorization holder of the originator product. If no originator product is marketed, one of the concerned generic companies is encouraged to act as the contact point. Such coordination between concerned marketing authorization holders aims to ensure that healthcare professionals in Saudi receive a single DHPC covering all the medicinal products affected by a single safety concern (same active substance or a class review). The marketing authorization holder acting as contact point for the SFDA and on behalf of all other marketing authorization holders should be specified in the agreed communication plan.
GVP Annex III	**Add**: New annex has been added.
Xvi.add. I.2. Documents that should be submitted with the RMM	**Add:** "Translation Profession License" if there is Arabic version of educational materials.
XVI.Add.I.3.3. Requirement for the format of educational materials	**Add:** • The first draft of the aRMMs should be submitted in a word format or readable pdf. • After the initial approval of aRMMs content, MAH should submit a designed aRMMs for final approval.

I.C.1.2. Qualifications of the qualified person responsible for pharmacovigilance in KSA	**Add:** The training must cover at least pharmacovigilance competencies as following: Pharmacovigilance methods MedDRA coding. ICSRs processing activities Evidence based –medicine, how to conduct literature search. Causality assessment Case Narrative Writing for Reporting Adverse Events Pharmacovigilance quality management Introduction to pharmaco-epidemiology Biostatistics Basics of signal detection Medical Aspects of Adverse Drug Reactions Risk benefit assessment in Pharmacovigilance National pharmacovigilance regulations PSUR/PBRER overview RMP overview PSMF overview Risk communication, DHPC
I.C.1.2. Qualifications of the qualified person responsible for pharmacovigilance in KSA	**Update:** **Before**: the QPPVs should have basic training every two years in Pharmacovigilance, epidemiology, and have to be licensed by Saudi Commission for Health Specialties. **After**: Moreover, the QPPVs should have training every **three** years in Pharmacovigilance, epidemiology, and have to be licensed by Saudi Commission for Health Specialties.

VI.C.2.1.1. Spontaneous reports	**Add:** MAHs must have an Arabic webpage included the communication channels with the local QPPV. MAHs may consider utilizing this page to facilitate the collection of reports of suspected adverse reactions by providing adverse reactions forms for reporting, or appropriate contact details for direct communication (See VI.B.1.1.4).
I.C.1. Overall pharmacovigilance responsibilities of the applicant and MAH in KSA	**Add:** Moreover, any Marketing Authorization Holder (MAH) must register their full-time QPPV and Deputy through the Saudi Vigilance System registration form (https://ade.sfda.gov.sa/Qppv/Register). This registration must include an official MAH memo to the local QPPV, official contact details having names of the QPPV and Deputy and valid pharmacovigilance training certificates and thier qualifications.
II.C.3.2.4. National PSSF section on "computerized systems and databases"	**Add:** In addition, the MAH must periodically reconcile the line listing of received local ICSRs to ensure the completeness of the local database.
IX.C.1. Roles and responsibilities of MAH	**Delete:** 9.2. Taking the necessary actions in line with the suggestions by following the signals published every month under the heading "Recommendations of the Pharmacovigilance Risk Assessment Committee on Safety Signals" on the official EMA website. a. If the proposal requires any addition to SPC/PIL, the MAH of the original drug should apply to the SFDA for a variation according to section IX.C.3 and notify the NPC via email (npc.drug@sfda.gov.sa) within 7 calendar days of submitting the variation to the reference country. b. If additional information is requested from the MAH, this issue shall be notified to the NPC and additional information must be submitted to the SFDA as well at the same time as the EMA. c. Other proposals should be considered which including monitoring PBRERs, making routine pharmacovigilance, or reporting that there is no need to do anything at this stage. Documents demonstrating this situation should be archived and promptly presented to the SFDA upon request.
IX.C.1. Roles and responsibilities of MAH	**Delete:** 9.3. Taking the necessary actions in line with the suggestions by following the signals conclusions published under the heading “Drug Safety Update" on the Medicines and Healthcare products Regulatory Agency (MHRA) official website.

IX.C.1. Roles and responsibilities of MAH	**Delete:** 9.4. Taking the necessary actions in line with the suggestions by following the signals published every three months under the heading "Possible signal of new safety information/serious risks detected in the FDA adverse event reporting system (FAERS)" on the FDA's official website.
IX.C.1. Roles and responsibilities of MAH	**Delete**: 9.5. Taking the necessary actions in line with the suggestions by following the safety reviews conclusions/recommendations published periodically under the heading "Safety Reviews (MedEffect™ Canada)" on the Health Canada official website.
IX.C.1. Roles and responsibilities of MAH	**Add:** 9.2.Taking the necessary actions in line with the suggestions received from regulatory authority/health authority that is mentioned in the World Health Organization Listed Authority (WHO-WLAs) and have the vigilance function listed. The list is available in WHO website “List of WHO Listed Authorities WLAs”
IX.C.1. Roles and responsibilities of MAH	**Add:** 9.2.1 If the proposal requires any addition to SPC/PIL, the MAH of the original drug should apply to the SFDA for a variation according to section IX.C.3 and notify the NPC via email (npc.drug@sfda.gov.sa) within 21 calendar days of submitting the variation to the reference country.
IX.C.1. Roles and responsibilities of MAH	**Add:** 10. If any international regulatory authority not mentioned in WHO-WLAs, requested safety changes such as SPC/PIL update, the QPPV shall submit the MAH signal assessment report and cover letter to NPC via email (npc.drug@sfda.gov.sa) within 180 calendar days of that request in the reference country.