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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
<b>Senior PV Specialist (SPVS)</b>	<ul style="list-style-type: none"> <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>
<b>Marketing Authorization Holder's (MAH) Qualified Person responsible for Pharmacovigilance (QPPV)/ Head of PV Department (HPVD)</b>	<ul style="list-style-type: none"> <li>• Initiating SC to HCPs/non- HCPs</li> <li>• Review and approval of SC documents</li> </ul>
<b>Quality Assurance Manager (QAM)</b>	<ul style="list-style-type: none"> <li>• Compliance monitoring</li> <li>• Assessment of SC results</li> </ul>
<b>System Administrator (SA)</b>	<ul style="list-style-type: none"> <li>• Publishing of the DHPC / Information material in the resources</li> </ul>

## 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».



## V. PROCEDURE

### A. General Specification

#### 1. SC Aims

- Providing timely, evidence-based information on the safe and effective use of MPs.
- Facilitating changes to healthcare practices (including self-medication practices) where necessary.
- Changing attitudes, decisions and behaviors in relation to the use of MPs.
- Supporting risk minimization behavior.
- Facilitating informed decisions on the rational use of MPs. In addition to the above effective, high-quality SC can support public confidence in the regulatory system.

#### 2. SC to HCPs

a) A DHPC should be disseminated when there is a need to take immediate action, or change current practice, in relation to a MP.

b) Situations when a DHPC may become necessary are the following:

- a suspension, withdrawal or revocation of an MA for safety reasons;
- an important change to the use of a MP due to the restriction of an indication, a new contraindication, or a change in the recommended dose due to safety reasons;
- a restriction in availability or discontinuation of a MP with potential detrimental effects on patient care.

c) Other situations where dissemination of a DHPC should be considered are:

- new major warnings or precautions for use in the product information;
- new data identifying a previously unknown risk or a change in the frequency or severity of a known adverse reaction;
- new evidence that the MP is not as effective as previously considered;
- new recommendations for preventing or treating adverse reactions or to avoid misuse or medication error with the MP;
- ongoing assessment of an important potential risk, for which data available at a particular point in time are insufficient to take regulatory action.

#### 3. SC to non-HCPs

Communication material in lay language (e.g. using a questions & answers format) helps patients and the general public to understand the scientific evidence and regulatory actions relating to a safety concern. Lay language documents should contain the RA's recommendations and advice for risk minimisation for patients, and should be accompanied by relevant background information.

#### 4. SC Forms

SC to HCPs/non-HCPs can be carried out in the following forms: