Republic of Iraq
Ministry of Health \ Environment
Directorate of Technical Affairs
Pharmacy Department
Iraqi Pharmacovigilance Center

Good Pharmacovigilance Practice Guideline

For Pharmaceutical Companies, Marketing Authorization Holders and their Representatives in Iraq

Pharmacovigilance Practice Guideline

IRAQI PHARMACOVIGILANCE CENTER

Good Pharmacovigilance Practice Guideline for Pharmaceutical Companies, Marketing Authorization Holders and their Representatives in Iraq V 2.0

Version	Author	Effective Date	Comments
1.0	Iraqi Pharmacovigilance Center	01.01.2020	Final Good Pharmacovigilance Practice Guideline for Pharmaceutical Companies, Marketing Authorization Holders and their Representatives in Iraq.
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SUMMARY OF MAJOR CHANGES IN VERSION 2.0

Section	Description of changes
Introduction	Removal of the medical devices from the coverage of this guideline
Abbreviations, Module VI and across the whole document	ADR added side by side with AE
Module I	Point 6 added: The IPC accepts delegation of all Pharmacovigilance activities to a third party that will represent the MAH.
Module II- 1: Pharmacovigilance System Master File (PSMF/PSSF)	A summary of the document is required, not a complete file document
Module II, III, VI, VII, XV and across the whole document.	Working days changed to calendar days
Module V	Add point regarding the exception from submission
Module VI- 1-B	Delete the following paragraph even if not associated with an adverse event which will be classified as a serious ADR
Module VI- 1- C, D	Delete the following paragraph: Even if not associated with an adverse event
Module VI-1-E	E – add – which will be considered as serious AEs/ADRs
Module VI-1- F	Delete the whole paragraph and change it to another updated details An unexpected therapeutic or clinical benefit from use of the product.
Module VI-2-C	Add: Time table for Medication errors, off- label use, adverse events resulting from quality complaints
Module VI-2-C, D	Add serious and non-serious timeline for reports other than AEs/ADRs
Module VI-2-D	Change time lines for no cases submission
Module VI- 4	Add: all types of studies including PASS and … Add: if no solicited reporting form is available at the end of the paragraph
Module VI-3-A	Split the paragraph
Module VI-5-B	The old paragraph replaced by a new one
Module VII-1- B	Add as point B: the submission for non EURD molecules
Module VII- 2-B	Cancel the need for table submission
Module VII-1-A,B	Delete and registration and add it above
Module IX-A	Inform IPC of all emerging safety issues replaced all emerging signals
Module IX-B	Inform IPC of all validated signals after final assessment within 14 calendar days replaced confirmed global signals within 2 months
Annex IV	Added PSMF/PSSF check list.

Table of Contents

Introduction

Monitoring the safety of medicinal products is considered as one of the main elements in assuring safe, effective and good quality products. Therefore and as is the case of other countries, there have been several circulars issued by the Iraqi Pharmacovigilance Center during the last years (2012-2017). These regulations focused on setting up the essential components that regulate the follow- up of safety of pharmaceutical products by their pharmaceutical companies in Iraq.

In order to keep up with the latest development of the field of Pharmacovigilance and medicinal products safety on the local, regional, and international levels, the current guideline included several amendments and updates on the previous regulations to cover the actual needs of Iraq in this perspective and to be in a harmony with the guidelines released by the corresponding departments of regional and international regulatory authorities.

The current guideline in its second version is divided into 12 active modules out of 16, according to the structure followed in the second version of the Good Pharmacovigilance Practice for Arab Countries, with more focus on the responsibilities assigned to each of the pharmaceutical companies / marketing authorization holders (MAHs) and their representatives and the Iraqi Pharmacovigilance Center. The current guideline cover all pharmaceutical products that are in use and considers all pharmaceutical companies, MAHs, Drug Scientific Bureaus that are working in Iraq both in the private and public sectors, as well as Iraqi Kurdistan Region.

The Iraqi Pharmacovigilance Centre prepared this guideline and the final version was issued following comments, discussions and suggestions from the Registration Department, National Board for Drugs Selection, KIMADIA/Media-unit, Pharmaceutical companies' local, regional and international representatives, Vigihub organization from Egypt, and ISOP Middle East chapter. In this updated version of the guideline, inputs received from all stakeholders were taken into consideration and the IPC will continue to update this guideline whenever required in the future.

Abbreviations

ADR	Adverse Drug Reaction
AE	Adverse event
CIOMS	Council for International Organizations of Medical Sciences
DHPC	Direct Healthcare Professional Communication
DLP	Data Lock Point
DTA	Directorate of Technical Affairs
EMA	European Medicine Agency
EURD List	European Union Reference Dates List
ICSR	Individual Case Safety Report
IPC	Iraqi Pharmacovigilance Center
LSR	Local Safety Responsible
MAH	Marketing Authorization Holder
NBDS	National Board for Drug Selection
PASS	Post-Authorization Safety Study
PBRER	Periodic Benefit Risk Evaluation Report
PSMF	Pharmacovigilance System Master File
PSSF	Pharmacovigilance System Sub Master File
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SDEA	Safety Data Exchange Agreement
QPPV	Qualified Person Responsible for Pharmacovigilance

Module I
Pharmacovigilance Systems & their Quality Systems

1. The Pharmaceutical Company / Marketing Authorization Holder (MAH) or its representative shall apply the Pharmacovigilance system within the organizational structure of the company and shall be responsible for its maintenance. The summary of the system (Summary of EU/Global PSMF) shall be submitted to the IPC during all post marketing stages when requested by the IPC. The registration department shall be notified upon registration and re-registration of biologicals.

2. The Pharmaceutical Companies / MAHs or their representatives are committed to name a medically qualified person (should have a minimum of bachelor degree of pharmacy or medicine) responsible for Pharmacovigilance activities in Iraq with the title Local Safety Responsible (LSR). The LSR should be Iraqi and a resident of Iraq.
3. Concerning representation of the Pharmaceutical Companies / MAHs in Iraq:

    a) The scientific bureaus or agents representing one or more pharmaceutical company / MAH operating in Iraq shall provide us with name(s) of company(ies) represented, name(s) of the medicinal products promoted by the agent and which are mentioned in the Safety Data Exchange Agreement (SDEA), and name(s) of their (LSR) / Qualified Person Responsible for Pharmacovigilance (QPPV) and the regional QPPV and their backup details (including for both; qualifications, courses attended, telephone number and e-mail address for communication).

    b) The Multinational pharmaceutical companies, having branches in Iraq wishing to deal directly with the IPC, may send names of their QPPV in addition to the nominated LSR in Iraq, QPPV/ LSR and the backup details (including for both qualifications, courses attended, telephone number, e-mail address for communication) and name(s) of their medicinal products.

    c) The QPPV/ LSR and the backup must have specific Pharmacovigilance training; provided that training should cover the subjects shown in (Annex 1), including the basic and/or additional trainings depending on the representation level. The pharmaceutical company / MAH or the

scientific bureaus shall provide us with evidence proving that their representatives have attended the basic and /or additional training; and should provide the topics trained on.

d) In the event that the pharmaceutical company/ MAH or its agent(s), the scientific bureau is unable to train the LSR/QPPV and the backup, the IPC must be notified accordingly by a formal letter so as to enable the center to perform the basic training and coordinate with the relevant authorities including international organizations, etc. The pharmaceutical company/ MAH or scientific bureau should bear all expenses of their nominees' trainings.

4. The pharmaceutical company/ MAH or its representative in Iraq shall provide, upon request, the IPC with SDEA, or its equivalent file, signed by the pharmaceutical company/ MAH and its representative in Iraq, concerning the following up of the safety of medicinal products in Iraq. Such agreement shall indicate the responsibility of each party regarding: training, ICSR management, submission timelines, reconciliation, archiving, etc.

5. The pharmaceutical company / MAH or its representative in Iraq, each shall be responsible for managing and maintaining their quality system related to Pharmacovigilance that will be run by QPPV / LSR. This system must be effective to maintain the performance and its improvement.

6. The IPC accepts delegation of all Pharmacovigilance activities to a third party that will represent the MAH.

Module II

Pharmacovigilance System Master File (PSMF/PSSF)

1. The pharmaceutical company / MAHs shall prepare and approve the Pharmacovigilance system master file (Global/EU PSMF), containing detailed description of the Pharmacovigilance system assigned for one medicinal product or a set of medicinal products. For companies / MAHs having branches in Iraq, a local PSMF shall be prepared. The mentioned file summary shall be available upon registration and/or re-registration of biologicals copying the IPC and upon request from the IPC within 14 (fourteen) calendar days from date of request (Annex 2).

2. The pharmaceutical company / MAH representative in Iraq shall submit the PSSF within 14 (fourteen) calendar days upon request from the IPC and the file must be kept at the location of the representative (LSR) and its contents shall be as indicated in (Module II clause C.3.2) of the Good Pharmacovigilance Practice Guideline for Arab countries (Annex 3).

3. The pharmaceutical companies/MAHs and their representatives shall maintain the PSMF/PSSF as illustrated in point 1 and 2 above without the need to refer to or notify the IPC of the updates and it should be maintained as indicated in (Module II clause B.4) of the Good Pharmacovigilance Practice Guideline for Arab countries (Annex 4).

4. In case a third party specialized in Pharmacovigilance, work for the pharmaceutical company/ MAH or the scientific bureau (the third party), PSMF may replace the PSSF after making amendments specific to Iraq.

Module III
Pharmacovigilance Inspection

1. IPC shall periodically visit the pharmaceutical companies/ MAHs and scientific bureaus in Iraq to follow up with the implementation of the Pharmacovigilance requirements.

2. The visits (virtual or onsite) shall be conducted in an announced or unannounced manner to the pharmaceutical company / MAHs and the scientific bureaus representing them. The pharmaceutical company/ MAH or its representative shall provide all the inspection requirements (files and/or workers, etc.).

3. The pharmaceutical company / MAH and its representative shall be notified of the inspection plan and the type of files required (Standard operative procedures, RMPs, interviews, presentations, etc.) two months prior to the start of the inspection in case announced.

4. The inspection team shall take notes and present them to the pharmaceutical company/ MAH or its representative. In the event of major or critical findings, the inspection team shall send the inspection report within 30 calendar days after the day of inspection, and the pharmaceutical company/ MAH or its representative shall inform the IPC of the corrective and preventive plan within a period of time to be agreed upon. After the agreed period, the pharmaceutical company / MAH or its representative shall submit final report about the closure of all corrective and preventive actions

5. During the inspection, "The Audit Report" that illustrates the internal audits findings may be requested by the IPC for review

Module IV
Pharmacovigilance Audits

1. The pharmaceutical company / MAH and its representative(s) shall conduct a periodical audit of its Pharmacovigilance system as well as its quality system. The dates and results of the audit must be documented and followed.
2. Based on the audit results, the pharmaceutical company / MAH and its representatives(s) shall prepare and implement an appropriate plan with details of corrective and preventive actions.
3. The Pharmaceutical Company/ MAH and its representative(s) shall maintain a list of all completed, and planned audits as described in the Pharmacovigilance system master file annex together with documenting and following up all dates and results of the audits.

Module V
Risk Management Plan (RMP)

1. The pharmaceutical companies / MAH shall directly or through their representatives in Iraq submit the file of risk management and minimization plan to the IPC in the following cases:
   a) For all new registrations and renewals of all pharmaceutical products.
   b) When there are significant changes to the medication, for example introducing new indications, adding a new age group.
   c) Upon release of an updated version of a previously submitted RMP by the pharmaceutical company/ MAH.
   d) Upon request by IPC.
   e) The registration department shall be also notified during registration and re-registration of biological products, in addition to the IPC.
2. Files are accepted in the two formats EU /Core or global, except for Biologicals where the files must be EU/RMP format.

3. The Pharmaceutical companies / MAH or its representative shall highlight/define the activities to be implemented in Iraq when submitting the RMP to IPC.

4. The IPC shall study the file and inform the relevant parties (when needed) and the pharmaceutical company / MAH or its representative in case there are comments on the implementation of the plan clauses.

5. The pharmaceutical companies / MAH shall directly or through their representatives in Iraq answer the comments and agree on the clauses that will be implemented in Iraq.
6. The pharmaceutical companies / MAHs directly or through their representatives have the right to apply for an exception from RMP submission with proper reasoning and the IPC has the right to accept or reject the application.

Module VI
Management & Reporting of Adverse Reactions to Medicinal Products

1. The pharmaceutical companies / MAHs or their representatives shall follow up on the safety and effectiveness of their medicinal products in Iraq and inform the IPC with the following domestic data:

    a. Expected and unexpected serious and non-serious adverse events (AEs)/ adverse drug reactions (ADRs).

    b. Decreased or lack of efficacy including cases of drug resistance.

    c. Medication errors associated with serious or non-serious AEs/ADRs.

    d. Off-Label use associated with serious and non-serious AEs/ADRs.

    e. Cases of suspected transmission of any infectious disease(s), through contaminated drug, vaccines, blood products and biologicals which will be considered as serious AEs/ADRs.

    f. Serious and non-serious AEs/ADRs associated with quality complaints including counterfeit and substandard products.

2. The pharmaceutical company / MAH or its representative shall report the mentioned above data, to the IPC according to the following timelines:

    a. All domestic serious and fatal cases shall be reported within 15 (Fifteen) calendar days from date the report is received by the pharmaceutical company/ MAH or its representative (day zero).

    b. Non-serious domestic cases shall be reported within 90 (ninety) calendar days from date the report is received by the pharmaceutical company/ MAH or its representative (day zero) using CIOMS or E2B (R2 or R3) and not line listing.

    c. Serious reports of decrease or lack of efficacy, medication errors, off- label use, cases of suspected transmission of any infectious disease(s); through contaminated drug, vaccines, blood products and biologicals and AEs/ADRs associated with quality complaints including counterfeit and

substandard products to be submitted within 15 calendar days from date the report is received by the pharmaceutical company/ MAH or its representative (day zero).

d. Non serious reports of decrease or lack of efficacy, medication errors, off- label use through vaccines, blood products and biologicals and AEs/ADRs associated with quality complaints including counterfeit and substandard products to be submitted within 90 calendar days from date the report is received by the pharmaceutical company/ MAH or its representative (day zero).

e. If there are no cases, we shall be notified periodically every six months (last week of January and the last week of July).

f. The above dates shall be adhered to in follow-up reports. If the initial report is serious, the follow-up report shall be complied with the same reporting dates, even if the case is downgraded.

3. The above-mentioned reports can be sent as paper based official mail or through e-mail to iqphvc@yahoo.com and iraqiphvc@moh.gov.iq as follows:

   a. Using the CIOMS form officially approved by the IPC (for MAH with no E2B system).

   b. Electronically through E2B system (R2, R3) and all the companies that apply this system are obliged to send reports via XML file to the above e- mail addresses; provided that one file shall not contain more than (20 reports).

   c. The language accepted in the reports is English.

   d. Companies / MAHs can report the domestic cases either from inside or outside of Iraq.

4. The pharmaceutical companies / MAHs or their representative shall inform IPC about all reports in Iraq issued as a result of all types of studies including Post Authorization Safety Studies (PASS) or Observational Studies. If no solicited reporting form is available; CIOMS and E2B (R2, R3) are accepted to report case(s) observed in a particular study. (see module VIII)

5. The IPC shall:
   a. Confirm receipt of the report(s).
   b. Publish an annual report of the ICSRs statistics available in the data on the MOH and DTA official websites.

Module VII
Periodic Safety Update Report/ Periodic Benefit-Risk Evaluation Report (PSUR –PBRER)

1. The pharmaceutical company/ MAH shall prepare periodic safety updated reports (PSUR/PBRER) that include identification of changes in the risk-benefit balance and follow up on the effectiveness to be presented to IPC (and to the registration department for biologicals) for all registered medicinal products periodically as follows:
    a. PSUR/PBRER submission frequencies to be harmonized with EMA European Union Reference Dates (EURD) list.
    b. For non EURD molecules, the latest available PSUR-PBRER shall be submitted upon registration and renewal of registration to the IPC.
    c. For biologicals; the latest available PBRER/PSUR shall be submitted upon registration, and renewal to both registration department and IPC.
    d. IPC shall be provided with the current approved PBRER/PSUR file upon request within fourteen (14) calendar days from date of receiving the request.
    e. Period of seventy (70) calendar days from the data lock point (DLP) is allowed for submission to the IPC for reports covering one year or less, and if the report covers longer period, then ninety (90) calendar days from DLP will be allowed for submission.
2. The pharmaceutical company/ MAH or its representatives in Iraq shall:
    a. Submit the report as paper based mail (on CD) or by the e-mail to iqphvc@yahoo.com and iraqiphvc@moh.gov.iq
    b. A cover letter/title page or in the body of the email to be submitted with the PBRER/PSUR mentioning the conclusion of the PBRER/PSUR.
3. Format and content of the report will be adapted and as stated in the (Module VII) ICH-E2C (R2) format.
4. The IPC shall review the PBRER/PSUR file and inform all the relevant regulatory bodies in Iraq (if necessary) and the pharmaceutical company/ MAH or its representative(s) in the event of comments on the document.
5. The pharmaceutical company/ MAH or its representative(s) shall answer the comments received and commit to take the appropriate measures as per the recommendations and agreed upon actions with the IPC.

6. The pharmaceutical companies/MAHs directly or through their representatives have the right to apply for an exception from PSUR/PBRER submission with proper reasoning and the IPC has the right to accept or reject the application.

Module VIII
Post Authorization Safety Studies (PASS)

1. After obtaining approvals for this type of studies inside Iraq (from the relevant authorities in the Ministry of Health including any of the following; Central Research Committee, National Board for Drug Selection (NBDS), Central Pharmaceutical Research Committee, Medicinal Policy Committee), the concerned pharmaceutical company/MAH or its representative shall submit a copy of the study file to the IPC.

2. The pharmaceutical company/MAH or its representative shall use the solicited reporting form included within the study protocol and incase no such form is available, the CIOMS form shall be used and the following information are mandatory in each report (study ID, study type, patient ID).

3. The IPC shall review the product's safety related part of the study and inform the pharmaceutical company / MAH or its representative of the review result prior to the start of the study.

4. When the pharmaceutical company/MAH or its representative receives reports on safety of a certain medicinal product in the study, the IPC should be informed accordingly as shown in clauses (1 and 2 of module VI) of this guideline.

5. When the study is completed, the pharmaceutical company/ MAH or its representative shall send a copy of the final report on the study results to the IPC.

6. The conditional approval is subject to the same regulations as mentioned in PASS.

Module IX
Signal Management

1. The pharmaceutical company/MAH, directly or through its representative in Iraq shall:

    a. Immediately inform the IPC of all emerging safety issues and any safety issues resulting from the signal detection activities that may affect the public health and the risk benefit balance of a medicinal product, being an emergency, and shall inform us of the actions taken in this respect in case such measures are needed.

    b. Inform the IPC of all validated signals after final assessment and provide the IPC with a list of those that represent a new or changed risk and those which were refuted within 14 calendar days from day zero (day received by regional/ local PV officer) from the date of the finalized assessment report.

    c. Provide the IPC with all information that is useful for assessment of the signals upon request depending on the updated designated medical events (DMEs) EMA list.

2. The IPC shall issue the outcomes of signal assessment of the national database and take the necessary actions and inform the pharmaceutical company/ MAH (or its representative) concerned in addition to dissemination of this information to medical and health personnel in the public and private sectors in Iraq, and all relevant authorities when needed.

Module X
Additional Monitoring

1. The pharmaceutical company/MAH shall, directly or through its representative in Iraq conduct additional monitoring in the following cases:

    a. All products published in the EMA list for additional monitoring.
    b. All biologicals, registered in the Iraqi Ministry of Health and not in scope of point A.
    c. PASS studies.
    d. Products with conditional approval.
    e. Any other product as requested from the IPC.

2. Inverted Black triangle (▼) application is used to express presence of additional monitoring of the medicine. In the event that the pharmaceutical company/MAH is unable to apply, we must be informed by an official letter stating the justifying reasons.

3. The IPC shall, in collaboration with the competent authorities, issue and circulate a list of medicinal products for this purpose.

Module XV

Safety Communication

1. The pharmaceutical companies / MAHs or their representatives in Iraq shall notify the IPC as soon as possible of any safety updates concerning their medicinal products marketed in Iraq, which have been approved by the country of origin and any emerging information related to the safety of the medicinal products taking into account the uses adopted, registered and traded in Iraq.

2. For Direct Healthcare Professional Communication (DHPC):

    a. It shall be distributed by the pharmaceutical company / MAH or its representative when necessary to take prompt and immediate actions to minimize risk of the medicinal product or to modify the current practices for using the ingredient of the product or upon request from the IPC.

    b. Draft proposal letter shall be sent with the plan for dissemination including the method(s) of distribution and targeted groups; together with determining the period of time for completion of distribution (when approved by the pharmaceutical company/ MAH and its representative) in two copies; hard copy and/or soft copy; provided that the first paragraph of the letter should refer to the approval of the Ministry represented by the IPC, in addition to, means of communication of the IPC, means of communication with the pharmaceutical company/ MAH and its representative in the clause promoting reporting.
    c. The IPC shall review and propose the required changes, if any, within 2 – 7 (two - seven) calendar days from date of receipt.
    d. Upon completion of the required changes by the pharmaceutical company/ MAH and its representative (if any), the IPC shall be provided with the final amended version and final approval from the IPC will be granted.
    e. Upon completion of DHPC dissemination, the IPC shall be provided with a report detailing the procedure with evidence of distribution.
    f. The means used shall be translated into Arabic when necessary.

g. The IPC shall, in collaboration with pharmaceutical companies / MAHs and their representative issue and circulate a unified DHPC when more than one pharmaceutical company /MAH and its representative is involved.

Module XVI
Risk Minimization Measures; Selection of Tools and Effectiveness Indicators

1. Includes the following measures, which may need to apply one or more measures depending on the type of risk:

   [Educational programs, controlled access programs, other risk minimization measures (controlled distribution systems, pregnancy prevention program and DHPC) as printed materials, web-based platforms and other audio-video media].
2. The pharmaceutical company/ MAH and its representative must clearly and explicitly state that the tools used above are not for promotional purposes and should be stand-alone communication, and their main objective is to minimize risks.

3. Upon receipt of the highlighted/defined RMP activities to be implemented in Iraq, the IPC shall study part of the file pertaining to additional risk minimization measures and inform the pharmaceutical company / MAH and its representative when necessary to implement these measures.
4. When the IPC requests from the pharmaceutical company/ MAH and its representative to implement the measure(s):

   a) The content, the final form and the means used to publish it, shall be agreed upon (printed material, web-based platforms and other audio-video media).
   b) The pharmaceutical company/ MAH and its representative shall submit the plan for distribution method and the targeted group(s), specifying the proposed period of completion.
   c) Upon completion, we shall be provided with a report detailing the measure with evidence of implementation.
   d) In case of failure of the implemented measures, the pharmaceutical company/ MAH and its representative shall propose suggestive amendments that shall be implemented after the approval of the IPC.
   e) The MAH shall evaluate the effectiveness of the implemented measures and inform the IPC.

5. The used methods shall be translated into Arabic when necessary.

6. The IPC shall contribute to facilitating implementation of certain clauses of the plan when necessary and upon the request of the pharmaceutical company / MAH and its representative.

References

1. Pharmacovigilance Practice (GVP) for Arab Countries for Medicinal Products for Human Use (Version 2).
2. International Council for Harmonization (ICH) guidelines.
3. European Medicine Agency (EMA) guidelines.
4. Jordan Food and Drug Administration guidelines.
5. Saudi Food and Drug Authority guidelines.
6. Omani Guideline on Good Pharmacovigilance Practices for MAHs/ Pharmaceutical Companies, Version 1, 2017.

Annex I- Required training for QPPV/LSR

Essential training List	Pharmacovigilance methods
	ICSRs processing activities
	Case Narrative Writing for Reporting Adverse Events
	Medical Aspects of Adverse Drug Reactions
	National Pharmacovigilance regulations
	PV Planning & RMP
	Risk communication, DHPC
	Pharmacovigilance quality management
	How to prepare PSMF/PSSF
Additional training List	Evidence based –medicine, How to conduct literature search
	Pharmaco-epidemiology
	Biostatistics
	Signal detection
	How to prepare PSUR
	MedDRA coding
	Causality assessment
	Risk benefit assessment in Pharmacovigilance

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Annex II - Summary of Pharmacovigilance System Master File (PSMF) (Signed by the MAH - QPPV)

QPPV	Name:
	Country:
	Contact details:
	Tasks and Responsibilities: (according to safety agreement if applicable)
PSMF	Location

- This document should be submitted to the IPC upon registration and re-registration and upon request from the IPC incases mentioned earlier, copying the registration department in case of biologicals.

Annex III - Summary of local PSMF/ PSSF (Signed by the MAH representative And local safety responsible)

LSR	Name:
	Contact details:
	Tasks and Responsibilities**:** (according to safety agreement if applicable)
Local PSMF/PSSF	Location

- This document should be submitted upon request from the IPC.

Annex IV – Check list of local PSMF/ PSSF

II.B.4. Information to be contained in the PSMF/ PSSF		
No.	**PSMF/ PSSF section**	**Remarks**
	Cover Page:	
	1- The unique number (Revision No.)	
	2- The name of the MAH, QPPV or LSR (including third party).	
	3- The name of other concerned MAH(s) (sharing the Pharmacovigilance system). If applicable	
	4- The list of PSMFs/ PSSFs for the MAH (Products with a different Pharmacovigilance system) if applicable.	
	5- The date of preparation / last update.	
II.B.4.1.	**Qualified person responsible for Pharmacovigilance (QPPV)/ LSR.**	
	1- Description of the responsibilities.	
	2- Summary curriculum vitae (CV).	
	3- Contact details.	(Name, postal, telephone, fax and e-mail)
	4- Details of back-up arrangements.	
	5- Practical experience/ training.	(Attached checklist)*
II.B.4.2.	**Organizational structure of the MAH/ MAH's local office.**	(Diagram)
	1- The organizational structure of the marketing authorization holder(s)/ local office, showing the position of the QPPV/ LSR in the organization.	
	2- The site(s) where the Pharmacovigilance functions are undertaken covering individual case safety report collection, evaluation, safety database case entry, periodic safety update report production, signal detection and analysis, risk management plan management, pre- and post-authorization study management, and management of safety variations.	
	3- Delegated activities (contracts and agreements).	**Service providers** (e.g. medical information, auditors, patient support programme providers, study data management etc.) **Commercial arrangements** (distributors, licensing partners, co-marketing etc.) **Technical providers** (hosting of computer systems etc.) **Individual contractual**

		agreements
II.B.4.3.	**The sources of safety data.**	
	1- The description of the main units for safety data collection.	
	2- All parties responsible (including third parties).	
	3- Medical information sites.	List describing: (table) 1- Product. 2- Country. 3- Nature of activity. 4- Contact point for the site (address, telephone and e-mail).
	4- The description of the process for ICSRs from collection to reporting to national medicines authorities.	Flow diagrams shall be used to indicate the main stages, timeframes and parties involved.
	5- For safety data arising from studies. (list/ table)	The list should describe the status of each study / programme, the applicable country (ies), the product and the main objective. It should distinguish between interventional and non-interventional studies and should be organised per active substance. The list should include on-going studies/programmes as well as studies/ programmes completed in the last two years.
II.B.4.4.	**Computerised systems and databases.**	
	The location, functionality and operational responsibility for computerised systems and databases used to receive, collate, record and report safety information.	Validation status of computer system functionality should also be described, the change control, nature of testing, back-up procedures.
II.B.4.5.	**Pharmacovigilance processes.**	
	Description of the process, data handling and records for the performance of Pharmacovigilance. (Clear written procedures)	(Standard operating procedures, manuals, safety database).
	1- Continuous monitoring of product risk-benefit profile(s) applied and the result of evaluation and the decision making process for taking appropriate measures, this should include signal generation, detection and evaluation.	
	2- Risk management system(s) and monitoring of the outcome of risk minimisation measures.	
	3- ICSR collection, collation, follow-up, assessment and reporting.	
	4- PSUR scheduling, production and submission.	
	5- Communication of safety concerns to consumers, healthcare professionals and the national medicines authorities.	
	6- Implementation of safety variations to the summary of product	

	characteristics (SmPC) and patient information leaflets.	
	7- Quality issue, recall or withdrawal.	
II.B.4.6.	**Pharmacovigilance system performance.**	
	Description of the monitoring methods applied for performance of the Pharmacovigilance system. (Evidence of the on-going monitoring of performance of the Pharmacovigilance system)	List of performance indicators must be provided.
	1- An explanation of how the correct reporting of ICSRs is assessed.	Figures/graphs should be provided to show the timeliness of 15-day and 90-day reporting over the past year.
	2- A description of any metrics used to monitor the quality of submissions and performance of Pharmacovigilance.	Include information provided by national medicines authorities regarding the quality and timeliness of ICSR reporting, PSUR, RMP or other submissions. (PSUR checklist & RMP checklist)
	3- An overview of the methods used to ensure timeliness of safety variation submissions compared to internal and national medicines authority deadlines	Including the tracking of required safety variations that have been identified but not yet been submitted.
II.B.4.7.	**Quality system.**	
	1- Procedural documents.	
	- Description of the types of documents used in Pharmacovigilance (standards operating procedures, work instructions, manuals… etc).	
	2- Training.	
	- The organisational chart giving the number of people involved in Pharmacovigilance activities and Information about sites where the personnel are located.	
	- A summary description of the training concept, including a reference to the location training files, record as well as the trainings materials.	
	3- Auditing.	
	Information about quality assurance auditing of the Pharmacovigilance system.	
	- Description of the approach used to plan audits of the Pharmacovigilance system and the reporting mechanism and timelines.	List of the scheduled and completed audits (for a period of five years) concerning the Pharmacovigilance system. This list should describe: 1-The date(s) (of conduct and of report) 2-Scope and completion status of audits.
	- The audit report.	A brief description of the corrective and/or preventative action(s) associated with the significant finding. (Starting and resolving date).
	- A note associated with any audit where significant findings are	- The note is only removed once

	raised.	corrective action and/or sufficient improvement can be demonstrated. Amendment or removal of the notes must therefore be recorded in the logbook.
II.B.4.8.	**Annex to the PSMF/ PSSF.**	
	The qualified person responsible for Pharmacovigilance	**Annex A**
	- A list of tasks that have been delegated by the qualified person for Pharmacovigilance. - The curriculum vitae of the QPPV/ LSR and associated documents. - Contact details.	
	The organizational structure of the MAH	**Annex B**
	- A list of contracts and agreements. - A copy of the individual contractual agreements.	
	Sources of safety data	**Annex C**
	- Lists associated with the description of sources of safety data e.g. affiliates and third party contacts.	
	Computerized systems and databases	**Annex D**
	Pharmacovigilance process and written procedures	**Annex E**
	- Lists of procedural documents.	
	Pharmacovigilance system performance	**Annex F**
	- A list of performance indicators (where applicable).	
	Quality system	
	- A list of all completed audits, for a period of five years, and a list of audit schedules.	**Annex G**
	Products	**Annex H**
	- A list of medicinal products covered by the PSMF/ PSSF.	Name of the medicinal product. Name of the active substance(s). Authorization number and marketing status.
	Document and record control	**Annex I**
	- Logbook.	
	A logbook of any change of the content of the Pharmacovigilance system master file made within the last five years except the changes in annexes and the following QPPV information: CV, contact details, back-up arrangements and contact details. Other change control documentation should be included as appropriate. Documented changes shall include at least the date, person responsible for the change and the nature of the change.	