I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure of immediate interaction between PharmExpert LLC (Pharmex) and Marketing Authorization Holder (MAH) when receiving from Regulatory Authority (RA) regulatory decisions about recall and restrictions for the medicinal product (MP).

II. SCOPE

This procedure shall apply to Pharmex's staff who can get regulatory decisions about recall and restrictions for the MP.

III. RESPONSIBILITIES

Role	Responsibility
Pharmex's any employee who may receive regulatory decisions about recall and restrictions for the MPs	• Immediately informing Director/HPVD/SPVS
Head of Pharmacovigilance Department (HPVD) **Senior Pharmacovigilance Specialist (SPVS)**	• Informing MAH's QPPV • Performing causality assessment, sending results to MAH's QPPV • Storage of the documents
MAH's Qualified Person responsible for pharmacovigilance (MAH's QPPV)	• Verifying causality assessment • Preparing analytical summary and recommendation for action • Participating in the recall/restrictions process
Quality Assurance Manager (QAM)	• Compliance monitoring

IV. DEFINITIONS

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

Causality assessment – a method used for estimating the strength of relationship between drug(s) exposure and occurrence of adverse reaction(s).

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

V. PROCEDURE