### Website communication: Automatic e-mails

**08.01.2024**

**Adaptation of automatic e-mail velocity templates body text**

This document provides further information on the automatic e-mails sent by the FAMHP DTS system during procedures for Marketing Authorisation applications (new and variations). Below, all automatic e-mails are listed and extra information on their interpretation is provided.

1. **Acknowledgement of Receipt Dossier ID xxx**

**General information**

This e-mail is sent by the FAMHP once the submitted dossier has been uploaded in the system and has passed full compliance. This e-mail can be used as proof of implementation in the case of national type IA/IB variations, MRP CMS type IA/IB variations and MRP CMS type II variations.

Dear applicant,

We hereby confirm that we have received the **file** with the following characteristics in good order:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier subject or variation classification:

The technical and content validation of the file is started. We will contact you should any problems arise during validation.
If your dossier concerns a variation, please consult the table below for its implementation. For any other type of dossier, you will receive an automatic confirmation by e-mail as soon as the evaluation of the dossier starts.

|  |  |
| --- | --- |
| AdministrativeNational type IA-variation | If your dossier concerns an administrative variation or a national procedure variation type IA (single or group), please stop implementing the variation immediately if you receive a negative advice from the FAMHP within ' + 30/44/74/104/224(\*) calendar days'. |
| National type IB-variation | If your dossier concerns a national procedure, variation type IB (single or group), please start implementing the variation within 6 months if you do not receive any comments from the FAMHP within ' + 44/74/104/224 (\*) calendar days'.When you receive comments, you have 30 calendar days to submit the response via [CESP](https://cespportal.hma.eu/). If you do not receive a negative opinion after 30 calendar days following the date of submission of the answers, you may implement the variation if it concerns a single national variation type IB, or when the highest ranked variation within the variation group is a type IB variation. If the highest ranked variation within the group is a type II variation or a line extension, then the start date of the closing phase (which will be communicated to you later via e-mail) may be considered as the start date of the implementation period of the national type IB variation. |
| Please note: The above response times are only valid (1) in case the submitted national Type IB variation is included in the Commission Classification Guideline or (2) in case the applicant has invoked Article 5 of the Regulation 1234/2008 (\*\*) and the variation was classified as a Type IB variation. If this is not the case, and the submitted national Type IB variation is considered an 'unforeseen Type IB variation', the FAMHP reserves the right to seek advice from the CMDh. |
| (\*)- The FAMHP response time will be 30 calendar days for annual reports and/or variation groups containing only type IA variations.- The FAMHP response time will be 44 calendar days for variation groups whose highest ranked variation is a type IB variation (30 days timetable). The additional 14 days in the response time cover the validation period.- The FAMHP response time shall be 44, 74 or 104 calendar days for variation groups containing a type II variation as the highest ranked variation, depending on the timetable (30, 60 or 90 days) of the type II variation within the submitted variation group. The additional 14 days in the response period cover the validation period.- The FAMHP response time will be 104 calendar days if the highest ranked variation group contains an MRP line extension (90 days timetable) and 224 calendar days if the highest ranked variation group contains a DCP line extension (210 days timetable). The additional 14 days provided in the response time shall cover the validation period.(\*\*) Article 5 of Regulation 1234/2008 concerns seeking the advice of the coordination group in case of ambiguity in the classification of a variation. |
| MRP type IA/IB-variation | If your dossier concerns a mutual recognition procedure, variation IA/IB (single or in group), for which Belgium is CMS, please consider the date of receipt of the RMS approval as start date of the implementation period in case of a type IB variation. Please stop implementation of the type IA variation immediately upon receipt of the negative opinion of the RMS. |
| MRP type II variation | If your dossier concerns a mutual recognition procedure, type II (single or group), for which Belgium is CMS, please consider the date of receipt of the RMS approval + 30 calendar days as the start date of the implementation period. |
| It is important to note that the implementation of the above variations based on this mail is only valid in case the approved variation does not require an additional Marketing Authorisation (MA). In case an additional MA is required, you should wait for receipt of this MA before implementing the approved variation. |
| Parallel Import | If your dossier concerns a Parallel Import dossier, you must always wait for the receipt of a new Parallel Import Marketing Authorisation.In case of a new application, a renewal or a variation, you must wait for the approved document before implementing the change. |

The marketing authorisation holder may attach a copy of this automatic mail to the MA when submitting a dossier to Economic Affairs and to the RIZIV/INAMI when he is entitled to implement the variation. For this, the marketing authorisation holder declares in his honour that he has not received any remark from the FAMHP.

Kind regards,

1. **Acknowledgement of Receipt Dossier ID xxx**

In the future, the name of this automatic e-mail will be changed to ‘Acknowledgement of Receipt **Responses** Dossier ID xxxxx’

**General information**

This e-mail is sent by the FAMHP once the submitted **response** sequence (during validation, during assessment, during closing), has been uploaded in the system.

Dear applicant,

We hereby confirm that we have received your documents with the following characteristics in good order:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier subject or variation classification:

If the documents are answers, the evaluation of these answers will be started. We will contact you as soon as it is finished.

If the documents concern an update of an ASMF, please use the Dossier ID mentioned above for all future communication with the FAMHP.

Kind regards,

1. **Rejection of Dossier ID xxx**

**General information**

This e-mail is sent by the FAMHP once the submitted dossier is uploaded in the system and does not pass the full compliance requirements.

Dear applicant,

This is an automatic e-mail from the information system of the Federal Agency for Medicines and Health Products.

This e-mail is being sent to you to inform you that the FAMHP is refusing this application because the eCTD requirements were not complied with.

Characteristics of the application:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier subject or variation classification:

Please resubmit this dossier if you wish to continue with this application.
Kind regards,

1. **Assessment Start for Dossier ID xxx**

**General information**

This e-mail informs the applicant that the assessment phase begins and is sent for dossiers concerning the national procedure when an initial application, a type II variation, a renewal or an extension application is concerned. The e-mail is always sent in the case of parallel import dossiers.

Dear applicant,

This is an automatic e-mail from the information system of the Federal Agency for Medicines and Health Products.

The evaluation of the dossier will start on the date indicated after 'Day 0' below.

Entry date:
Day 0:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier subject or variation classification:

Marketing Authorisation (MA):
In case of a MA dossier, this means that the above-mentioned dossier is complete (according to article 10 or article 34 §2 of the Royal Decree of 14 December 2006) and that the evaluation phase has been started (according to articles 13 and 16 of the Royal Decree of 14 December 2006).

Specific for Parallel Import:
If your dossier concerns a request for parallel import, this means that the aforementioned dossier is complete (in accordance with article 5, §1 of the Royal Decree of 19 April 2001) and that the evaluation phase has been launched (in accordance with article 5, §2 and, where applicable, §3 of the Royal Decree of 19 April 2001).

We will inform you by e-mail in case of questions.

Kind regards,

1. **Closing Phase Start for Dossier ID xxx**

**General information**

This e-mail is sent by the FAMHP at the end of the assessment phase, once the closing phase begins. This is at the end of the European phase for MRP and DCP procedures.

At the moment, if you receive an automatic e-mail ‘Closing phase Start for Dossier ID’ for a national procedure, you can consider the date of the automatic e-mail as the approval date.

For all the MRP/DCP procedures, the automatic e-mail ‘Closing phase Start’ informs you about the start of the national closing phase. The approval date is the date received from the RMS.

**Specific points of attention**

1. If your dossier concerns a grouped variation for which **only part of the variations are approved and some have been withdrawn** **or refused**, this automatic e-mail will be sent with decision = split decision and in addition a manual e-mail will be sent to you detailing only the approved variations within the submitted grouped variation.
2. Please be aware of the fact that in case of a line-extension, the implementation can only be started once the marketing authorisation is received by the applicant.

Dear applicant,

This is an automatic e-mail from the information system of the Federal Agency for Medicines and Health Products.

We hereby confirm that the evaluation of the dossier with the following characteristics has been completed and that the closing phase has begun:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier decision:
Dossier subject or variation classification:

Marketing Authorisation (MA):
In the case of partial or full approval (Dossier Decision = split decision or approved) the national closing phase of the dossier will start.
[A checklist for the closure of new applications](https://www.fagg-afmps.be/sites/default/files/content/checklist_for_closing_off_of_a_dossier_-_vhb_pre.pdf) and [a checklist for the closure of a MA dossier VHBPOST](https://www.fagg-afmps.be/sites/default/files/content/WTA/checklist-closing-vhb_post_en.pdf) are available on the FAMHP website, which lists all the necessary documents for the closing phase. Please consult this checklist and verify whether you have already submitted all necessary documents. If not, you should mail the missing documents within 7 calendar days to Prelicensing@fagg-afmps.be in case of a new application, a variation, renewal or notification for homeopathic and herbal medicines and to fagg\_closing\_file@fagg-afmps.be in case of a variation, renewal or notification.
If the dossier also contains an update of the Risk Management Plan (RMP), please send the approved version of the RMP in PDF format to vig@fagg.be.

Only applicable for national type II variations:
If your dossier concerns a type II variation (single or group), which follows the national procedure, please consider the date of this mail + 30 calendar days as start date of the implementation period for the concerned type II variation(s). This is on the condition that the necessary closing documents have been submitted. The Chief Executive Officer intends to approve this variation, based on the positive scientific advice provided.

! It is **important** to note that the implementation of the above mentioned variations based on this mail is only valid in case the approved variation does not require an additional Marketing Authorisation (MA). In case an additional MA is required, you should wait for receipt of this MA before implementing the approved variation.

The marketing authorisation holder can attach a copy of this automatic mail to the MA when submitting a dossier to Economic Affairs and to the RIZIV/INAMI when he is entitled to implement the variation. For this, the marketing authorisation holder declares in his honour that he has not received any remark from the FAMHP.

In case of parallel import:
The national closing phase of the dossier will start. In the case of partial or full approval (Dossier decision = split decision or approved), you should wait for receipt of the (modified) marketing authorisation for parallel import before implementing.

Kind regards,

1. **Dossier ID xxx is closed**

**General information**

This e-mail is sent by the FAMHP only for variations with no or minor impact on the AMM, the SPC, the leaflet, labelling or mockup.

Dear applicant,

This is an automatic e-mail from the information system of the Federal Agency for Medicines and Health Products.

The following file has been closed:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier decision:
Dossier subject or variation classification:

Your file was finalised and in case of approval the data model of the FAMHP was adapted.
Please note: an adaptation of the closing documents has not been carried out. This will take place at the next closing of a variation with (major) impact on the closing documents.
The MAH can attach a copy of this automatic mail to the MA when submitting a dossier to Economic Affairs and to the RIZIV/INAMI.

Kind regards,

1. **Inactivation of Dossier ID**

**General information**

This e-mail is sent by the FAMHP when the dossier is inactivated.

Dear applicant,

This is an automatic e-mail from the information system of the Federal Agency for Medicines and Health Products.

We hereby confirm that the dossier with the following characteristics has been inactivated:

Entry date:
Dossier ID:
Medicinal product name:
Procedure type:
Procedure role:
Dossier type:
Procedure number:
Dossier subject or variation classification:

As the FAMHP has received no response or an unsatisfactory response after 2 reminders due to missing information to close the above-mentioned file, or at your explicit request, your dossier with the above-mentioned ID will be inactivated. This inactivation will take place in accordance with circular 521.

Upon reactivation of your dossier, a contribution for late closure will be requested in accordance with Article 28 and Annex VII, Title 1, Chapter 3 of the Law of 11 March 2018 on the financing of the Federal Agency for Medicines and Health Products.

Kind regards,