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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

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

Pharmex's personnel – staff of Pharmex and outsourced LCPPVs in the countries of responsibility.

Regulatory Intelligence – the process of providing strategic information that supports the making of effective and efficient decisions in relation to the regulatory aspects of the business.

Third party – the company partially/completely responsible for MAH's PV system or participate in the chain of functioning of PV system and directly/indirectly reports to MAH's QPPV (Qualified Person responsible for PV).

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

V. PROCEDURE

A. General Specification

1. RI Monitoring Coverage

The RI monitoring process covers the following activities:

- Selection of relevant publicly available data sources.
- Collection of the data related to (including, but not limited) the updates of information about Medicinal Products (MP) according to the latest scientific knowledge, including the assessment of the safety profile, recommendations of Regulatory Authorities (RA), regulatory measures, updates in PV legislations.
- Analysis of the significance of these data.
- Generation, from the analysis of significant information for the definition of the regulatory strategy.
- Safety communication of the implications of this information for the PV system.

2. RI Data Collection

Collected data within the scope of RI monitoring procedure may be including, but not limited to:

- Direct Healthcare Professional Communication letters;
- requests for making safety changes to the summary of product characteristics (SmPC) / package leaflet (PL);
- recall/restrictions of MPs;
- withdrawn of Marketing Authorization;
- regulatory updates.

3. RI Data Sources

Data sources of RI monitoring within this SOP may be official webpages of the following organizations including, but not limited to: