Guideline on Safety Communication

NATIONAL MEDICINES REGULATORY AUTHORITY

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Safety Communication

In the scope of this chapter, safety communication refers to 'important new safety information', which means new information about a previously known or unknown risk of a medicine which has or could have an impact on a medicine's risk-benefit balance and its condition of use.

Throughout the life cycle of the medicinal product information relating to the benefit-risk profile of the product may need to be communicated to stakeholders as the appropriate target audiences including, public, patients and healthcare professionals who use (i.e. prescribe, handle, dispense, administer or take) medicinal products.

1. Objectives of safety communication

Safety communication aims at:

- providing timely, evidence-based information on the safe and effective use of medicines;
- facilitating changes to healthcare practices (including self-medication practices) where necessary;
- changing attitudes, decisions and behaviors in relation to the use of medicines;
- supporting risk minimization behavior;
- facilitating informed decisions on the rational use of medicines.
- effective high-quality safety communication can support public confidence in the regulatory system.

2. Content of safety communication

The information in the safety communication shall NOT be misleading and shall be presented objectively. Safety information should NOT include any material or statement which might constitute advertising. Should be tailored to the appropriate audiences with clear and accurate message. Furthermore, the effectiveness of safety communication should be evaluated where appropriate.

Safety communication should contain:

- important new information on any authorized medicinal product which has an impact on the medicine's risk-benefit balance under any conditions of use;
- the reason for initiating safety communication clearly explained to the target audience;

- any recommendations to healthcare professionals and patients on how to deal with a safety concern;
- when applicable, a statement on the agreement between the MAH and the MNRA on the safety information provided;
- information on any proposed change to the product information (e.g. the summary of product characteristics (SmPC) or package leaflet (PL));
- any additional information about the use of the medicine or other data that may be relevant for tailoring the message to the targeted audience;
- a list of literature references, when relevant or a reference to where more detailed information can be found, and any other background information considered relevant;
- where relevant, a reminder of the need to report suspected adverse reactions in accordance with national spontaneous reporting systems.

3. Means of safety communication

Relevant communication tools and channels should be considered when issuing a safety communication in order to reach the target audiences. Different communication tools and channels are:

- Direct healthcare professional communication (DHPC)
- Documents in lay language for patients
- Press communication or press releases
- Website
- Social media and other online communications
- Bulletins and newsletters
- Responding to enquiries from the public
- Publications in scientific journals and journals of professional bodies.

4. Direct healthcare professional communication (DHPC)

A direct healthcare professional communication (DHPC) is one of the most commonly used safety communication tool. It is defined as a communication intervention by which important safety information is delivered directly to individual healthcare professionals by a MAH or NMRA, to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product. DHPCs are not replies to enquiries from healthcare professionals.

The DHPCs should be granted approval by the NMRA before its dissemination by the MAH or its local representative.

A DHPC should be complemented by other communication tools and channels and the principle of providing consistent information should apply.

A DHPC should be included as an additional risk minimization measure as part of a risk management plan.

4.1. Situations when dissemination of DHPC should be considered

A DHPC should be disseminated in the following situations when there is a need to take immediate action or change current practice in relation to a medicinal product:

- suspension, withdrawal or revocation of a marketing authorization for safety reasons;
- an important change to the use of a medicine 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 medicine with potential detrimental effects on patient care.
- 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 risk;
- new evidence that the medicinal product is not as effective as previously considered;
- new recommendations for preventing or treating adverse reactions or to avoid misuse or medication errors with the medicinal product;
- ongoing assessment of an important potential risk, for which data available at a particular point in time are insufficient to take regulatory action (in this case, the DHPC should encourage close monitoring of the safety concern in clinical practice and encourage reporting, and possibly provide information on how to minimize the potential risk);
- upon request of the NMRA in any situation where the NMRA considers it necessary for the continued safe and effective use of a medicinal product.

4.2. DHPC Requirements for MAHs

The MAHs and their local representative have the following requirements:

4.2.1. Preparation of DHPC

Taking into consideration the situations stated above when the dissemination of DHPC may be needed; when drafting a DHPC by the MAH or its local representative, the template (see Appendix 1) and the guidance provided in the annotations in the template should be followed as appropriate.

4.2.2. Notification about requested DHPCs in other countries

In cases where a medicines authority in other country requests the dissemination of a DHPC in its territory for a medicinal product authorized also in Sri Lanka, the MAH or its local representative should notify in writing the NMRA in a timely manner with copy of the DHPC and relevant information. This is in the context of the national requirement to notify the NMRA of any new information which may impact the benefit-risk balance of a medicinal product.

The need for any subsequent communication, e.g. a DHPC, in Sri Lanka should be considered and agreed on a case-by- case basis.

4.2.3. Submission and granting approval of DHPC

The MAH or its local representative should not start disseminating the DHPC prior to obtaining the NMRA approval. For this purpose, the following should be submitted for approval:

- draft **DHPC**;
- **the dissemination list** also known as "intended recipient list": the intended recipients HCPs groups may be general practitioners, specialists, pharmacists, nurses; hospitals/ambulatory care/other institutions as appropriate. The list should specify the intended recipients number, specialty and geographical distribution; When defining the target groups of recipients, it should be recognized that it is not only important to communicate with those HCPs who will be able or likely to prescribe or administer the medicinal product, but also to those who may diagnose adverse reactions, e.g. emergency units, poison centers, or to appropriate specialists, e.g. cardiologists. It is also important to consider provision of DHPCs to relevant pharmacists (hospital and /or community) who serve as information providers within healthcare systems and provide assistance and information to Patients, HCPs, including hospital wards and poison centers, as well as the general public.

- **timetable for disseminating** the DHPC: the proposed timetable should be appropriate according to the urgency of the safety concern (usually 15 calendar days is considered appropriate);
- **dissemination mechanism**: how the DHPC is planned to be disseminated, the proposed mechanism should be selected appropriately to meet the dissemination timetable.

The last 3 items above are known as the communication plan.

The MAH and its local representative should allow a minimum of two working days for review by NMRA. The NMRA may request changes, as appropriate. Upon completion of the required changes by MAH and its local representative, the final version should be submitted to the NMRA for final approval.

4.2.4. Submission modalities

The MAH should submit the above mention documents with a cover letter in the form of one full original hard copy and one soft copy, after approval by the NMRA; the MAH will receive back the hard copy stamped with" approved", while the soft copy will be retained at the NMRA.

4.2.5. Dissemination of DHPC

The MAH and its local representative should adhere to the Communication Plan agreed with the NMRA. Any significant event or problem occurring during the DHPC dissemination which reveals a need to change the Communication Plan or a need for further communication to Healthcare Professionals, this should be notified in a timely manner to NMRA to be approved.

4.2.6. Measuring the effectiveness of DHPC

DHPC is considered effective when the message transmitted is received and understood by the targeted healthcare professionals in the way it was intended, and appropriate action is taken by them.

After dissemination of a DHPC, the MAH and its local representative should:

- Conduct a closing review,
- Submit a progress report to the NMRA containing the number of healthcare professionals who received the DHPC and any difficulty identified during the dissemination of the DHPCs (e.g. problems related to the list of recipients or the timing and mechanism of dissemination).

- Take appropriate action as needed to correct the situation/ difficulty identified or prevent similar problems in the future.

4.3. DHPC coordination

Where there are several MAHs of the same active substance and/or a class of products for which a DHPC is to be issued, a single consistent message should be delivered.

For each DHPC, MAHs should arrange to have one of concerned MAHs as the coordinator.

- The coordinator acts on behalf of all concerned MAHs as the contact point for the NMRA.
- Where generics are involved, the contact point should normally be the MAH of the originator product.
- If no originator product is marketed in a Sri Lanka, one of the concerned generic companies is encouraged to act as the contact point, this may be assigned by NMRA.
- This coordinator should be specified in the agreed communication plan (see Appendix 2) to facilitate coordination.
- All concerned marketing authorization holders – facilitated by coordinator- should collaborate, so that a single DHPC is prepared and circulated in Sri Lanka.
- The circulated DHPC should cover all medicinal products containing the concerned active substance and/or a class authorized in Sri Lanka.

4.4. Publication of DHPCs

The NMRA may publish the final DHPC on its website or its social media channels. This should be aligned to the timing of the DHPC dissemination by the MAH and its local representative.

For more guidance on the structure and process and preparation of safety communication, refer to the *EMA Guideline on good pharmacovigilance practices (GVP) Module VX.*

The GVP Modules on Product- or Population-Specific Considerations should be consulted as applicable to DHPC

Appendix 1: Template of Direct Healthcare Professional Communication

<Date>

<Active substance, name of medicinal product and main message>

(e.g. introduction of a warning or a contraindication)>

Dear Healthcare professional,

<Name of marketing authorization holder> in agreement with <the NMRA> would like to inform you of the following:

Summary

Guidance: This section should be in bold/larger font size than the other sections of the DHPC and preferably in bullet points.

- <Brief description of the safety concern in the context of the therapeutic indication, recommendations for risk minimization (e.g. contraindications, warnings, precautions of use) and, if applicable, switch to alternative treatment>
- <Recall information, if applicable, including level (pharmacy or patient) and date of recall>

Background on the safety concern

Guidance: This section may include the following information:

<Brief description of the therapeutic indication of the medicinal product>

<Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship, and, if known, the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors)>

<An estimation of the frequency of the adverse reaction or reporting rates with estimated patient exposure>

<A statement indicating any association between the adverse reaction and off-label use, if applicable>

<If applicable, details on the recommendations for risk minimization>

<A statement if the product information is to be or has been revised, including a description of the changes made or proposed> ***Guidance: No need however to include or attach the precise text of the product information which, at the time of dissemination of the DHPC may not be available as final and approved)***

<Place of the risk in the context of the benefit>

<The reason for disseminating the DHPC at this point in time>

<Any evidence supporting the recommendation (e.g. include citation(s) of key study/ies)>

<A statement on any previous DHPCs related to the current safety concern that have recently been disseminated>

<Any schedule for follow-up action(s) by the marketing authorization holder/NMRA, if applicable>

Call for reporting

<A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

<For biological medicinal products, also include a reminder to report the product name and batch details>.

<Mention if product is subject to additional monitoring and the reason why>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes (if applicable)

<Link/reference to other available relevant information, such as information on the website of a NMRA>

<Additional scientific information, if applicable>

<List of literature references, if applicable>

Appendix 1: Template of Communication Plan for Direct Healthcare Professional Communication

DHPC communication Plan		
Active substance(s)		
Safety concern and purpose of the communication	***Consider using the title of the DHPC to describe the safety concern***	
DHPC coordinator		
DHPC recipients	***List all (groups of) recipients of the DHPC in this section with numbers of intended recipient and their geographical distribution , e.g. general practitioners, specialists, community pharmacists, hospital pharmacists, nurses, professional societies, national associations.***	
	MAH names	Corresponding product name
Concerned MAH(s)	***Add rows as needed***	
Timetable		Dates
DHPC and communication plan approved by NMRA		
Dissemination of DHPC		***Start & end dates for dissemination***
Closing review & Progress report		