I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for distribution of duties and responsibilities for the timely and informative provision of responses by PharmExpert LLC (Pharmex)/Marketing Authorization Holders (MAH) to requests from the Regulatory Authorities (RA) of the countries where Pharmex has activity.

II. SCOPE

This procedure shall apply to staff of Pharmex who may be involved in receiving of the requests from RAs.

III. RESPONSIBILITIES

Role	Responsibility
Pharmex's staff	• Transmitting RA's request to HPVD/SPVS in a timely manner
Senior Pharmacovigilance (PV) Specialist (SPVS)	• Registration of correspondences with RA • Preparation of response letter and reference documents
Head of PV Department (HPVD)	• Review and approval of the documents related response
MAH's QPPV (Qualified Person responsible for PV)	• Review and approval of the documents related response
Quality Assurance Manager (QAM)	• Compliance monitoring

IV. DEFINITIONS

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

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

V. PROCEDURE

A. General Specification

Pharmex promotes the development of effective cooperation with the RAs in the countries of activity in order to effectively communicate on the safety of the use of Medicinal Products (MP).

Timely and high-quality responses to requests of the RAs are one of the criteria for assessing the Pharmex's quality system of PV system.

R01T-SOP-PV-017 «RA Requests Log»

VII. INTERNAL REFERENCES

SOP-PV-004 «Local PV Activity»

SOP-QA-001 «GDocP»

SOP-QA-003 «Pharmacovigilance Glossary»

VIII. REVISION HISTORY, APPROVALS

Issuance Date	Revision Number	Summary of Revisions
01-Jan-2023	00	New SOP
Written by: HPVD PharmExpert LLC 02-Jan-2023	Reviewed by: QAM PharmExpert LLC 02-Jan-2023	Approved by: Director PharmExpert LLC 02-Jan-2023