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I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for collecting, assessing and reporting of Adverse Events (AE) by PharmExpert LLC (Pharmex) occurring during clinical trials (CT) and Post-Marketing Safety Studies (PASS) in accordance with the Good Pharmacovigilance Practices (GVP) and Good Clinical Practice (GCP).

II. SCOPE

This procedure shall apply to collecting, assessing and reporting of AEs by Pharmex occurring during CT and PASS.

This SOP is applicable to Pharmex's staff who may be involved in obtaining and exchanging information on the AEs.

III. RESPONSIBILITIES

Role	Responsibility
Pharmex's staff	• When receive AEs act in accordance with the working instruction «Internal Communication»
Senior Pharmacovigilance Specialist (SPVS)	• Collecting, assessing and reporting of AEs
Head of Pharmacovigilance Department (HPVD)	• Quality Control (QC) of AE assessment results • Review and approval of completed case report
Sponsor	• Review and approval of assessment results • Review and approval of completed case report before submission
Quality Assurance Manager (QAM)	• Compliance monitoring

IV. DEFINITIONS

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

Adverse event (AE) − in the context of a CT: any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment.

A subject means an individual who participates in a CT, either as recipient of an Investigational medicinal product or as a control.

Adverse reaction (AR) – A response to a MP which is noxious and unintended. Response in this contest means that a causal relationship between a MP and an AE is at least a reasonable possibility.

Investigational medicinal product (IMP) − medicinal product which is being tested or used as a reference, including as a placebo, in a CT, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

Investigator´s Brochure (IB) − a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects.

Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.

Reference Safety Information (RSI) − the information used for assessing whether an adverse reaction is expected. This is contained in either the Investigator's Brochure (IB) or in the Summary of Product Characteristics (SmPC).

Serious Adverse Event (SAE) − an AE which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

Solicited reports – a reports of suspected ARs are those derived from organized data collection systems, which include: clinical trials, non-interventional studies, registries, post-approval named patient use programs, other patient support and disease management programs, surveys of patients or healthcare professionals (HCP), compassionate use or name patient use, information gathering on efficacy or patient compliance.

Suspected Unexpected Serious Adverse Reaction (SUSAR) − an adverse reaction that is classified in nature as both serious and unexpected (which isn't consistent with the information about the IP listed in the relevant reference documentation - an Investigator's Brochure).

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

V. PROCEDURE

A. General Specification

1. Solicited Reports

Solicited reports of suspected ARs are those derived from organized data collection systems, which