CBG MEB

MEDICINES EVALUATION BOARD

Policy Document

Direct Healthcare Professional Communications (DHPCs)

MEB 44

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2. Introduction

A *Direct Healthcare Professional Communication* (DHPC) is a one-off, additional risk minimisation measure used to inform healthcare providers directly about new, important information about a medicinal product. The need to send out a DHPC, including a proposal for an English text, is geared in most cases to the European level (*Pharmacovigilance Risk Assessment Committee* (PRAC), *Committee for Medicinal Products for Human Use* (CHMP), *Coordination Group for Mutual Recognition and Decentralised Procedures – Human* (CMDh)). The Board then decides whether the DHPC will be implemented at the national level.

This document is based on the *Guideline on Good Pharmacovigilance Practices (GVP) Module XV – Safety communication*, and focuses specifically on the Dutch situation. This document describes the procedure for the implementation of DHPCs in the Netherlands, and provides instructions for translating the DHPC, identifying the target groups and their distribution. The starting point is that the information in the DHPCs is optimally consistent with the usability for healthcare providers, which improves the effectiveness of this additional risk minimisation measure.

3. Scope of the document

The information in this document is based on scientific research (dissertation S. Piening 2013) and feedback from Dutch clinical practice.

This guideline provides general recommendations and is not a detailed work instruction. It presents a framework for the way in which the Medicines Evaluation Board (MEB) deals with DHPCs and the considerations that are made when assessing them.

In all proposals, the starting point is that the marketing authorisation holder is responsible for the entire process regarding the translation and distribution of DHPCs in the Netherlands. A single marketing authorisation holder can act on behalf of several marketing authorisation holders if there are multiple marketing authorisation holders.

This policy document focuses on the communications to the BIG-registered healthcare providers with prescribing authority (art. 3 and art. 36a of the Individual Health Care Professions Act), since these may be the official target groups of a DHPC. With each DHPC, the decision will be made as to who should receive the DHPC and the method of information dissemination needed.

4. Other relevant documents

GVP module XV – Safety Communication (Rev 1)

GVP Annex II – Templates: Direct Healthcare Professional Communication (DHPC) (Rev 1)

5. General guidelines

If it has been established for a medicinal product that a DHPC must be sent in the Netherlands, the marketing authorisation holder must provide the following documents:

- The English version of the established DHPC if the decision concerns a European procedure
- Dutch translation of the established English DHPC in 'MS Word' format
- Distribution plan including the target groups for whom the DHPC is intended
- Number of prescribers and/or users of the medicinal product in the Netherlands
- One (or more) photos of the product to be attached with the DHPC, intended for the publication of the MEB news item. In case of a joint DHPC drafted by several marketing authorisation holders, the relevant marketing authorisation holders may select an appropriate photo of one or more products, as long as the name of the active substance is clearly visible.

The aforementioned documents cannot be handled as part of an ongoing procedure but will have to be submitted as a separate national procedure. They are submitted to the MEB in the same way as for other procedures.

The marketing authorisation holder must clearly state in the accompanying letter that it concerns the submission of a DHPC. If the marketing authorisation holder has questions about submission of the material, the case manager of the MEB of the medicinal product can be contacted.

After the Dutch translation of the DHPC has been established, the marketing authorisation holder must immediately submit an anonymised version, dated but without personal data in Word format. This will be published on the MEB website. The version of the DHPC that will be sent out to the target group must include personal data.

Personal data are any information which are related to an identified or identifiable natural person. For example names and signatures, but also email addresses. If the name of a natural person can be identified from the email address, this email address is not allowed to be published on the MEB website. The marketing authorisation holder must therefore use an email address without personal data, for example department@organisation.tld or an abbreviation (first letter first name) (two letters last name)@organisation.tld. Within these examples, no natural person can be identified from the email addresses.

5.1. A single DHPC for multiple products

At present, there is no legal requirement for marketing authorisation holders to cooperate in case of a joint DHPC, although *GVP Module XV - Safety communication* indicates the following: 'In each Member State, when several marketing authorisation holders are concerned (i.e. when the DHPC covers several products with the same active substance or products of the same therapeutic class), marketing authorisation holders are strongly encouraged to arrange for one marketing authorisation holder to act on behalf of all

concerned marketing authorisation holders as the contact point for the national competent authority.'

If a DHPC that applies to multiple products (innovator and generics, or different innovators/generics, parallels) is sent, the MEB expects that one DHPC will be sent on behalf of the joint marketing authorisation holders. All marketing authorisation holders must cooperate on a joint DHPC, regardless of whether their product is on the market or not. In an annex to the DHPC, an overview is given on the products referred to in the DHPC. In the introductory sentence, the DHPC mentions both the product name of the innovator product (if applicable) and the substance name. In the continuation of the DHPC, only the substance name is mentioned.

At the request of the marketing authorisation holder, the MEB can provide a list of marketing authorisation holders. The marketing authorisation holder of the innovator product is expected to take responsibility for the procedure for the translation and transmission of the joint DHPC. If an innovator product is no longer available on the Dutch market, the marketing authorisation holder of the generic product with the largest market share then in force is requested to assume this role.

6. Dutch translation

The main aspects of the translation are: a) what message must be conveyed?; b) what information does a healthcare provider need in practice?; and c) what concrete action is expected from the healthcare provider?

At present, the Dutch translation of a DHPC is followed as closely as possible at the European level, or translated as literally as possible. Since this does not always enhance the clarity of the message, it is possible to deviate from the English text in structure and/or choice of words.

In addition, the DHPC must be in line with the template and standard phrases as shown in Annex 1 of this document.

7. Formatting

7.1. Design of letterhead and envelope

In order to increase the recognisability and reliability of DHPCs, both the letterhead and the envelope must have a uniform appearance:

- There are no logos of marketing authorisation holder(s) on the letterhead or envelope
- Both the letterhead and the envelope must contain the logo of an orange or white hand.
- The DHPC is signed by the marketing authorisation holder(s).

- The letter contains a footer: *Belangrijke, niet-commerciële risico-informatie over een farmaceutisch product*
- The envelope contains the text:

Belangrijke, niet-commerciële risico-informatie over een farmaceutisch product

7.2. Orange or white hand

During the assessment of the translation of the DHPC, the case manager of the MEB coordinates the target groups and the need for an orange hand envelope (OHE) with IGJ. An OHE is considered on a case-by-case basis, but the following situations require an OHE:

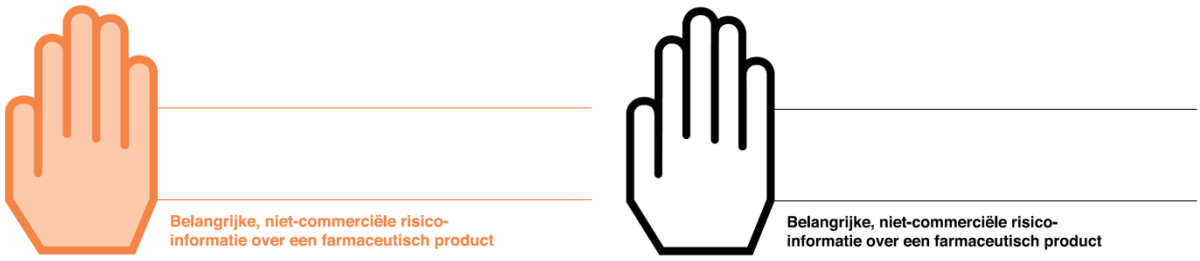
- containment indication
- addition of a new contraindication
- change in the patient's therapy
- additional visit by the patient to the doctor or pharmacist is necessary
- recall at the pharmacy and patient level

This is not a definitive list of conditions for an OHE. The need for this is considered on an individual basis.

The marketing authorisation holder is responsible for applying for the OHEs from the Association Innovative Medicines, https://www.verenigginnovatievegeneesmiddelen.nl. This should be done as soon as possible in connection with the delivery time of the envelopes.

The white hand envelope (WHE) should be used for the other DHPCs. This WHE must also be applied for via the VIG in the same way as for the OHE.

The addition of the logo of an orange or white hand on both letterhead and envelope serves two purposes: it increases the recognisability of DHPCs and distinguishes it from commercial information.



8. Distribution plan

Target groups are usually indicated at the European level. These should be translated to the Dutch situation. The marketing authorisation holder should submit a distribution plan for this as part of the implementation procedure. A critical consideration must also be given to the healthcare providers to whom the DHPC should be addressed, including healthcare providers in training. In addition to the healthcare providers covered by the so-called art. 3 professions (included in the BIG Register) art. 36a professions (physician assistant, clinical technologist, Bachelor medical care provider, nursing specialist) may also prescribe medicinal products.

A limited distribution to part of the target group is possible in exceptional cases, for example, with orphan medicinal products. The marketing authorisation holder will have to describe in a proposal for limited distribution in the distribution plan the method by which the exact target group will be identified and reached.

9. Communications and logistics

9.1. Timelines

The timelines for DHPCs are set at the European level in the majority of cases. In determining these timelines, the time required for the implementation and coordination at the national level is taken into account.

If necessary, the professional organisations of the healthcare providers involved will be informed during the national implementation phase about a DHPC announced by the MEB. Depending on the set timelines, this takes place as soon as the English text is available (usually on the last day of the PRAC/CHMP meeting), or when the Dutch translation becomes available. In this way, unambiguous communication can be prepared so that healthcare providers are informed of the relevant case as quickly as possible.

9.2. Electronic distribution

In the current digital age, the MEB would like to aim toward distributing DHPCs digitally. This does not replace a paper letter but supplements it. Of course, the greater speed of electronic distribution compared to paper distribution is also important here. Marketing authorisation holders are advised to send their DHPC in both paper and electronic form to the defined target groups.

Annex 1: Standard phrases DHPC

Date

Belangrijke risico-informatie: [*subject*]

Geachte heer/ mevrouw,

For centrally authorised products and MRP/DCP products for which there is coordinated EU action, the first sentence reads:

In overleg met het Europese geneesmiddelenagentschap (EMA), het College ter Beoordeling van Geneesmiddelen (CBG) en de Inspectie Gezondheidszorg en Jeugd (IGJ) wil [*marketing authorisation holder*] u informeren over…..

For national action only, the first sentence reads:

In overleg met het College ter Beoordeling van Geneesmiddelen (CBG) en de Inspectie Gezondheidszorg en Jeugd (IGJ) wil [*marketing authorisation holder*] u informeren over….

Samenvatting

[point-by-point enumeration, bold and larger font]

[…]- brief description of the message in context of indication, recommendations for risk minimisation (contraindication, warnings, precautions, and alternative therapy, if relevant.

- recall information, if relevant

Aanvullende informatie

[…]

- The indication should be included here.

Melden van bijwerkingen bij het Nederlands Bijwerkingencentrum Lareb *[if relevant / depending on the subject]*

▼ Dit geneesmiddel is onderworpen aan aanvullende monitoring. Daardoor kan snel nieuwe veiligheidsinformatie worden vastgesteld.*[If applicable]*

Het is belangrijk om na toelating van het geneesmiddel vermoedelijke bijwerkingen te melden. Op deze wijze kan de verhouding tussen voordelen en risico's van het geneesmiddel voortdurend worden gevolgd. Beroepsbeoefenaren in de gezondheidszorg wordt verzocht alle vermoedelijke bijwerkingen te melden via het Nederlands Bijwerkingen Centrum Lareb; website www.lareb.nl.

Contactinformatie

Indien u vragen heeft of meer informatie wenst met betrekking tot *[product name]*, kunt u contact opnemen met *[department]* van *[marketing authorisation holder]*, te bereiken via telefoonnummer *[telephone number]*, of via *[e-mail address without personal data]*.

Met vriendelijke groet,

[*name, signature of authorised person, if necessary*]

NB: Deze DHPC is verstuurd aan de volgende zorgverleners: *[enumeration of the target groups]*

- List of literature references *[if applicable]*

[as a footnote on all pages of the letter:
'Belangrijke, niet-commerciële risico-informatie over een farmaceutisch product'

Bijlages:

- List of marketing authorisation holders involved *[if applicable with a joint DHPC]*
- Official product information of the product or only the relevant sections, indicating the changes [*if applicable*]