I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for proposing changes to the product information (e.g. the summary of product characteristics (SmPC) or package leaflet (PL) of the medicinal products (MP) based on the new safety data in accordance with Good Pharmacovigilance Practices(GVP).

II. SCOPE

This procedure shall apply to the processes of proposing safety changes to the SmPC and PL by PharmExpert LLC (Pharmex).

III. RESPONSIBILITIES

Role	Responsibility
Senior Pharmacovigilance Specialist (SPVS)	• Proposing suggestions for making changes to the SmPC/PL • Registration of proposed changes to the SmPC/PL • Sending the draft to the MAH's QPPV • Informing MP circulation entities • Storage and archiving
Marketing Authorization Holder's Qualified Person responsible for Pharmacovigilance (MAH's QPPV)	• Review and approval of proposed safety changes to the SmPC/PL
Quality Assurance Manager	• Compliance monitoring

IV. DEFINITIONS

Abbreviations used in the text are spelled out on its first mention.

PL – the leaflet in every pack of MP that contains information on the medicine for end-users, such as patients and animal owners.

SmPC – a document describing the properties and the officially approved conditions of use of a MP. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively.

For other terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

V. PROCEDURE

A. Safety Changes

New safety data can be found during:

b)Provide comments to SPVS for making corrections if any.

c)Approve the final application form by signature.

3. Registration of Safety Changes

SPVS within 2 business days:

Register the safety changes in the «Safety Changes Register» (R02T-SOP-PV-010).

4. Informing Third Parties

SPVS within 5 business days:

Inform 3rd parties involved in circulation of MP about to be made changes in the PL in accordance with the SOP-PV-012 «Safety Communication to HCPs_non-HCPs».

5. Storage and Archiving

a)Folder path for storage:

- «Safety Changes Register»: <Safety Communication/Country N/SmPC-PL>.
- «Safety Changes Application Form» signed by MAH's QPPV:<Safety Communication/Country N/SmPC-PL/YYYY/Company N>.
- New safety letter identified during local regulatory intelligence: <Safety Communication/Country N/DHPC/YYYY/Company N
- New safety letter identified during global regulatory intelligence: <Safety Communication/Global SC/DHPC/YYYY/Company N>.

b)Archiving is performed in accordance with SOP-QA-001 «GDocP».

VI. ANNEXURE

R01F-SOP-PV-010 «Safety Changes Application Form»

R02T-SOP-PV-010 «Safety Changes Register»

VII. INTERNAL REFERENCES

SOP-PV-012 «Safety Communication to HCPs_non-HCPs »

SOP-QA-001 «GDocP».

SOP-QA-003 «Pharmacovigilance Glossary»

VIII. REVISION HISTORY AND APPROVALS

Application form for changes in SmPC/PL

Date		New safety data	
Product name		Source	
Country		Reference document	
MAH		Prepared by	

Paragraph number/title	Current version	Proposed version

Approved by:

MAH's QPPV