Guidance for marketing authorisation holders on drafting direct healthcare professional communications

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Introduction

A direct healthcare professional communication aims to ensure safe and effective use of a marketed medicine. It is delivered directly to healthcare professionals by marketing authorisation holders or by competent authorities such as the MHRA. However, direct healthcare professional communication should not include any material that might constitute advertising or be considered promotional or commercial.

Guidance for marketing authorisation holders

Module XV – Safety communication of the European Guideline on good pharmacovigilance practices (GVP) — outlines the obligations of marketing authorisation holder and competent authorities for pharmacovigilance of licensed medicines. A marketing authorisation holder must ensure that it has an appropriate system of pharmacovigilance and risk management to assure responsibility and liability for marketed medicines, and to ensure appropriate action can be taken when necessary.

Accurate and timely communication of emerging data for risk is integral to pharmacovigilance. Direct healthcare professional communications (also known as “Dear Dr Letters”) are an important communication tool that can aid education and risk management for healthcare professionals.

In the event of communication from a marketing authorisation holder to healthcare professionals, the content and timeline for distribution should be agreed with the MHRA (and with other competent authorities as necessary).

Part XV.B and XV.C of the guidance document outlines the roles for marketing authorisation holders on pharmacovigilance communication. Section C.2 of part XV explains the content, format, and dissemination of direct healthcare professional communications. Section 5.1 outlines the key principles for public communication. These include:

- healthcare professionals should be notified of significant, new, or emerging information before the general public
- a direct healthcare professional communication should not usually be distributed before the corresponding regulatory procedure has been completed
- agreement is generally needed between the marketing authorisation holder and competent authorities (and other partners as appropriate) on the content and format of the information, recipients, and distribution timetable.

Situations where a direct healthcare professional communication 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 Summary of Product Characteristics (eg new warnings or contraindications, reduced recommended dose, or restricted indications or availability); or a change in the balance of benefits and risks for a medicine.
Pre-communication planning for direct healthcare professional communications

Module XV guidance also outlines contact points for marketing authorisation holders when proposals for a direct healthcare professional communication are initiated, which can vary depending on the authorisation route of the medicine.

The marketing authorisation holder should submit a draft communication plan to the contact that includes: objective, timetable, recipients, dissemination method, related communications and post-communication strategy.

Key principles for preparation of a direct healthcare professional communication

The direct healthcare professional communication template should be followed and is provided at the annex II of the Guideline on good pharmacovigilance practices (GVP).

Briefly, the template shows that the letter should be arranged with the following sections:

- summary—brief description of safety information and recommendations; this section should be in a larger font compared with the rest of the text
- further information—detail of safety information (with frequency of event or adverse reaction), risk in the context of benefit, reference to annexed revised product information, follow-up action
- recommendations—advice and instructions for risk minimisation
- call for reporting of suspected adverse reactions to the Yellow Card Scheme

Suggested wording is as follows:

- ‘Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:
  - all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
  - all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

- It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/.

- Alternatively, prepaid Yellow Cards for reporting are available:
  - by writing to FREEPOST YELLOW CARD (no other address details necessary)
  - by emailing yellowcard@mhra.gsi.gov.uk
  - at the back of the British National Formulary (BNF)
by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
or by downloading and printing a form

- When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.
- communication—details of other related public communication, and contact details for further information
- annexes—revised product information, reference list, and other information.
- the text should be written in English and translations should be provided as necessary. The following should also be considered:
  - safety information should be clear and concise; it should not exceed two pages
  - the reason for dissemination should be explained (eg availability of new data)
  - recommendations to healthcare professionals should be given on how to minimise risk, if known
  - the safety concern should be placed in the context of the overall benefit of treatment
  - safety information must be objective and not misleading
  - if time allows, the text should be reviewed by representatives of the target audience
  - the direct healthcare professional communication should include the content of any information communicated directly to the general public
  - estimated timescales for follow-up action should be stated
  - contact details for further information should be provided, including the website address, telephone number, and postal address of the marketing authorisation holder
  - relevant references should be cited as an annex.

Other editorial considerations

- If relevant, insert a black triangle next to the brand name of the medicine to indicate that it is under intensive monitoring.
- It may be useful to refer at least once to the recommended International Nonproprietary name (rINN) or British Approved Name (BAN) as well as the medicine’s brand name.
- Use active sentences rather than passive (eg change “patients were requested to complete a questionnaire” to “patients completed a questionnaire”).
- 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.
- Use SI units.
- Consider that the audience may be a wide range of healthcare professionals (eg 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 (eg consider dispenser/community-facing roles, and those who may identify an adverse reaction).