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Module XV

Safety Communication

Version 1.0

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List of Abbreviations

DHPC:	Direct Healthcare Professional Communication
HCP:	Healthcare Professional
MAH:	Marketing Authorization Holder
PL:	Package Leaflet
SmPC:	Summary of Product Characteristics

XV.A. Introduction

This Module provides guidance to Marketing Authorization Holders (MAHs) on how to communicate and coordinate safety information in Lebanon.

Communicating safety information to patients and Healthcare Professionals (HCPs) is a public health responsibility and is essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe, and effective use of medicines, preventing harm from adverse reactions, and contributing to the protection of patients and public health.

Safety communication is a broad term covering different types of information on medicinal products, including statutory information as contained in the product information (i.e., the Summary of Product Characteristics (SmPC), Package Leaflet (PL), and the labelling of the packaging). Although some principles in this Module (i.e., sections XV.B.1. and XV.B.2.) apply to all types of safety communication, the module itself focuses on the communication of "**new or emerging safety information**" which means new information about a previously known or unknown risk of a medicine which has or may have an impact on a medicine's benefit-risk balance and its condition of use.

Communication of important new safety information on medicinal products should take into account the views and expectations of concerned parties, including patients and HCPs.

Communication is distinct from transparency, which aims to provide public access to information related to data assessment, decision-making, and safety monitoring performed by the competent authority. Section XV.B. of this Module describes the principles and means of safety communication.

Section XV.C. guides the coordination and dissemination of safety communications in Lebanon. Both sections give particular consideration to Direct Healthcare Professional Communications (DHPCs) and provide specific guidance on preparing them. This is because of the central importance of DHPCs in targeting HCPs and because of the level of coordination required between MAHs and the national competent authority in their preparation.

XV.B. Structures and processes

XV.B.1. Objectives of safety communication

Safety communication aims at:

- Providing timely, evidence-based information on the safe and effective use of products;
- Facilitating changes to healthcare practices (including self-medication practices) where necessary;
- Changing attitudes, decisions, and behaviors in relation to the use of products;
- Supporting risk minimisation actions;
- Influencing policy-making;
- Educating HCPs, patients, and consumers;
- Protecting patients from harm;
- Increasing public confidence in the regulatory system.

XV.B.2. Principles of communication

The following principles of safety communication are applied:

- Safety communication delivers relevant, clear, accurate, and consistent messages and reaches the right audiences at the right time for them to take appropriate action;
- The need for communicating safety information should be considered throughout the pharmacovigilance and risk management process, and should be part of the risk assessment and risk minimization measures.
- There should be adequate coordination and cooperation between the different parties involved in issuing safety communications (e.g., the national competent authority and MAHs);
- Safety communication should be tailored to the appropriate audiences (e.g., patients and HCPs) by using appropriate language and taking account of the different levels of knowledge and information needs whilst maintaining the accuracy and consistency of the information conveyed;
- Information on risks should be presented in the context of the benefits of the medicine and include available and relevant information on the seriousness, severity, frequency, risk factors,

time to onset, reversibility of potential adverse reactions, and, if available, expected time to recovery;

- Safety communication should address the uncertainties related to a safety concern. This is of particular relevance for new information, which is often communicated while the national competent authority is conducting its evaluations; the usefulness of communication at this stage needs to be balanced against the potential for confusion if uncertainties are not properly represented.
- Information on competing risks, such as the risk of non-treatment, should be included where appropriate.
- Patients and HCPs should, where possible, be consulted and messages pre-tested early in the preparation of safety communications, particularly on complex safety concerns;
- Relevant safety communication should be complemented at a later stage with follow-up communication (e.g., on the resolution of a safety concern or updated recommendations);
- Safety communications should comply with relevant requirements relating to individual data protection and confidentiality.

XV.B.3. Target audience

The primary target audiences for safety communication should be patients and HCPs who use (i.e., prescribe, handle, dispense, administer, or take) medicinal products.

As primary target audiences, HCPs play an essential role. Effective safety communication enables them to give clear and useful information to their patients, thereby promoting patient safety and confidence in the regulatory system. Both HCPs in clinical practice and those involved in clinical trials should be provided with appropriate information on any safety concerns at the same time.

Patient, consumer, and HCP organisations can play a role as multipliers as they can disseminate important safety information to target audiences.

The media is also a target audience for safety communication. The capacity of the media to reach out to patients, HCPs, and the general public is a critical element for amplifying new and important information on medicines. The way safety information is communicated through the media will influence the public perception, and it is therefore important that the media receives safety information directly from the

competent authority in addition to the information they receive from other sources, such as from the MAHs.

XV.B.4. Content of safety communication

Safety communication should contain:

- Important emerging information on any authorized medicinal product that has an impact on the medicine's benefit-risk balance under any conditions of use;
- The reason for initiating safety communication is clearly explained to the target audience.
- Any recommendations to HCPs and patients on how to deal with a safety concern;
- Information on any proposed change to the product information (e.g., the SmPC or PL);
- A list of literature references, when relevant, or a reference to where more detailed information can be found;
- Where relevant, a reminder of the need to report suspected adverse reactions in accordance with national spontaneous reporting systems. The following are details on how to access the reporting system in Lebanon:
  https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon
  - .

Scan QR Codes to Report:	
a. ADRs Following Medication Use	**b. AEFIs Following Vaccine Use**
Or use the following link: LNPVP: e-Reporting eForm	Or use the following link: LNPVP: VigiMobile eForm

The information in the safety communication should not be misleading and shall be presented objectively. Safety information should not include any material or statement that might constitute advertising.

XV.B.5. Means of safety communication

The use of communication means is considered when issuing safety communication in order to reach the target audiences and meet their growing expectations. Different communication tools are available. The various means of communication are discussed in the section below.

XV.B.5.1. Direct healthcare professional communication (DHPC)

A DHPC is defined as a communication intervention by which important safety information is delivered directly to individual HCPs by the MAHs or competent authority, in special cases, 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, nor are they meant as educational material for routine risk minimization activities. A DHPC may be an additional risk minimization measure as part of a risk management plan.

The preparation of DHPCs involves cooperation between the national competent authority and the MAHs. An agreement between these parties should be reached before a DHPC is issued. The agreement covers both the content of the information (see section XV.B.4) and the communication plan, including the intended recipients and the timetable for disseminating the DHPC; i.e., the time required to reach all intended recipients. (for more details, see section XV.C.2).

Where there are several marketing authorization holders of the same active substance for which a DHPC is to be issued, a single consistent message should normally be delivered.

XV.B.5.2. Documents in lay language

Public 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. It can also be an additional tool that HCPs can use in their communication with patients. Lay language documents should contain the national competent authority's recommendations and advice for risk minimization for patients and HCPs, and should be accompanied by relevant background information. Lay language documents should be useful to members of the public who have an interest in the subject but do not have a scientific or regulatory background. Reference should be made to other communication materials on the topic for direct readers so that they can find further information. Whenever possible and appropriate, it is advised that patients and HCPs are involved during the preparation of lay language documents to ensure that the information they deliver is useful and adapted to the target audience.

The national competent authority in Lebanon publishes lay language documents on its web-portal (accessed through the link below) and may additionally disseminate them to relevant parties such as patients and HCP organizations (Orders and Syndicates).
https://moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon.

XV.B.5.3. Press communication

Press communication includes press releases and press briefings, which are primarily intended for journalists.
The national competent authority may send press releases directly to journalists in addition to publishing them on their websites. This ensures that journalists, in addition to obtaining information from other sources, receive information that is consistent with the authority's scientific assessment. Interaction with the media is an important way to reach out to a wider audience as well as to build trust in the regulatory system.
Although aimed at journalists, press releases will be read by other audiences such as HCPs, patients, and the general public. Reference should therefore be made to related communication materials on the topic. In cases where a DHPC and/or a communication from a competent authority is also prepared, HCPs should ideally receive it prior to or around the same time as the publication or distribution of a press release so that they are better prepared to respond to patients.
Press briefings with journalists should be considered by the national competent authority for safety concerns or other matters relating to the safety of products that are of high media interest or when complex or public-health-sensitive messages need to be conveyed.

XV.B.5.4. Website(s)

A website is a key tool for the public actively searching the internet for specific information on medicinal products. The national competent authority, as well as the MAH, should ensure that important safety information published on the websites under their control is easily accessible and understandable by the public. Information on websites should be kept up-to-date, with any information that is out-of-date marked as such or removed.

When required, refer to the following website as the official source of safety information:
https://moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon.

XV.B.5.5. Social media and other online communications

Online safety information may also be disseminated via social media and other web tools. When using newer, more rapid communication channels, special attention should be paid to ensure that the accuracy of the information released is not compromised. Communication practices should take into account emerging digital communication tools used by the various target audiences.

XV.B.5.6. Bulletins and newsletters

Bulletins and newsletters provide at regular intervals information about medicinal products and their safety and effectiveness. These tools may serve as reminders of previous communications. A large audience can be reached with these tools by using web-based and other available means.

When required, refer to the following website as the official source for bulletins and newsletters dissemination:
https://moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon.

XV.B.5.7. Responding to enquiries from the public

The national competent authority and MAHs should have systems in place for responding to enquiries about the safety of medicinal products from individual members of the public. Responses should take into account the information that is in the public domain and should include the relevant recommendations to patients and HCPs issued/agreed by the national competent authority. Where questions relate to individual treatment advice, the patient should be advised to contact a HCP.

XV.B.5.8. Other means of communication

In addition to those discussed above, there are other tools and channels, such as publications in scientific journals and journals of professional bodies.

Some tools and channels may be used in the context of risk management; risk minimization measures often include specific programs for risk communication. Tools used in such programs, such as patient alert cards or healthcare professional safety guidance, are outside the scope of this module and will be described in more detail in Module XVI.

XV.B.6. Effectiveness of safety communication

Safety communication is considered effective when the message transmitted is received and understood by the target audience in the way it was intended, and appropriate action is taken by the target audience. Where possible, mechanisms should be introduced in order to measure the effectiveness and impact of the communication. A research-based approach will normally be appropriate in order to establish that safety communications have met the standard of XV.B.2. This approach may measure different outcomes, including behavior, attitudes, and knowledge. When evaluating the effectiveness of safety communication, the scope of the evaluation may be broadened to include factors other than the performance of the individual tools used in the safety communication (see section XV.C.2.4 relating to the processing of DHPCs).

XV.B.7. Quality system requirements for safety communication

In accordance with the quality system requirements described in Module I of the Guideline on Good Pharmacovigilance Practices for Lebanon, procedures should be in place to ensure that safety communications comply with the principles of communication outlined in section XV.B.2, as appropriate. In particular, the communications should be subject to quality controls to ensure their accuracy and clarity. For this purpose, review procedures with allocated responsibilities should be followed and documented.

XV.C. Operations in Lebanon

XV.C.1. Sharing of safety announcements in Lebanon

Patients and HCPs increasingly look at the national competent authority as a provider of important information on medicine products. A good level of coordination of safety communication between all parties involved in the healthcare system is of particular importance so that HCPs and patients receive consistent information on regulatory decisions.

XV.C.1.1. Requirements for marketing authorization holders in Lebanon

As soon as a MAH intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product, and in any event, before the public announcement is made, the MAH shall be required to inform the national competent authority in Lebanon.

Informing the national competent authority at the same time as the public (i.e., without advance notice) should only occur exceptionally and under justified grounds. Whenever possible, the information should be provided under embargo at least 24 hours prior to its publication. The MAH shall ensure that information to the public is presented objectively and is not misleading.

Whenever a MAH becomes aware that a third party intends to issue communication that could potentially impact the benefit-risk balance of a medicinal product authorized in Lebanon, the MAHs should inform the national competent authority and make every effort to share the content of the communications.

XV.C.1.2. Consideration for third parties

Third parties (e.g., scientific journals, learned societies, patient organizations) are encouraged to inform the national competent authority of any relevant emerging information on the safety of medicinal products authorized in the country and, if publication is planned, to share the information ahead of publication.

XV.C.2. Direct healthcare professional communications (DHPCs) in Lebanon

A DHPC (see section XV.B.5.1) is usually disseminated by one or a group of MAHs for the respective medicinal product(s) or active substance(s), either at the request of the national competent authority, or on the MAH 's own initiative.

The MAH should seek the agreement of the national competent authority regarding the content of a DHPC (and communication plan) prior to dissemination.

XV.C.2.1. 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 medicinal product 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 medicinal product with potential detrimental effects on patient care situations, such as:

    - If the temporary supply interruption affects a critical medicine for which no therapeutic alternative is available, and the interruption could have serious consequences on patient care.
    - If the unavailability is linked to a safety concern, such as a batch recall or a manufacturing problem that might impact product quality.
    - If the interruption is expected to last longer than initially anticipated, and patients or healthcare providers need to be informed to manage treatment plans accordingly.
    - If the product is being discontinued permanently, requiring patients to be transitioned to alternative therapies.
    - If the product is used in chronic or life-threatening conditions, where even short-term unavailability could pose a risk to ongoing treatment outcomes.

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 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 error 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).

The national competent authority may disseminate (in special cases) or request the MAH to disseminate a DHPC in any situation where it is considered to be necessary for the continued safe and effective use of a medicinal product.

XV.C.2.2. Notification about requested DHPCs in other countries

When a medicines authority in another country requests the dissemination of a DHPC in its territory for a medicinal product authorized also in Lebanon, the MAH should notify in writing the national competent authority in Lebanon in a timely manner with a copy of the DHPC and relevant information.

The need for subsequent dissemination of such DHPC in Lebanon should be considered and agreed on a case-by-case basis.

XV.C.2.3. Submission and granting approval of DHPC

When drafting a DHPC the following should be followed:

- The template provided in Appendix 1 of the present Module and adapted from the Guideline on Good Pharmacovigilance Practices (GVP) for Arab Countries - Version 3, dated December 2015, on pages 546-547, and accessed through the following link: *https://who-umc.org/media/164038/the-good-pharmacovigilance-practice-for-arab-countries-v3-12-2015.pdf*; and

- The guidance provided in the annotations of Figure 1: “Flowchart for the processing of Direct Healthcare Professional Communications (DHPCs) in Lebanon”.

The MAH should submit the following to the national competent authority in Lebanon:

- Draft DHPC; and
- 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 recipient's name, 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 the provision of DHPCs to relevant pharmacists (hospital and /or community).
- Timetable for disseminating the DHPC: the proposed timetable should be appropriate according to the urgency of the safety concern (usually a maximum of 30 calendar days is considered appropriate, and this should be included in the DHPC Plan);
- Dissemination mechanism: how the DHPC is planned to be disseminated, and the proposed mechanism should be selected appropriately to meet the dissemination timetable.

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

XV.C.2.4. Measuring the effectiveness of DHPC

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

During the DHPC dissemination, the MAH should adhere to the agreed communication plan.
After dissemination of a DHPC, MAHs should conduct a closing review and inform the national competent authority about the number of HCPs who received the DHPC and about 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). When needed, appropriate action should be taken to correct the situation or prevent similar problems in the future.

The MAH should notify the NCA with any updates that may emerge during the DHPC dissemination process.

XV.C.2.5. 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 the concerned MAHs as the coordinator.

- The coordinator acts on behalf of all concerned MAHs as the contact point for the national competent authority; if not agreed, this may be assigned by national competent authority;
- This coordinator should be specified in the agreed communication plan (see Appendix 2) to facilitate coordination;
- All concerned MAHs – facilitated by the coordinator- should collaborate to cover technical and financial aspects, so that a single DHPC is prepared and circulated in Lebanon. Additionally, the dissemination plan should be jointly coordinated and agreed upon to determine the responsible party for its implementation. The circulated DHPC should include the name of all medicinal products containing the concerned active substance and/or a class authorized in Lebanon as well as the logos and contact details of all the concerned MAHs, and signed by the coordinating MAH.

XV.C.2.6. Translation of DHPCs

The usual language for preparing the DHPCs will be English. An Arabic translation of the DHPCs may be required if this is suitable to (part of) the intended receipts.

XV.C.2.7. Publication of DHPCs

The national competent authority may publish the final DHPC on its official website. The timing for such publication should be aligned with that of the dissemination of DHPC in the country. The national competent authority may also issue an additional safety announcement and disseminate the DHPC to relevant HCP organizations as appropriate.

XV.C.2.8. Overall Steps of the DPHC processing:

***Step 1*:** After identification of the need for a DHPC according to the criteria in section XV.C.2.1, the MAH should submit the communication plan documents in the form of one full original hard copy and one soft copy. After approval by the national competent authority, the MAH will receive back the hard copy stamped with “approved”, while the soft copy will be retained at the authority

***Step 2*:** The MAH should allow a minimum of two working days for the provision of comments; however, whenever possible, a longer review period should be granted. The timing may be adapted according to the urgency of the situation. The MAH may proceed only after receiving formal approval

***Step 3*:** The national competent authority will review the DHPCs.

***Step 4**:* DHPC content and communication plan are agreed.

***Step 5**:* The MAH can start disseminating the DHPC, and the national competent authority may publish the final DHPC on its official website.

***Step 6**:* A closing review should be performed by the MAH after dissemination of a DHPC.

Step 7: The MAH is to notify the NCA of any updates that may emerge during the dissemination process

Refer to the flow chart in Figure 1 below describing the processing of DHPCs.

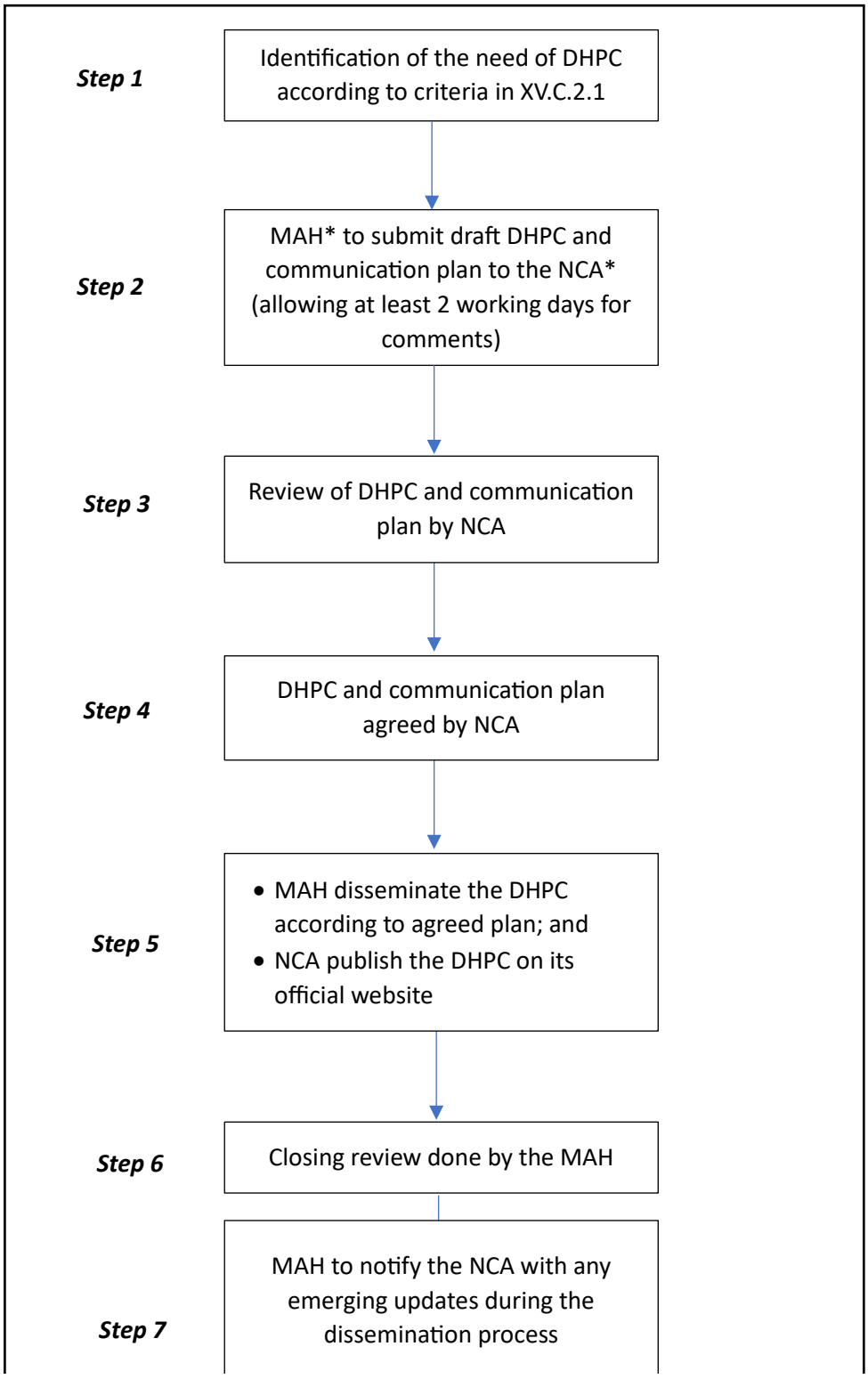

Figure 1: Flow chart for the processing of Direct Healthcare Professional Communications (DHPCs) in Lebanon

**MAH: Marketing Authorization Holder*
NCA: National Competent Authority

Appendix 1. Template: Direct Healthcare Professional Communication (DHPC)

<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> would like to inform you of the following:

Summary

Style guide: This section should be in a larger font size than the other sections of the DHPCand preferably in bullet points.

- <Brief description of the safety concern, 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>

<A statement indicating that the information is being sent in agreement with the national competent authority, if applicable>

Further information on the safety concern and the recommendations

<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), also the reason for disseminating the DHPC at this point>

<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>

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

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

<A schedule for follow-up action(s) by the marketing authorization holder/national competent authority, if applicable>

Further information

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

<Therapeutic indication of the medicinal product, if not mentioned above>

Call for reporting

<A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system>

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

<Details *(e.g., name, postal address, website address)* on how to access the nationalspontaneous reporting system>

Company contact point

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

Annexes

<Relevant sections of the Product Information that have been revised (with changes made visible)>

<Detailed scientific information, if necessary>

<List of literature references, if applicable>

Appendix 2. Template: 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 the number of intended recipients and their geographical distribution, e.g., general practitioners, specialists, community pharmacists, hospital pharmacists, nurses, professional societies, and national associations.***	
	MAH names	Corresponding product name
Concerned MAH(s)	***Add rows as needed***	
Timetable		Dates
DHPC and communication plan approved by the national competent authority		
Dissemination of DHPC		***Start & end dates for dissemination***
Closing review		

**For coordinated DHPC: The circulated DHPC should include the name of all medicinal products containing the concerned active substance and/or a class authorized in Lebanon as well as the logos and contact details of all the concerned MAHs, and signed by the coordinating MAH.*