

MEDICINES CONTROL COUNCIL



PROCESS FOR HANDLING DEAR HEALTHCARE PROFESSIONAL LETTERS RELATING TO SAFETY AND MEDICINE SAFETY ALERTS

1 Definition

- 1.1 A Dear Health Care Professional (DHCP)-letter (also referred to as a Dear Doctor letter) is a letter distributed by an applicant or a holder of a certificate of registration for a medicine to medical practitioners and other health care professionals to convey important information about medicines. Such letters can be requested by the MCC or initiated by the applicant.
- 1.2 A DHCP letter which contains any safety information about a medicine must be submitted to the MCC for review and approval prior to distribution. If such a DHCP letter is distributed without MCC approval, the MCC will initiate a process whereby corrective action will be required by the applicant.
- 1.3 The DHCP letter which contains safety information, as well as the envelope in which it is to be mailed, must be clearly marked in bold and font Times New Roman size 14 or Arial size 14:

IMPORTANT MEDICINE SAFETY INFORMATION

This statement, or any statement which may be similar in order to attract the attention of the recipient, may not be used for any other DHCP letter which does not contain safety information.

- 1.4 The DHCP letter should be concise and ideally one (1) page only, and no longer than two (2) pages.

2 Process

- 2.1 The applicant submits the draft DHCP letter, with full motivation, to the Central Pharmacovigilance Office, including an electronic copy (PhV-DHCPL@health.gov.za) (~~Mr Mukesh Dheda: dhedam@health.gov.za~~).
- 2.2 Every draft DHCP letter must be accompanied by the most recently approved package insert (PI) and patient information leaflet (PIL) for the medicine concerned.
- 2.3 If the consequence of the new information is an amendment to the package insert, the applicant must include the proposed package insert simultaneously, in which the proposed changes are indicated. The applicant must also submit such a proposed PI and PIL for evaluation to the relevant unit of the secretariat at the same time.

2 Process continued

- 2.4 The DHCP letter should include a statement that the package insert is in the process of being reviewed to reflect the relevant information, if applicable.
- 2.5 The Pharmacovigilance Unit shall inform the DHCP letter review group of the proposed DHCP letter and provide the review group with all the necessary documents and/or information.
- 2.6 The DHCP letter review group will ensure that the draft DHCP letter is reviewed as quickly as possible, but no longer than five (5) working days after receipt.
- 2.7 The applicant will be informed of any amendments to the proposed DHCP letter. The applicant will be given an opportunity to respond to any such amendments, no longer than 10 working days.
- 2.8 If no agreement can be reached between the DHCP letter review group and the applicant on the content of the letter within 30 working days of the initial communication from the applicant, the matter will be referred to Council or EXCO, whichever meets the soonest.
- 2.9 The proposed envelope for the DHCP letter will also be reviewed by the DHCP letter review group to ensure that it contains the appropriate markings relating to the content.
- 2.10 The target group(s) for receipt of the DHCP letter must be clearly identified by the applicant at the time of submission and agreed upon by the DHCP letter review group.
- 2.11 The DHCP letter must be distributed within 14 calendar days of the applicant being informed of approval by the review group.
- 2.12 Following distribution, applicants must be able to identify which members of the professions have been targeted in the mail communication and confirm the distribution.
- 2.13 The DHCP letter review group will inform the Pharmacovigilance Committee at its meeting immediately following approval of the DHCP letter.
- 2.14 The Pharmacovigilance Committee will present all approvals of DHCP letters as part of its report to Council.
- 2.15 The approved DHCP letter shall be posted on the MCC website (www.mccza.com).
- 2.16 The information relating to a DHCP letter may also be issued as a Medicine Safety Alert by Council.

NB: The DHCP letter for important safety information shall not contain any material that can be viewed as promotional in nature.

PROCESS FOR HANDLING OF MEDICINE SAFETY ALERTS**1 Definition**

- 1.1 A Medicine Safety Alert contains information about an important medicine safety issue. It may relate to new safety information or may emphasize information already known. A Medicines Safety Alert will usually be published in one or more local popular journals read by health care professionals, as well as on the MCC website.
- 1.2 A Medicine Safety Alert may follow the issue of a Dear Health Care Professional or may be in response to any other medicine safety issue arising locally or internationally. The Medicines Safety Alert should indicate whether the safety concern has arisen with the use of the medicine in accordance with the approved package insert, or whether it has arisen with use outside of the approved package insert, if relevant.
- 1.3 A Medicine Safety Alert is usually drafted by the regulatory authority.

2 Process

- 2.1 The National Adverse Drug Event Monitoring Centre (NADEMC) drafts the Medicine Safety Alert or coordinates the drafting of the Medicine Safety Alert.
- 2.2 The Medicine Safety Alert is made available to the applicant concerned for comment within 14 days of communication by the secretariat. The applicant will be informed of the name of the journal(s) in which the Medicine Safety Alert is intended to be published.
- 2.3 The applicant should provide information in support of any objection it has to either publication of the Medicine Safety Alert or to any information or wording contained in the Medicine Safety Alert.
- 2.4 The Medicine Safety Alert will include a statement that the package insert is in the process of being updated if this is relevant.
- 2.5 The draft Medicine Safety Alert is presented to the Pharmacovigilance Committee and Council, respectively, for review.
- 2.6 Council has the right to make a final decision on publication of a Medicine Safety Alert.
- 2.7 The Medicine Safety Alert will then be published in appropriate local medical/scientific journals and posted on the MCC website.

UPDATE HISTORY

Date	Reason for update	Version & publication
30 July 2003	"Process for handling Dear Dr Letters and Drug Alerts" First version published as Circular	Circular 7 of 2003
May 2006	Amended to be in new format of guidelines and communications	Version 2, May 2006
Aug 2014	Overall editing <i>in t al</i> to address timelines 1.2, new 1.4 2.1, 2.2, 2.3, 2.5, 2.6, 2.7, 2.8, 2.10 2.13 (now 2.11), 2.14 (now 2.12) 3 deleted	Version 3, Sept 2014
Immediate effect	Implementation	
Aug 2014 / March 2015	Change of address for electronic copy of the letter	Version 3_1, March 2015