

National Marketing Authorization Application

This procedure is used for the **Marketing Authorization Application** of **Medicinal Products** in one **Country/State**. In the **European Union**, it can be used for **Medicinal Products** that do not need to be authorized via the **centralized procedure** and have not already been authorized by any **Member State**.

Milestones are marked in dark orange, **main project activities** in avocado green, and **significant events** are in regular text. Comments and explanations are given for **significant events**. Using **milestones**, **project activities**, and **significant events** along with other features of **Enriched Email**, the progress of project realization can be monitored in real “**real-time**”.

Below are presented all **significant events** that can be selected by a designated **regulatory project person**, nominated **Assistant**, or **Agent** when sending or receiving **enriched email messages** during the realization of this type of **Corporate Project**. The designated **regulatory project person**, as the **designated follower** of the **enriched emails** for the specific project, also receives copies of all **enriched email messages** sent by the **Assistant** or **Agent** and is forwarded to all **enriched email messages** received by the nominated **Assistant** or **Agent**.

Automatically generated **enriched email notifications**, sent or received, cannot be selected and are presented here for illustrative purposes only.

Replies to **significant events** are not shown. If a reply message to the **significant event** is not sent as a reply, a **regular email message** can be set as a reply to a previous message using replication, one of the **Enriched Email** features.

The procedure model can be easily modified by adding, deleting, or changing milestones, activities, and significant events to suit particular needs/requests.

Milestones, activities, and significant events

Initiated

Initial Submission Preparation

- (int-out) Internal CC eCTD Request
- (int-out) Internal submission eCTD Request

- (int-out) Internal info Request
- (ext-out) Pre-submission dialog with NCA
- (ext-out) NCA access to ASMF restricted part Request
- (int-out) Internal payment Request
- (auto-in) Notif. - Technical validation started
- (auto-in) Notification of initial submission

Submitted

Content Validation by NCA

- (ext-in) Submission receipt by NCA
- (ext-in) Validation request - issues (NCA checklist)
- (ext-in) Validation positive (NCA checklist)

Validation request

Validation Response Preparation

- (int-out) Internal submission eCTD Request
- (int-out) Internal Info Request
- (int-out) Internal Payment Request
- (ext-out) Draft validation response
- (ext-in) Advise to withdraw the application
- (ext-in) Validation positive (NCA checklist)
- (auto-in) Notification of Validation Response submission

Validation response submitted

Assessment Report Preparation

- (ext-in) Submission receipt by NCA
- (ext-in) Draft Comment/Question
- (int-out) Internal info Request
- (ext-in) Assessment Report (AR) - List of Questions

Preliminary Assessment Report received

Consultation - NCA and Applicant

- (int-out) Internal submission eCTD Request
- (int-out) Internal CC eCTD Request
- (int-out) Internal info Request
- (ext-in) Comment/Question (brise se)
- (ext-out) Draft Response
- (ext- out) External Info Request
- (ext-in) Notification on questions relating to the restricted part of ASMF
- (ext-in) Final Assessment Report (FAR) - positive
- (auto-in) Notification of Response submission
- (ext-in) Clock off Notification (RSI)

Clock off

Response Preparation

- (int-out) Internal CC eCTD Request
- (int-out) Internal info Request
- (ext-out) External Info Request
- (ext-out) Draft Response
- (ext-in) Comment/Question (dodati)
- (ext-out) Request for a 90-day extension
- (ext-out) Request for withdrawal of the application
- (auto-in) Notification of the Response submission

Response submitted

Final Assessment Report Preparation

- (ext-in) Submission receipt by NCA
- (ext-in) DraftComment/Question
- (ext-in) Final Assessment Report (FAR) - positive
- (ext-in) Final Assessment Report (FAR) - negative

FAR forwarded to the Committee

Committee session preparation - session

- (ext-in) Approval reached notification
- (ext-in) Approval not reached notification

Approval reached

Finalization of SPC, PIL, and Labelling

- (int-out) Internal eCTD Request
- (ext-out) Draft proposal of SPC, PIL, and Labeling
- (auto-in) Notification of Final SPC, PIL, and Labelling submission

Final SPC, PIL, and Labeling submitted

Granting of Marketing Authorizations

- (ext-in) Acknowledgment of submission receipt by NCA
- (ext-in) Marketing Authorization(s)
- (auto-in) Notification of the MA processing and initial submission closing

Refusal

Refusal Decision Preparation

- (ext-in) Refusal Decision

Closing