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#### I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for preparation and communicating safety information to Healthcare Professionals (HCPs) and non-Healthcare Professionals (non-HCPs) e.g. patients, consumers, non-specialists in pharmaceutical sector, general public, other interesting parties in accordance with the Good Pharmacovigilance Practices (GVP).

# II. SCOPE

This procedure shall apply to staff of PharmExpert LLC (Pharmex) involved in Safety Communication (SC).

### III. RESPONSIBILITIES

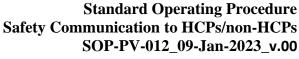
| Role   | Responsibility  |
|--|---|
| Senior PV Specialist (SPVS)  | <ul> <li>Receiving from RA request for SC to HCPs/non-HCPs</li> <li>Initiating SC to HCPs/non- HCPs</li> <li>Preparation and submission of SC documents to RA</li> <li>Systematically assessment and reporting of SC results</li> </ul> |
| Marketing Authorization Holder's (MAH) Qualified Person responsible for Pharmacovigilance (QPPV)/ Head of PV Department (HPVD) | <ul> <li>Initiating SC to HCPs/non- HCPs</li> <li>Review and approval of SC documents</li> </ul>  |
| Quality Assurance Manager (QAM)  | <ul><li>Compliance monitoring</li><li>Assessment of SC results</li></ul>  |
| System Administrator (SA)  | Publishing of the DHPC / Information material in the resources  |

## IV. DEFINITIONS

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

**Direct Healthcare Professional Communication** (**DHPC**) - a communication intervention by which important safety information is delivered directly to individual healthcare professionals by a MAH or a RA, to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product (MP).

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







- Press communication
- Website
- Social media and other online communications
- Bulletins and newsletters
- Inter-authority communication
- Responding to enquiries from the public
- Other means of communication

# 5. Initiation of SC

Initiator on publication of DHPC letter / Information material for non-HCPs may be RA or MAH.

# **B. Process**

| Responsibility           | Process description  |  |
|--------------------------|--|--|
| 1. Request or Initiative |  |  |
|                          | a) Upon receiving request from RA on dissemination of DHPC / Information material for non-HCPs, response to the RA in accordance with the SOP-PV-017 «Handling of RA Requests» and then start the SC process from the ¶ 2. |  |
| SPVS                     | b) On identification by Pharmex need on dissemination of DHPC / Information material for non-HCPs, notify the MAH's QPPV within 24 hours by phone or e-mail providing evidence and reference documents.                    |  |
|                          | c) If initiator on dissemination of DHPC   |  |
|                          | d) / Information material for non-HCPs is MAH, miss the above points a, b.   |  |
| 2. Preparation Stage     |  |  |
|                          | a) Prepare within 2 business days in a local language (SOP-QA-010 «Translation of documents») of the respective country:   |  |
| SPVS                     | <ul> <li>DHPC letter using the «DHCP Template» (R01T-SOP-PV-012), or</li> <li>Information material for non-HCPs, and</li> <li>«DHPC SC Plan» (R02T-SOP-PV-012)</li> </ul>  |  |
|                          | b) For preparation of the SC documents use the subfolder: «draft», «under review» and «released». Folder path: <qa development="" document="" preparation="" sc="">.</qa>  |  |
|                          | c) Prepare the drafts of SC documents in the subfolder: «draft».   |  |