HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
Marketing Authorisation Holders on Direct Healthcare Professional Communications

1 INTRODUCTION

A Direct Healthcare Professional Communication (DHPC) aims to promote safe and effective use of a marketed medicine. It is delivered directly to healthcare professionals by marketing authorisation holders (MAHs) or by competent authorities such as the Health Products Regulatory Authority (HPRA). However, a DHPC should not include any material that might constitute advertising or be considered promotional or commercial.

This document provides specific guidance on submitting DHPCs to the HPRA, and should be read in conjunction with GVP Module XV – Safety Communications.

2 OBLIGATIONS OF MARKETING AUTHORISATION HOLDERS AND NATIONAL COMPETENT AUTHORITIES

A marketing authorisation holder must ensure that it has an appropriate system of pharmacovigilance and risk management for marketed medicines and must take appropriate action when necessary.

The communication of safety information to patients and healthcare professionals is essential to achieve the objectives of pharmacovigilance. The pharmacovigilance legislation includes a number of provisions to strengthen safety communication and its coordination:

- Directive 2010/84/EU amending Directive 2001/83/EC, Regulation (EU) No. 1235/2010 amending Regulation (EC) No. 726/2004, and
- Commission Implementing Regulation (EU) No. 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No. 726/2004 and Directive 2001/83/EC).

GVP Module XV – Safety Communications provides guidance to MAHs on how to communicate and coordinate safety information in the EU. Accurate and timely communication of emerging data for risk is integral to pharmacovigilance. DHPCs are an important communication tool that can aid education and risk management for healthcare professionals.

In the event of communication from an MAH to healthcare professionals, the content and timeline for distribution should be agreed with the HPRA (and with other competent authorities as necessary). The supporting risk assessment should be clearly presented and the issues highlighted in the DHPC template (in GVP Module XV) should be fully addressed.

All draft DHPCs and communication plans are referred to the Pharmacovigilance Risk Assessment Committee (PRAC) as indicated in GVP Module XV. PRAC recommendations are provided to the Committee for Medicinal Products for Human Use (CHMP) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh), as relevant.

3 KEY PRINCIPLES FOR COMMUNICATION OF SAFETY INFORMATION

GVP Module XV – Safety Communications describes the principles and content of safety communications including DHPCs. These include the following:

- Healthcare professionals should be notified of significant, new or emerging information in a timely manner and the reason for initiating the communication should be detailed;

- Information on risks should be presented in the context of the benefits of the medicine and should include appropriate information on the seriousness, severity, risk factors, time to onset and reversibility of adverse reactions. Information on competing risks, such as the risk of non-treatment, should be included where appropriate and possible. Appropriate quantitative measures should be used when describing and comparing risks;

- The uncertainties related to a safety concern should be addressed and updated as further evidence becomes available;

- A DHPC should not usually be distributed before the corresponding regulatory procedure has been completed;

- The DHPC should include the content of any information communicated directly to the general public;

If time allows, the text should be reviewed by representatives of the target audience;

- Agreement is needed between the marketing authorisation holder and competent authorities (and other partners as appropriate) on the content and format of the information with consideration of the supportive evidence, recipients, and distribution timetable.

4 WHEN TO USE A DHPC

Situations where the use of a DHPC should be considered as part of the risk-management process include:

- Suspension, withdrawal, revocation of a marketing authorisation with recall of the medicine from the market for safety reasons;

- Important changes to the use of a medicine due to 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;

- A change in the balance of benefits and risks for a medicine (e.g. new data identifying a previously unknown risk or a change in the frequency of a previously known risk; substantiated knowledge that the medicinal product is not as effective as previously considered);

- New recommendations for treating or preventing adverse reactions;

- 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 minimise the potential risk).

5 COMMUNICATION PLANNING FOR A DHPC

The MAH should submit a draft distribution plan to the HPRA that includes: objective, timetable, an up-to-date list of recipients, dissemination method, communication plan, related communications and post-communication strategy.

6 JOINT DHPCS

In the event that a DHPC is required for an active substance and two or more MAHs are obliged to distribute the same DHPC, the HPRA recommends that MAHs collaborate to distribute a single joint DHPC, where appropriate[1]. The HPRA will facilitate the joint submission of DHPCs, where appropriate.

7 TEMPLATE FOR PREPARING A DHPC

The DHPC template should be followed and is provided as Annex II to GVP Module XV. In summary, the template shows that the letter should be arranged with the following sections:

7.1 Heading

The heading should specify the main message of the DHPC.

7.2 Summary

Provide a brief description of safety concern and recommendations for risk minimisation (this section should be in a larger font size compared to the rest of the text and preferably be in bullet points).
Include a statement indicating that the information is being sent in agreement with the national competent authority or EMA, if applicable.

[1] It is acknowledged that it may not always be possible to collaborate due to differences in formulations or routes of administration, etc., that could impact on the information being provided.

7.3 Further information on the safety concern and recommendations

Include the following details:
- Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship);
- Reason for disseminating the DHPC at this point in time;
- If needed, details on the recommendations for risk minimisation;
- Placing of the risk in the context of the benefit;
- An estimation of the frequency of the adverse reaction or reporting rates with estimated patient exposure;
- Statement indicating any association between the adverse reaction and off-label use, if applicable.

7.4 Follow-up actions

A schedule for follow-up action(s) by the MAH or national competent authority should be included, if applicable.

7.5 Further information

Include a link or reference to other available relevant information, such as information on the website of a competent authority.

7.6 Call for reporting of suspected adverse reactions

Include a reminder of the need and mechanism for reporting adverse reactions in accordance with the national spontaneous reporting system as per the QRD template, Appendix V, Adverse Drug Reaction Reporting Details. Requested wording is as follows:

Call for reporting:
Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

7.7 Company contact point

Provide contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address.

7.8 Annexes

Include revised product information, detailed scientific information, reference list including literature references, and other information.

Note that safety communications should deliver relevant, clear, accurate and consistent messages.

Other editorial suggestions include:

- It may be useful to refer at least once to the recommended International Nonproprietary Name (rINN) as well as the medicine's brand name;
- Avoid abbreviations that may be unfamiliar to healthcare professionals; if they are necessary, spell them out first time and include the abbreviation in brackets after;
- Avoid over-use of bold and italics for emphasis; block italics can be difficult to read;
- The use of S.I. units;
- Consider that the audience may be a wide range of healthcare professionals (e.g. range of disciplines and level of specialist knowledge relating to the safety information). The language should reflect a potentially diverse audience: the information may be relevant to professionals wider than those who prescribe or administer a medicine (e.g. consider dispenser/community-facing roles and those who may identify an adverse reaction).

8 SUBMISSION OF DHPC COMMUNICATIONS TO THE HPRA

The following must be submitted as part of a DHPC submission to the Vigilance Assessment section via medvigilance@hpra.ie:

- DHPC submission form for MAHs, please see the 'Publications and Forms' section of www.hpra.ie
- Draft DHPC letter
- Communication plan
- List of recipients

HPRA
05 May 2020