

CMDv/GUI/003

GUIDANCE

for

**Management of e-mail use during procedures
and standardisation of subheadings**

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1.- INTRODUCTION

E-mails are a quick way of communicating, which is appreciated by Applicant, reference member state (RMS) and concerned member state (CMS) especially during mutual recognition procedure (MRP) or decentralised procedure (DCP) where time is limited.

2.- AIM AND SCOPE

The aim of this guidance document is to propose an accepted policy for the use of e-mails during procedures, which takes into account the need to communicate as quickly as possible and also the need for RMS and CMS to correctly identify each correspondence and to work on the relevant documents.

Moreover, the harmonisation of headings permits a faster identification of the subject by readers, and an easier archive of e-mails related to procedures.

3.- REFERENCES AND RELATED DOCUMENTS

- Directive 2001/82/EC¹
- Volume 6A, Chapter 7 of the Notice to Applicants²
- Best Practice Guide on Mutual Recognition Procedure CMDv/BPG/001
- Best Practice Guide on Decentralised Procedure CMDv/BPG/002
- Best Practice Guide on Repeat Use Procedure CMDv/BPG/003
- Best Practice Guide on Renewals CMDv/BPG/007
- Best Practice Guide on Automatic Validation of MRP CMDv/BPG/008
- Best Practice Guide on Type IA Variations CMDv/BPG/004
- Best Practice Guide on Type IB Variations CMDv/BPG/005
- Best Practice Guide on Type II Variations CMDv/BPG/006
- BPG/015 Best Practice Guide for The classification of unforeseen variations
- Best Practice Guide on the handling of PSURs CMDv/BPG/014
- Website address: <http://www.hma.eu/cmdv.html>
- Website address EMA,
http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true

4.- DESCRIPTION OF THE PROCEDURE

4.1. General rule on electronic submission

Electronic submission of dossiers can be used, but it is up to the Applicant to check whether paper copies of dossiers still need to be sent to each competent authority as stated in the Notice to Applicants Volume 6A chapter 7.

¹ as amended by Directive 2004/28/EC

² Notice to Applicants (Volume 6) is available on the website of the Commission (<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev6.htm>).

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For better efficiency and in order to reach the correct correspondent within the national competent authorities, the following e-mail boxes should be used by the RMS and CMS:

| e-mail boxes | Use |
|--|--|
| mrna | New application for MRP, DCP Repeat use procedures Extension of an existing MA Referral to CMDv |
| mrve | Variation (single or grouped), Renewal worksharing |
| V-CMD.PSUR | Periodic Safety Update Report (PSUR) |
| xx-y.art5- variations@xxy.eudra.org | Requests for unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008 |

Whatever the step in the procedure, e-mails originating from Applicants should be sent to the RMS. The RMS is then in charge of forwarding them to the CMSs via Eudranet. This ensures that everybody has received the same documentation and that the RMS is aware of each sending. Applicants wishing to address a NCA within Europe should make use of the contact details given in the CMDv GUI 001 Contact Points for General Inquiries as published on the CMDv website.

Applicant's mail attachments should not exceed the size of 2 MB (zip files must be used if necessary). Attention should be paid to the electronic size of logo, where included in the documents. To limit the number of multiple sendings, the RMS should check with the Applicant that the documentation is complete before forwarding it to the CMS.

When the RMS/Applicant is forwarding Applicant's documentation by e-mails, the number of e-mails sent should not exceed 2 per application at any one time and the size of the attachments should be of reasonable electronic size (zip files must be used if necessary). If possible pdf files should not be used since they are difficult to compress.

Preferably EudraLink, a secure electronic transmission facility offered by the EMA should be used (for further details please contact the EudraLink helpdesk: eudralink@ema.europa.eu).

4.2. Standardisation of e-mail headings

4.2.1. Procedure Number

Procedure number is one of the mandatory items of information. However, since most RMS send their e-mail to the whole list (e.g. list-V-MRNA...), it is difficult for CMS to identify if they are involved or not, only by reading the heading if it consists of only the procedure Number.

This could be avoided if:

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- at the beginning of a procedure, RMS and CMS create specific lists of recipients for each procedure (where applicable, i.e. in cases where not all MS are involved);
or
- for those that can use the CTS automatic generating e-mail option, they should make sure that the correct addresses are included, i.e. the MRNA or MRVE mail boxes;

In addition the following information must be included:

- The RMS and CMS are listed initially at the beginning of the e-mail unless this is clear from the addressees.
and
- RMS or CMS should add systematically the name of the product in the title. The Invented name may not be identical in all CMS, and for consistency one should choose to mention in the title, only the Invented name as registered in the RMS.

4.2.2. Procedure Step

It can be useful to identify quickly what is the purpose of a particular e-mail. This may be done by using acronyms or wordings, for example :

4.2.2.1. MRP/DCP

| | |
|--|--|
| NOT | Notification to CMS for incoming procedure |
| AR | RMS's Assessment report |
| End of dispatch | Notification of the dispatch table, stating the useful dates for the automatic validation procedure. |
| Validation <initials of the Member State (MS)> | Validation comments from a specific MS |
| TT | Timetable |
| Day xx – com <initial of the MS> | Day xx comments or objections by MS |
| Day xx -LOQ | Consolidated list of questions circulated by RMS to Applicant and CMS. |
| Day xx - Resp-LOQ | Responses to the consolidated list of questions (from Applicant) |
| Day xx - AR-Resp-LOQ | RMS Assessment report on the applicants responses to the consolidated list of questions |
| Day xx - SPC | RMS new proposal of SPC at day xx |
| Day xx - SPC com <initials of CMS> | Comments of CMS on day xx SPC |
| END | Notification by RMS / end of the MRP/DCP |
| END - com <initial of the MS> | Comments of CMS on the end of procedure's e-mail |

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|-------------------|--|
| END –rev1,2,3...n | Correction by RMS of the reviewed version of the product information at the end of procedure |
|-------------------|--|

If there are modifications to the End of procedure's e-mail following CMS comments, the RMS should send an updated End of procedure's e-mail.

4.2.2.2. Referral to the CMDv

| | |
|---|--|
| Reasons for Referral to CMDv - <initial of the country> | Notification from disagreeing Member State(s) of the reasons for the negative opinion |
| Ref. CMDv – NOT | RMS initiates the referral by sending the final AR, product information and the explanation of the grounds for referral from disagreeing Member State(s). |
| Ref. CMDv – Day 0 - LOC | RMS starts the procedure and distributes a draft list of concerns to all Member States. |
| Ref. CMDv – pre CMDv com <initial of the country> | <u>First CMDv meeting</u> : MSs to clarify the reasons for referral and the positions from RMS and CMS. Decision to be taken on the list of concerns to be sent to the applicant. |
| Ref. CMDv – Resp | Applicant sends a response document to the RMS. The RMS to forward the response immediately to all CMDv members |
| Ref. CMDv – AR-Resp | RMS circulates an assessment of the Applicant's response. |
| Ref. CMDv – AR-resp com <initial of the country> | <u>Second CMDv meeting</u> : scientific discussion, possible hearing and decision. Members of CMDv should preferably state their view on the response document to all members 3 working days before the meeting. Agreement to be reached in principle. |
| Ref. CMDv – Position <initial of the country> | All CMS confirm their position to the RMS and applicant |
| Ref. CMDv - END | <u>Day 60</u> : - if <u>agreement</u> has been reached the RMS should record the agreement, close the procedure, inform the applicant and finalise the AR. - if <u>failing consensus</u> , the RMS should immediately inform the EMA and the applicant and provide a detailed statement of the unresolved issues and the reasons for the disagreement and refer the procedure to the CVMP. |

4.2.2.3. Variations and renewals

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The same principles and acronyms can be used for both variation and renewal procedures.

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4.2.2.4. Examples

Some typical examples from the start of a procedure to its conclusion

| RMS | CMS |
|---|---|
| FR/V/022/001/MR*- Invented Name — NOT | |
| FR/V/022/001/MR*- Invented Name – AR | |
| FR/V/022/001/MR*- Invented Name – end of dispatch | |
| | FR/V/022/001/MR*- Invented Name –validation ES |
| FR/V/022/001/MR*- Invented Name – TT | |
| | FR/V/022/001/MR*- Invented Name – Day 54 - com PT |
| FR/V/022/001/MR*- Invented Name – LOQ | |
| FR/V/022/001/MR*- Invented Name – AR Resp– LOQ | |
| | FR/V/022/001/MR*- Invented Name – day 77 - com PT |
| FR/V/022/001/MR*- Invented Name – Day 82 SPC | |
| | FR/V/022/001/MR*- Invented Name – Day 82 SPC – com IT |
| FR/V/022/001/MR*- Invented Name – End | |
| | FR/V/022/001/MR*- Invented Name – End – com ES |
| FR/V/022/001/MR*- Invented Name – End – rev1 | |

*The name of the medicinal product and the procedure number should be in compliance with CTS.