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.

SPVS/HPVD	24 hours	g) Notify MAH's QPPV about request of RA.
SPVS/HPVD/MAH's QPPV/Other stakeholders	24 hours	h) Discuss RA's request and intended response. i) Arrange meeting, if required.
SPVS	Within the time frame indicated by RA	j) Prepare the response and accompanying documents. k) Coordinate the response with all stakeholders.
MAH's QPPV		l) Approve the final version of the response and reference document, if any.
SPVS		m) Save the document(s). Folder path: <RA/Country N/RA requests/YYYY/Outgoing>. n) Register outgoing documents in the «RA Requests Log».
		o) Send the final version of the response document to the LCPPV for submission to the respective country's RA (SOP-PV-004 «Local PV Activity») in accordance with a local regulatory requirement, OR p) Where applicable, make direct electronic submission of the response document to the respective country's RA and make sure that a response is received.
	Within 15 days	q) Track the submitted documents and make sure RA is satisfied with the answer and no additional documents are required. r) Inform MAH's QPPV about completion of the process of providing a response to the request of the RA.
2. Storage and Archiving		
SPVS	1 day	a) Original documents related the process are stored in the protected storage or transferred to a third party as set forth in the contract.
Not applicable		b) Archiving is performed in accordance with SOP-QA-001 «GDocP».

VI. ANNEXURE