ELECTRONIC PRE-SUBMISSION OF MARKETING AUTHORISATION APPLICATIONS

USING THE PORTAL SMUH-AIM

INFARMED
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
ELECTRONIC PRE-SUBMISSION OF MAA

• Required for MAA applications by:
  – National procedure (NP)
  – Mutual recognition & decentralised (MRP/DCP) with Portugal as RMS or CMS (including MRP ou RUP with PT as RMS for which preparation of assessment report is required previously to the European procedure).

• It is not required for
  – simplified registration of homeopathic medicinal products, traditional herbal medicinal products and allergen products
Payment of fees integrated in SMUH-AIM

Create application

Issue Payment Form

Issue ATM reference for payment

Payment

Automatic reconciliation

Submission of the dossier to INFARMED

Validation of MAA (DAM)

If fee is INCORRECT

Correction of Payment form by Infarmed (partial refund of fee/additional payment requested)

MAA by NP/MRP/DCP

Method for payment: ATM reference, with reference to cost of fee and period for payment

NOTE: applicants providing payment from abroad must contact tesouraria@infarmed.pt after issuing reference for payment in the portal
Change of procedure status in SMUH-AIM

- Create application in SMUH
- Filling in progress
- Cancel payment form
- Applicant: Validate application + Issue payment form
- Issue payment details
- Awaits payment
- Applicant: Issue payment reference
- Automatic reconciliation
- Payment of fee valid
- Missing payment of fee
- Applicant: submission of MAA to Infarmed
- DAM: Validation & Management
- Correction to Payment form + Issue Ref.
- DAM: Correction to payment form (by Infarmed only)
- Submitted
Using SMUH: browser requirements

• The portal should be accessed using Internet Explorer.
• The version of the browser should be confirmed in the menu Help > About Internet Explorer.
• In case of version 8 or higher, the compatibility mode must be activated.
Using SMUH: browser requirements

Compatibility mode is not active, click to activate

Compatibility mode active
Using the portal

The following steps should be taken for electronic pre-submission of MAA:

- **Create new application**
- **Submit application**
  - 2.1 Validate request
  - 2.2 Issue payment form
  - 2.3 Issue payment reference

3. **View submitted applications**
1. Create new application

1.1 Enter the page for creation of new applications using the button “New application”
1. Create new application (cont.)

1.2 Fill in the details of the application to submit in the online form

1.3 Save the information filled using the button “Save”
2.1 Validate the online form

Press “Validate” in order to validate the filling of the online form

- If mandatory information is required, the corresponding messages will be shown. The applicant should access the form and fill in the missing information.

- If the filling is considered complete, the checkbox for selection of the application will be available.
2.2. Issue payment form

Select the applications to be included in the same payment form

(Note: only applications concerning strengths or pharmaceutical forms of the same MAA should be selected for inclusion in the same payment form).

Press button “Issue payment form”
2.2. Issue payment form (cont.)

Fill in the contact person information (name/telephone/email) for whom should be send information concerning the payment of fees

Further to confirmation of issuing of payment form, the procedure status of all applications included in the payment form, will be changed to “Issue payment details”
2.3. Issue Payment Details

Enter the screen **View of payment form** using the link “Open” in Search result list

Issue payment details using the button “Issue payment reference” → the procedure status will be changes to “Awaits payment”

“Cancel Payment form” → the payment form will be cancelled and the procedure status will be changed “Filling in progress”

NOTE: The generation of payment form is performed using automatic calculation rules applied to the information in the online form, therefore applicants should consider the need to appropriate filling of the form.
2.3. Issue Payment Details (cont.)

Payment made from national territory:
* Payment by ATM reference → entity, reference, period for payment and cost (€) of fee will be indicated in the portal and via email.

Payment made from abroad:
* Applicants must issue payment details (payment reference as previously described)
* After issuing the reference, applicants must Human, Financial and Property Resources Departament by email tesouraria@infarmed.pt in order to get alternative details for payment

The MAA (i.e. the dossier) should only be submitted to INFARMED after electronic pre-submission of the application in SMUH-AIM and validation of payment of fee (confirm in the portal by procedure status “Payment of fee valid”).
3. View applications submitted

Applicants may access the screen for viewing submitted application using the link under “Procedure number” or “Medicinal product name” in the initial screen.