DECISION

No. 3/29.02.2008

on approval of the Guideline on Direct Healthcare Professional Communication

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order No. 485/09.05.2005, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 29.02.2008, in accord with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

DECISION

Single article. – The Guideline on the Direct Healthcare Professional Communication is approved, according to the Annexes which are integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINE
on Direct Healthcare Professional Communication

CHAPTER I
General principles

Art. 1. – This Guideline is a translation into Romanian and an adaptation of chapter „Direct Healthcare Professional Communication" – Part II – of Eudralex, Volume 9a - PHARMACOVIGILANCE.

Art. 2. – (1) The aim of this Guideline is to establish principles for the content and format of Direct Healthcare Professional Communications (DHPCs) (commonly called „Dear Doctor-letters" (DDL)), as well as describing situations where dissemination of DHPCs should be considered.

(2) This Guideline also aims to describe the main requirements and procedures for such communications on the safe and effective use of medicinal products for human use.

(3) DHPCs relating to quality defects with medicinal products are outside the scope of this Guideline.

CHAPTER II

II.1 Legal basis of direct communications to healthcare professionals

Art. 3. – Directive 2001/83/EC and Regulation (EC) No 726/2004 impose requirements on Competent Authorities in Member States, including the European Medicines Agency (EMEA) for communication to the public on matters relating to pharmacovigilance and the safe use of medicinal products.

Art. 4. – In addition to this, such communication is considered as part of the risk management process (see the NMA Scientific Council Decision No. 13/2007 – Chapter III).

II.2 Definition of Direct Healthcare Professional Communication

Art. 5. – (1) A Direct Healthcare Professional Communication (DHPC) is defined as information aimed at ensuring safe and effective use of medicinal products which is delivered directly to individual Healthcare

Professionals by a Marketing Authorisation Holder, or by the NMA (this excludes direct personal replies to requests from individual Healthcare Professionals).

(2) Such DHPCs should not include any material or statement which might constitute advertising within the scope of Title VIII and IX of Directive 2001/83/EC, or which is considered to be promotional or commercial by the Competent Authority.

II.3 Key Principles for Public Communication on Medicinal Products

Art. 6. – The following key principles should be considered for public communication on medicinal products in general and by means of DHPCs in particular:

a) Provision of information about the safe and effective use of medicinal products supports appropriate use and should be considered as a public health responsibility.

b) Communication of such information needs to be considered throughout the risk management process (see the Scientific Council Decision No. 13/2007, Chapter III).

c) It is essential that such information is communicated to Healthcare Professionals and relevant partners including Patient and Healthcare Professional organisations, learned societies and pharmaceutical wholesalers.

d) In principle, significant new or emerging information should be brought to the attention of Healthcare Professionals before the general public, in order to enable them to take action and respond to Patients adequately and promptly. The important function of Healthcare Professionals in disseminating such information to Patients and the general public is recognised and should be supported.

e) The overriding principle should be to ensure that the right message is delivered to the right persons at the right time.

f) Effective communication on safe and effective use of medicinal products authorised in the European Union (EU) entails:

- Co-operation of all partners;
- Co-ordination between relevant partners, within and, if possible, outside the EU; and
- A strategy which meets the requirements resulting from the urgency to communicate and the expected public health impact of the information.

g) A DHPC should not usually be distributed before the corresponding regulatory procedure has been completed, however, exceptionally (e.g. in the case of an urgent safety restriction) there may be a need to disseminate a DHPC prior to completion of a procedure. For centrally authorised medicinal products, the appropriate point in time for dissemination of a DHPC is usually once the CHMP Opinion has been adopted.

h) In general, an agreement between the Marketing Authorisation Holder and the NMA/the EMEA (and other partners as appropriate) is needed on the format and content of the information, recipients and the timetable; the agreed timetable for release of the information should be fully respected by all partners.

II.4 Situations Where a Direct Healthcare Professional Communication Should Be Considered

Art. 7. – Dissemination of a DHPC is usually required in the following situations:

a) Suspension, withdrawal or revocation of a marketing authorisation with recall of the medicinal product from the market for safety reasons; or

b) Important changes to the Summary of Product Characteristics (SPC), for instance those introduced by means of an urgent safety restriction (e.g. introduction of new contraindications, warnings, reduction in the recommended dose, restriction of the indications, restriction in the availability of the medicinal product); or

c) Completion of a referral procedure triggered for safety concerns which results in a significant change to the medicinal product information; or

d) In other situations relevant to the safe and effective use of the medicinal product at the request of the NMA or, in the case of centrally authorised product, at the request of the EMEA or European Commission.

Art. 8. – Other situations where dissemination of a DHPC may be appropriate include:

a) A change in the outcome of the evaluation of the risk-benefit balance due to:

- new data, in particular from a study or spontaneous reports that identify a previously unknown risk or a change in the frequency or severity of a known risk; or
- new data on risk factors and/or on how adverse reactions may be prevented; or

- substantiated knowledge that the medicinal product is not as effective as previously considered ; or

- evidence that the risks of a particular medicinal product are greater than those of alternatives with similar efficacy; or

b) Availability of new recommendations for treating adverse reactions; or

c) Ongoing assessment of a possible significant risk, but insufficient data at a particular point in time to take any regulatory action (in this case, the DHCP should encourage close monitoring of the safety concern in clinical practice and encourage reporting, or provide information about means to minimise the potential risk); or

d) A need for communication of other important information, in particular where the issue has been/is the subject of significant media coverage.

e) In cases where a regulatory agency outside the EU independently requests dissemination of a DHPC in their territory for a medicinal product also authorised in the EU, the Marketing Authorisation Holder should notify the appropriate Competent Authority in the EU/ the EMEA. The need for any subsequent action in the EU should be considered and agreed on a case-by-case basis.

Art. 9. – A DHPC should not be used to provide safety information which does not require urgent communication or is otherwise important to be communicated to Healthcare Professionals at individual level, such as changes to the SPC which do not impact on the conditions of appropriate use of the medicinal product.

II.5 Key Principles for Preparation of Texts for Direct Healthcare Professional Communications

Art. 10. – When drafting a DHPC, the Template (see Annex 1) and the Guideline provided there should be followed as appropriate, together with the principles described below:

a) The message of the DHPC should be clear and concise with regard to the safety concern; it should not exceed two pages.

b) The reason for dissemination of a DHPC at a particular point in time should be explained.

c) Recommendations to Healthcare Professionals on how to minimise the risk should be provided if known.

d) The safety concern should be placed in the context of the overall benefit of the treatment and not be presented as stand-alone information.

e) The Marketing Authorisation Holder should ensure that pharmacovigilance information to the general public (this includes Healthcare Professionals) is presented objectively and is not misleading. This requirement is legally binding in accordance with Article 24(5) of Regulation (EC) No. 726/2004 for centrally authorised medicinal products and for nationally authorised medicinal products, including those authorised through the mutual recognition or decentralised procedures, in accordance with Art 104 (9) of Directive 2001/83/EC which is transposed in Art. 816 (8) of Title XVII – The medicinal product of Law No. 95/2006.

f) In general, the texts of DHPCs should be reviewed by, or if the timetable allows, tested among representatives of the target groups of Healthcare Professionals in order to assess clarity and understanding of the risk and expected adherence to the recommendations provided in the DHPC. Alternatively, standard phrases may be tested and subsequently used, as appropriate, particularly in urgent situations.

g) In order to allow Healthcare Professionals to prepare responses to questions from Patients, the DHPC should also include the content of any information communicated directly to the general public; in case of suspension, withdrawal or revocation of a marketing authorisation, the DHPC should detail the type and procedure of recall of the medicinal product(s) from the market (e.g. pharmacy or patient level, date of recall).

h) Public communication of the safety information issued to any target population by other Competent Authorities and other public bodies, ideally within and outside the EU, should be taken into account.

i) The DHPC should include a reminder of the need to report suspected adverse reactions in accordance with national spontaneous reporting systems.

j) The estimated time schedule for follow-up action, if any, by the NMA/EMEA or the Marketing Authorisation Holder should be provided.

k) A list of contact points for further information, including website address(es), telephone numbers and a postal address to write to, should be provided at the end of the DHPC.

l) A list of literature references should be annexed, when relevant.

m) The DHPC may include a statement indicating that the DHPC has been agreed with the NMA/the EMEA.

II. 6 The Processing of Direct Healthcare Professional Communications

II.6.1 The Roles and Responsibilities of Marketing Authorisation Holders, the NMA and the EMEA

Art. 11. – The Competent Authorities are those who have issued a marketing authorisation for the medicinal product concerned.

Art. 12. – For centrally authorised medicinal products, the Competent Authority is the European Commission, however the EMEA (via the Committee for Medicinal Products for Human Use (CHMP)) normally deals with DHPCs on behalf of the Commission.

Art. 13. – For medicinal products authorised through the mutual recognition or decentralised procedures, the Competent Authorities are those of the Reference Member State (RMS) and the Concerned Member State(s) (CMS(s)); for practical reasons, the RMS usually takes over co-ordination of consistent and synchronised DHPCs in the RMS and all CMSs.

Art. 14. – For purely nationally authorised medicinal products, the Competent Authorities are those of the Member States where the medicinal product is authorised, but it is suggested that one Member State may take the lead in coordinating the process with the Marketing Authorisation Holder and apply synchronised timetables across all relevant Member States.

Art. 15. – Consequently, the contact points for the Marketing Authorisation Holders with regard to DHPCs are as follows:

a) for centrally authorised medicinal products: the EMEA together with the Rapporteur (with parallel submission of documentation to all Member States);

b) for medicinal products authorised through the mutual recognition or decentralised procedures: the RMS or, in case of several products authorised through the mutual recognition or decentralised procedures with the same active substance and different RMSs, the Lead Member State agreed between the RMSs and CMS(s) (with parallel submission of documentation to all RMS(s) and CMS(s));

c) for purely nationally authorised medicinal products: the Member States where the medicinal product is authorised or, if agreed between these Member States, the designated Lead Member State for the safety concern (with parallel submission of documentation to all Member States where the medicinal product is authorised); and

d) for medicinal products subject to referral procedures: the EMEA in relation to CHMP Opinions and Commission Decisions and otherwise the RMS or the EMEA, as appropriate (see below in this Section for further details).

Art. 16. – Where the Marketing Authorisation Holder proposes or is requested by the NMA/the EMEA to disseminate a DHPC, the relevant national Competent Authority(ies)/the EMEA should be provided with:

a) the proposed Communication Plan; including

b) the proposed communication text of the DHPC; and

c) the proposed texts of any related communication documents (see Art. 26 (2) Pre-communication phase: Preparation of a DHPC)

Art. 17. – (1) The timing of the submission should allow the NMA/the Agency (CHMP) reasonable time (a minimum of two working days) to comment on the Communication Plan and the proposed communication texts prior to their finalisation.

(2) Exceptionally, less than two working days may be acceptable in the case of some urgent safety restrictions.

(3) The Marketing Authorisation Holder should take into account comments from the NMA/the EMEA and discuss any outstanding issues when finalising these proposals.

(4) Ideally, the Marketing Authorisation Holder should closely co-operate with the Rapporteur/RMS/Member State(s) to finalise the text of the DHPC.

(5) The final Communication Plan and communication texts should be submitted to the NMA/the EMEA.

Art. 18. – Member States and the EMEA should use the Rapid Alert-Non Urgent Information System (see The Scientific Council Decision No. 25/2007) in order to keep each other and the European Commission informed during all the phases of the communication process.

Art. 19. – The NMA and the EMEA should keep their Press Officers informed about any DHPC.

Art. 20. – (1) Marketing Authorisation Holders are reminded of the legal obligations described in Article 24(5) of Regulation (EC) No 726/2004 and Article 104(9) of Directive 2001/83/EC which is transposed in Art. 816 (8) of Title XVII – The medicinal product of Law No. 95/2006.

(2) With the exception of the requirement to notify the EMEA for centrally authorised medicinal products and the Competent Authority for nationally authorised medicinal products, the requirements in both legal texts are identical and are reproduced here for ease of reference:

"The Marketing Authorisation Holder may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior or simultaneous notification to the National Medicines Agency [Art. 816 (8) of Title XVII – The medicinal product of Law No. 95/2006]/the EMEA [Regulation (EC) No. 726/2004].

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties."

Art. 21. – In addition, the following should be considered:

- For centrally authorised medicinal products:

a) In order to enable the EMEA and the NMA to fulfil their roles in public health protection, Marketing Authorisation Holders should give prior notification, allowing a minimum of two working days for comments by the Agency (CHMP) on the Communication Plan and the proposed communication texts; exceptionally, less than two working days may be acceptable in case of some urgent safety restrictions.

b) When a Member State considers it necessary that a DHPC concerning a centrally authorised medicinal product should be disseminated in its own territory, the EMEA (CHMP) should be informed at least two days prior to the proposed dissemination day and consider whether EU-wide dissemination of such a DHPC is necessary or dissemination in only one or more Member States is sufficient (taking into account e.g. availability of an interacting medicinal product in only a few Member States or differences in medical practice).

c) The CHMP will normally request recommendations on DHPCs from its Pharmacovigilance Working Party (PhVWP).

d) With regard to Member States' requirements in relation to the communication texts, recipients and the proposed dissemination mechanism, the Marketing Authorisation Holder should contact the relevant pharmacovigilance contact points at the national Competent Authorities in a timely manner for discussion and finalisation of the Communication Plan and communication texts including relevant translations (see Chapter II, Section 6.3, Translations).

- For medicinal products authorised through the mutual recognition or decentralised procedures:

a) Where a CMS considers dissemination of a DHPC is necessary, this CMS should contact the RMS to liaise with the Marketing Authorisation Holder prior to dissemination.

b) Rarely, it may only be necessary to send a DHPC in one/some Member States; however, the RMS and the CMS should always keep each other informed of any proposed action.

c) The PhVWP should provide recommendations at the request of a Member State.

d) Member States may have approval procedures for DHPCs for nationally authorised products in place, which may also apply to products authorised through the mutual recognition or decentralised procedures.

- For nationally authorised medicinal products:

a) The NMA has approval procedures for DHPCs in place; also for purely nationally authorised medicinal products, the NMA should inform the other Member States and the EMEA using the Rapid Alert/Non-Urgent Information System (see SCD No. 25/2007).

b) At the request of a Member State, a synchronised timetable for communication throughout the EU may be agreed by the PhVWP for purely nationally authorised medicinal products. Such agreement may be of particular importance in the case of DHPCs planned for purely nationally authorised medicinal products containing the same active substance as medicinal products authorised through the mutual recognition or decentralised procedures.

- For medicinal products subject to an ongoing referral procedure:

a) The review of comments on the proposed Communication Plan and communication texts will be undertaken by the Agency (CHMP) if such communications refer to outcomes of discussion at the level of the CHMP and subsequent Commission Decisions, i.e. in particular to CHMP Referral Opinions and review of monitoring conditions for marketing set out in the Commission Decision.

b) Otherwise, the (post-referral) RMS co-ordinates DHPCs as for products authorised through the mutual recognition or decentralised Procedures; the RMS needs to keep the Referral Rapporteur and the EMEA closely informed about any planned communication activities; the involvement of the CHMP will be considered on a case-by-case basis.

Art. 22. – (1) When a DHPC concerns an active substance or a class of active substances authorised through different procedures and/or involving overlapping roles and responsibilities of the NMA and the EMEA, the relevant partners should co-ordinate their respective activities, as needed within the EU pharmacovigilance system.

(2) The PhVWP should provide recommendations for such co-ordination at the request of the CHMP/EMEA or a Member State.

Art. 23. – For roles and responsibilities regarding the process of translation of communication texts, see Chapter II, Section 6.3.

Art. 24. – In cases where a DHPC is disseminated by the NMA in a Member State, the Competent Authority should provide the following to the Marketing Authorisation Holders concerned:

a) The communication plan, including:

b) the communication text of the DHPC; and

c) the texts of any related communication documents (see Chapter II, Section 6.2.(2) - Pre-communication phase: Elaboration of a DHPC).

Art. 25. – Nationally established procedures should be followed in such cases, and the Communication Plan should be circulated for information to the other Member States and the Agency using the Rapid Alert/Non-Urgent Information System (see SCD No. 25/2007).

II.6.2 Phased Approach to Processing

Art. 26. – The processing of a DHPC consists of four phases:

1. Consideration phase: Initiation of the process

Art. 27. – (1) The process may be initiated by the Marketing Authorisation Holder or by the NMA/the EMEA/the European Commission.

(2) When the Marketing Authorisation Holder considers that a DHPC may be necessary, the NMA/EMEA should be contacted and the documents required for the preparation of the DHPC submitted, as set out below.

(3) When a Competent Authority in a Member State (including the NMA), the European Commission or the Agency (CHMP) considers that a DHPC may be necessary, it is recommended that the national Competent Authority/the Agency sends a request letter (in case of urgency the Marketing Authorisation Holder may additionally be contacted by telephone and/or e-mail) requesting preparation of a DHPC draft and a Communication Plan.

(4) This request letter should provide the rationale for the request and the timetable for submission; when a request letter is received, the Marketing Authorisation Holder should designate a contact point within the company for liaison with the NMA/EMEA.

Art. 28. – (1) If the Marketing Authorisation Holder considers that a DHPC is not appropriate or requires additional clarification, a written request may be submitted to the NMA/the EMEA/ the European Commission.

(2) In cases where agreement cannot be reached regarding dissemination of a DHPC by the Marketing Authorisation Holder, a DHPC and/or a Public Statement may be issued by the NMA/the EMEA/the European Commission.

Art. 29. – (1) There may be situations in which more than one Marketing Authorisation Holder is involved in the dissemination of a

DHPC, e.g. where an interaction, a class-effect or generic medicinal products are concerned.

(2) In such situations, the objective is to provide consistent information to Healthcare Professionals and to avoid multiple DHPCs on the same safety concern from different Marketing Authorisation Holders which may lead to confusion.

(3) Where the number of Marketing Authorisation Holders involved is limited to two or three, they should work together to issue a single DHPC.

(4) For a larger number of Marketing Authorisation Holders or if a single joint DHPC is not agreed, the NMA may opt to issue the DHPC.

2. Pre-communication phase: Preparation of a DHPC

Art. 30. - Once the intention to disseminate a DHPC is confirmed, the Marketing Authorisation Holder should submit a draft Communication Plan including the following:

a) the objective of the DHPC and the draft DHPC and other communication texts (including amendments to the Product Information (SPC, Package Leaflet and Labelling), either mentioned in the DHPC text or, preferably, appended to the draft DHPC, if the final revised Product Information is available) as well as the key message to the public;

b) a proposed timetable covering the pre-communication, communication and post communication phases with regard to all communication and other relevant documents including translations (see Chapter II, Section 6.3, Translations); this timetable should include:

- timelines for comments on the Communication Plan and draft communication texts by the NMA/the EMEA (CHMP);

- timelines for agreement on final texts between the Marketing Authorisation Holder and the NMA/the EMEA (CHMP);

- timelines for agreement on the date and time of release of the DHPC and information to the general public (synchronised across the EU).

c) any draft Communication Plans and communication texts under discussion with other Competent Authorities (outside the EU for centrally authorised medicinal products and medicinal products authorised through the mutual recognition or decentralised procedures; within and outside the EU for purely nationally authorised medicinal products);

d) a list of proposed recipients (target groups, e.g. general practitioners, specialists, coroners, nurses; hospitals/ambulatory care/other institutions), including Member States' specificities, if appropriate;

e) a description of the dissemination mechanism in the Member State(s) where the DHPC is planned to be disseminated (e.g. by post);

f) a plan for user testing of the communication text, if appropriate;

g) a list of related communication documents, if appropriate, e.g. press release, questions & answers document, patient information sheet, and a description of their dissemination mechanisms in each Member State where the DHPC is planned to be disseminated;

h) a description of the strategy for the post-communication phase, including the evaluation of the effectiveness of the DHPC, as outlined below in this Section, No 4.;

i) an outline of proposed follow-up action and a draft Letter of Undertaking from the Marketing Authorisation Holder on further investigations, if applicable; and

j) a list of contact details of relevant partners.

Art. 31. - The proposed time and date for distribution should be considered carefully, with dissemination of a DHPC at the beginning of a week considered ideal; however the release of urgent information should not be delayed for this reason.

Art. 32. - Usually, any planned press release/Public Statement from either the NMA, the EMEA or the Marketing Authorisation Holder should be disseminated at the same date in all Member States, ideally at an agreed time of the day specified as London time.

Art. 33. – (1) When defining the target groups of recipients, it should be recognised that it is not only important to communicate with those Healthcare Professionals 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 centres, or to appropriate specialists, e.g. cardiologists.

(2) It is equally important to consider provision of DHPCs to relevant pharmacists who serve as information providers within healthcare systems and provide assistance and information to Patients, Healthcare Professionals, including hospital wards and poison centres, as well as the general public, in particular where media interest has arisen.

(3) The national professional associations of physicians, nurses and pharmacists should systematically receive DHPCs for further dissemination of the information to their members beyond the primary target groups of recipients.

Art. 34. – (1) The dissemination mechanism should take into account national policies for prompt identification of DHPCs, such as specific identifiers on the envelope (e.g. prominent red box warning) or use of a specific colour of notepaper.

(2) The use of such specific identifiers is encouraged to facilitate identification and focus Healthcare Professionals' attention.

3. Communication phase: Dissemination of the DHPC

Art. 35. – (1) Implementation of the communication phase should adhere to the Communication Plan agreed between the Marketing Authorisation Holder and the NMA/the EMEA and should be accompanied by close monitoring of events by all partners.

(2) Any significant event or problem occurring during the communication phase should be communicated immediately between all relevant partners.

(3) If this reveals a need to change the Communication Plan or a need for further communication to Healthcare Professionals, this should be agreed between the Marketing Authorisation Holder and the NMA/the EMEA.

4. Post-communication phase: Follow-up of the DHPC

Art. 36. – (1) After dissemination of a DHPC, a closing review should be performed by the Marketing Authorisation Holder, identifying any event or problem occurring during the communication phase requiring a change to the Communication Plan, any non-adherence to the Communication Plan as well as any difficulties experienced during any of the above phases. Such difficulties may relate e.g. to the list of recipients or the date and mechanism of dissemination.

(2) The NMA/the EMEA should be informed about the outcome of this closing review and should also inform the Marketing Authorisation Holder of difficulties they identified.

(3) If the NMA/the EMEA is not satisfied, a written request should be made to the Marketing Authorisation Holder to correct the situation.

Art. 37. – (1) All partners should also perform internal reviews of their performance as part of integrated quality management and take appropriate action for improvement as needed.

(2) In general, evaluation of the public health impact and the effectiveness of DHPCs should be performed in order to evaluate if the DHPCs have been received in a timely manner (check in a small sample of the target population) and if the recommendations and key messages have been understood and followed (e.g. by means of healthcare professional surveys or other study designs).

(3) This evaluation should be performed by the Marekting Authorisation Holder and is specifically relevant where DHPCs are part of risk minimization activities in accordance with the applicable Risk Management Plan (see Chapter I.3).

II.6.3 Translations

Art. 38. – (1) For centrally authorised medicinal products and in most cases also for medicinal products authorised through the mutual recognition or decentralised procedures, the proposed communication texts will be submitted in English as working language.

(2) For medicinal products authorised through the mutual recognition or decentralised procedures, the working language could be another official Community language if agreed by the RMS and all CMSs.

Art. 39. – Once the communication texts are agreed with the Agency/RMS+CMS(s), the Marketing Authorisation Holder should prepare translations of the DHPC in all official EU languages, of the Member States where the medicinal product is marketed or, if appropriate, is made available by other means (e.g. compassionate use).

Art. 40. – (1) The draft translations should be submitted to all Member States/RMS+CMS(s) for a language review within a reasonable time (minimum of one working day).

(2) The Marketing Authorisation Holder should take account of comments from the national Competent Authorities/the Agency and discuss any outstanding issues when finalising translations.

Art. 41. – In the case of a centrally authorised medicinal product, the Marketing Authorisation Holder should provide the EMEA with a complete set of all final language versions of the DHPC and any related communication documents.