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I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for Regulatory İntelligence (RI) monitoring at PharmExpert LLC (Pharmex) in order to maintain compliance of Pharmacovigilance (PV) System with Good Pharmacovigilance Practices (GVP).

II. SCOPE

This procedure shall apply to Pharmex's personnel involved in RI monitoring process.

III. RESPONSIBILITIES

Role	Responsibility
Head of PV Department (HPVD)	• Preparing/renewal/revision of the RI monitoring resources list • Quality Control (QC) • Approval of to be reported findings before sending to Marketing Authorization Holder (MAH)/ Third party
Senior PV Specialist (SPVS)	• Continuous monitoring of the email account for availability of the important safety related information and regulatory updates • Storage of the documents related RI • Monthly verification of the RI monitoring results • Expedited reporting of important safety related information and regulatory updates to the MAH/Third party
Senior PV Specialist (SPVS)/PV Specialist (PVS)	• Completion of necessary logs • Regular reporting to the MAH/ Third party
Local Person responsible for PV (LCPPV)	• Translation, verification and QC of identified information during RI monitoring
Quality Assurance Manager (QAM)	• Compliance monitoring
System Administrator (SA)	• Set up/reconfigure and ensure Monitoring system performance

IV. DEFINITIONS

a) Global sources

- European Medicines Agency (EMA)
- The United States Food and Drug Administration (FDA)

b) Local sources

- RA of respective countries
- Legal acts (regulations, directives, guidance documents, decisions, recommendations and opinions) databases
- National medicine registers

4. RI Questionnaire

a) On starting of Pharmex's activity in a new country, HPVD/SPVS/LCPPV completes «RI Questionnaire» (R01T-SOP-PV-007) using local normative documents, folder path: <RI/Country N>.

b) SVPS keeps up to date the «RI Questionnaire».

c) File naming: <Country Code_RI Questionnaire_YYYY>.

d) Country specific regulatory requirements on request of MAH/Third party may be completed in other record forms. Such completed forms replace Pharmex's «RI Questionnaire».

B. Process

Process Steps/Responsible Persons/Process Description
1. Preparation Stage
HPVD at the beginning of every calendar year, until 31th January: a) Define/request from LCPPV to be monitored RI resources list. b) Define together with SA search strategy for each resource considering technical capabilities: • Automatic search using the specific keywords containing MAH name, MP's name and INN • Automatic search using general keywords related PV • Track only updates in the resources' content and then perform search c) Complete the «RI Resources Log» (R02T-SOP-PV-007). d) Save the completed «RI Resources Log» in the folder, path: <RI/Country N>. e) Name the file: <Country Code_RI Resources Log_YYYY>.