I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure of handling Medical Information (MI) enquiries at PharmExpert LLC (Pharmex).

II. SCOPE

This procedure shall apply to handling of MI by providing clinical and scientific information to facilitate safe and effective use of marketed products in the countries of responsibility.

This procedure is applicable to, but is not necessarily limited to all authorized documents/procedures.

III. RESPONSIBILITIES

Role	Responsibility
Senior PV Specialist (SPVS) **Head of PV Department (HPVD)**	• Handling of MI enquiries
Quality Assurance Manager (QAM)	• Compliance monitoring
LCPPV (Local Person Responsible for Pharmacovigilance)	• Communicating of MI requester

IV. DEFINITIONS

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

Medical Information (MI) – collection, handling and dissemination of information on medications, and their safe and correct use.

Package leaflet (PL) – the leaflet in every pack of medicine that contains information on the medicine for end-users, such as patients and animal owners.

Summary of product characteristics (SmPC) – a document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively.

Its information is updated throughout the life-cycle of the product as new data emerge.

The SmPC is the reference information used to determine expected or unexpected status of events for marketed products for the purpose of expedited reporting.

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

V. PROCEDURE

A. General Specification

MI responds to unsolicited requests for marketed and investigational products where authorized by local regulations.

1. Sources of MI

Sources of MI within this SOP may be including, but not limited to:

- All Healthcare Professionals: Physicians, Pharmacists, Nurses, Other practitioners (e.g., nurse practitioners, physician assistant)
- Other Life Science Professionals: Research scientists (i.e., PhD's), Non-HCP Formulary Decision Makers
- Other groups: Patients, caregivers, payers

2. Causes of MI

MI may arise due to the following reasons, including but not limited to:

- off-label use of approved products
- investigational products
- on-label use of approved products when additional MI is needed

3. Intake of requests

MI enquiries can be received through the following intake channels:

- calls/messages to the phone numbers
- email addresses
- MI requested form submitted by Pharmex personnel
- social media

B. Process

Process and Stages
1. MI Enquiries Intake