STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Communication of Safety Concerns to Consumers HCP's and Regulatory Authorities	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Communication of ……..products Safety Concerns to Consumers, Health Care Professionals (HCP's) and Regulatory Authorities.

2.0 SCOPE:

This Standard procedure is applicable to ……. including all subsidiaries.

3.0 RESPONSIBILITY:

3.1. Pharmacovigilance (PV)Department:

Preparation of this SOP, drafting and communicating safety information to consumers, HCP's and regulatory authorities. Distribution, Retrieval and Destruction of this SOP.

3.2. Pharmacovigilance Officer In-charge(PvOI):

Ensure proper preparation and communication of safety information. Review and approve the safety communication information for ……/subsidiaries product. Review, Training and effective implementation of this SOP.

4.0 ACCOUNTABILITY:

Pharmacovigilance officer In-charge.

5.0 PROCEDURE:

5.1 OBJECTIVES OF SAFETY COMMUNICATION:

5.1.1 Providing timely evidence-based information on the safe and effective use of medicines.

5.1.2 Facilitating changes to healthcare practices (including self-medication practices) where necessary.

5.1.3 Improving attitudes, decisions and behaviors in relation to the use of medicines.

5.1.4 Supporting risk minimization behavior.

5.1.5 Facilitating informed decisions on the rational use of medicines.

5.2. PRINCIPLES OF SAFETY COMMUNICATION:

5.2.1. The need for communication shall be considered throughout the Pharmacovigilance and risk management process and the planning of communication of safety concern shall be part of the risk assessment.

5.2.2. Communication of safety concern shall deliver relevant, clear, accurate and consistent messages and reach the right audiences at the right time.

5.2.3. Information on risk shall be presented in the context of the benefits of the medicine and shall include appropriate information on the seriousness, severity, risk factors, time to on set and

reversibility of adverse reactions.

5.2.4. Safety communication shall address the uncertainties related to a safety concern and shall be updated as further evidence becomes available.

5.2.5. Information on competing risks, such as the risk of non-treatment, shall be included where appropriate and possible.

5.2.6. In order for communication of safety concerns to be effective, consideration shall be given to strengthening messages by repetition, especially whenever a change in behavior is sought overtime.

5.2.7. The effectiveness of communication of safety concerns shall be evaluated where appropriate and possible

5.3. CONTENT OF COMMUNICATION OF SAFETY CONCERNS:

5.3.1. Communication of safety concerns shall describe in a clear and concise way any new important information on an authorized medicinal product which has an impact on the medicine's risk- benefit balance or condition of use .

5.3.2. The reason for initiating communication of safety concerns shall be clearly explained.

5.3.3. Any related recommendations to healthcare professionals and patients on how to deal with any safety concern with the medicinal product shall be provided if known.

5.3.4. The information shall not be misleading and shall be presented objectively. Information shall not include any material or statement which might constitute advertising or which is considered to be promotional or commercial.

5.3.5. When applicable, a statement on the agreement between the …….. and the regulatory authority on the safety information provided shall be included.

5.3.6. A list of literature references shall be annexed, when relevant.

5.4. MEANS OF COMMUNICATION:

5.4.1. Direct Healthcare Professional Communication (DHPC):

A DHPC is defined as a communication intervention by which important information is delivered directly to individual healthcare professionals by ……. or marketing client to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product. DHPC's are not replies to requests for information from individual healthcare professionals.

A DHPC shall be disseminated in the following situations:

- Suspension, withdrawal or revocation of a marketing authorization with recall of the medicinal product from the market for safety reasons.
- An important change to the product information, in particular restriction of an indication, new

contraindication, change in the recommended dose, major warnings or precautions for use.

- Restriction in availability which impacts on the medicinal product's current use by

  Patients and healthcare professionals

- New data identifying a previously unknown risk or a change in the frequency or severity or a known risk.
- Substantiated knowledge that the medicinal product is not effective as previously considered.
- New recommendations for treating or preventing adverse reactions.
- A regulatory authority shall request the …… to disseminate a DHPC in any situation where the authority considers it relevant to the safe and effective use of the medicinal product.

5.4.2. Documents in lay language:

Communication material in lay language (e.g using questions & answers format) helps patients and the general public to understand the scientific evidence and regulatory actions relating to a safety topic. Lay language documents shall contain the recommendations and advice for risk minimization to patients and healthcare professionals issued by the regulatory authority in relation to the safety concern and shall be accompanied by relevant background information.

Lay language documents are generally useful to members of the public who have an interest in the subject but do not have a scientific or regulatory background. Reference shall be made to other communication materials on the topic to direct readers to where they can find further information.

5.4.3. Press communication:

Press communication includes press releases and press briefings which are primarily intended for journalists. ……. may send press releases directly to journalists in addition to publishing them on their websites.

5.4.4. Website:

A website is a key tool for members of the public (including patients and healthcare professionals) actively searching the internet for specific information on medicinal products. Regulatory authorities as well as ……. shall ensure that important safety information is easily accessible by the public. Documents on websites shall be found easily via search engines as well as by navigating from the homepage.

5.4.5. Other web-based communications:

Online safety information may also be disseminated via web tools, such as social media applications. When using newer, more rapid communication channels, the accuracy of the information shall be ensured as for all communication. Communication practices shall be reviewed regularly and kept up to date with emerging communication tools used by the various target audiences.

5.4.6. Bulletins and newsletters:

Bulletins and newsletters provide new information about medicines and their safety and effectiveness at regular intervals to registered readers.

5.4.7. Responding to enquiries from the public:

Response to enquiries from the public shall be given as per applicable SOP's. Responses shall take into account the information which is in the public domain and shall include the recommendations to patients and healthcare professionals.

5.4.8. Other means of communication:

Other tools and channels exist such as publications in scientific journals, journals of professional bodies and their websites.

5.5. Effectiveness of communication of safety concerns:

5.5.1. Communication of safety concerns is considered effective when the transmitted message is received and understood by the target audience in the way it was intended and appropriate action is taken by the target audience.

5.5.2. Measuring effectiveness allows lessons to be learned and helps in making decisions on prioritizing and adapting tools and practices to meet the needs of the target audiences.

5.5.3. In case of DHPC's, the marketing authorization holder shall at least be responsible for evaluating the effectiveness of its dissemination and shall inform the regulatory authorities of the outcome and of any difficulties identified.

6.0 REFERENCE:

Not Applicable

7.0 DISTRIBUTION:

Not Applicable

8.0 ABBREVIATIONS:

DHPC	Direct Healthcare Professional Communication
HCP's	Health Care Professionals
PvOI	Pharmacovigilance Officer In-charge
NA	Not Applicable
SOP	Standard Operating Procedure

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9.0 ANNEXURES

Not Applicable

10.0 REVISION HISTORY:

Revision No.	Effective Date	Reason for Revision	Change Control No.
00		New SOP	NIL