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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)	• Receiving from RA request for SC to HCPs/non-HCPs • Initiating SC to HCPs/non- HCPs • Preparation and submission of SC documents to RA • Systematically assessment and reporting of SC results
Marketing Authorization Holder's (MAH) Qualified Person responsible for Pharmacovigilance (QPPV)/ Head of PV Department (HPVD)	• Initiating SC to HCPs/non- HCPs • Review and approval of SC documents
Quality Assurance Manager (QAM)	• Compliance monitoring • Assessment of SC results
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	
SPVS	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. 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	
SPVS	a) Prepare within 2 business days in a local language (SOP-QA-010 «Translation of documents») of the respective country: • DHPC letter using the «DHCP Template» (R01T-SOP-PV-012), or • Information material for non-HCPs, and • «DHPC SC Plan» (R02T-SOP-PV-012) b) For preparation of the SC documents use the subfolder: «draft», «under review» and «released». Folder path: <QA/Document development/SC preparation>. c) Prepare the drafts of SC documents in the subfolder: «draft».