

# **ELECTRONIC PRE-SUBMISSION OF MARKETING AUTHORISATION APPLICATIONS**

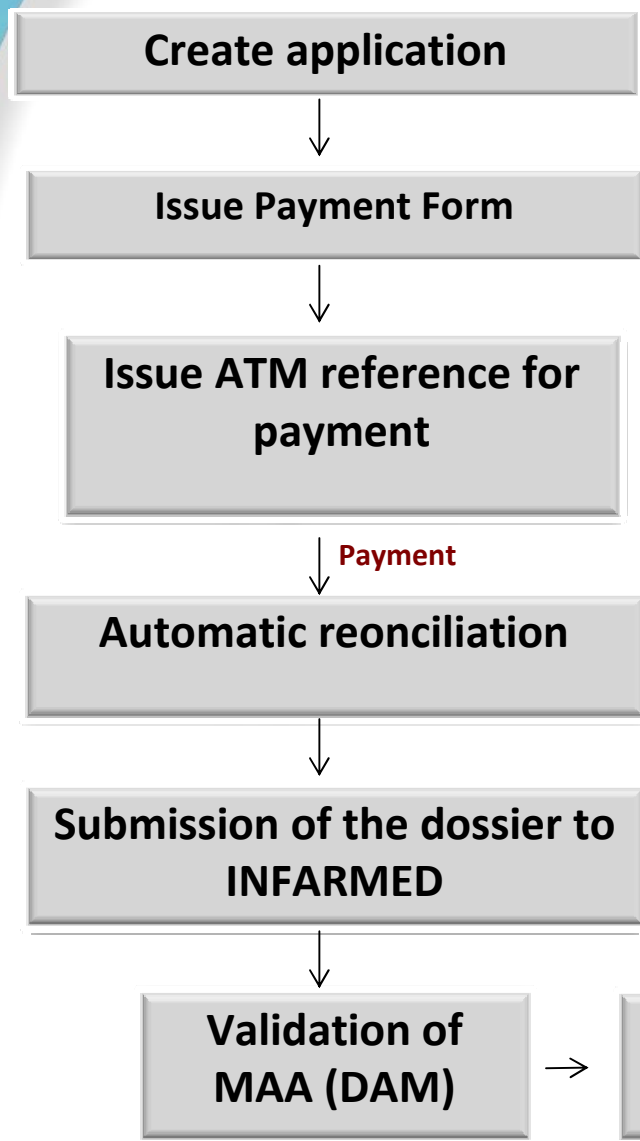
## **USING THE PORTAL SMUH-AIM**

**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

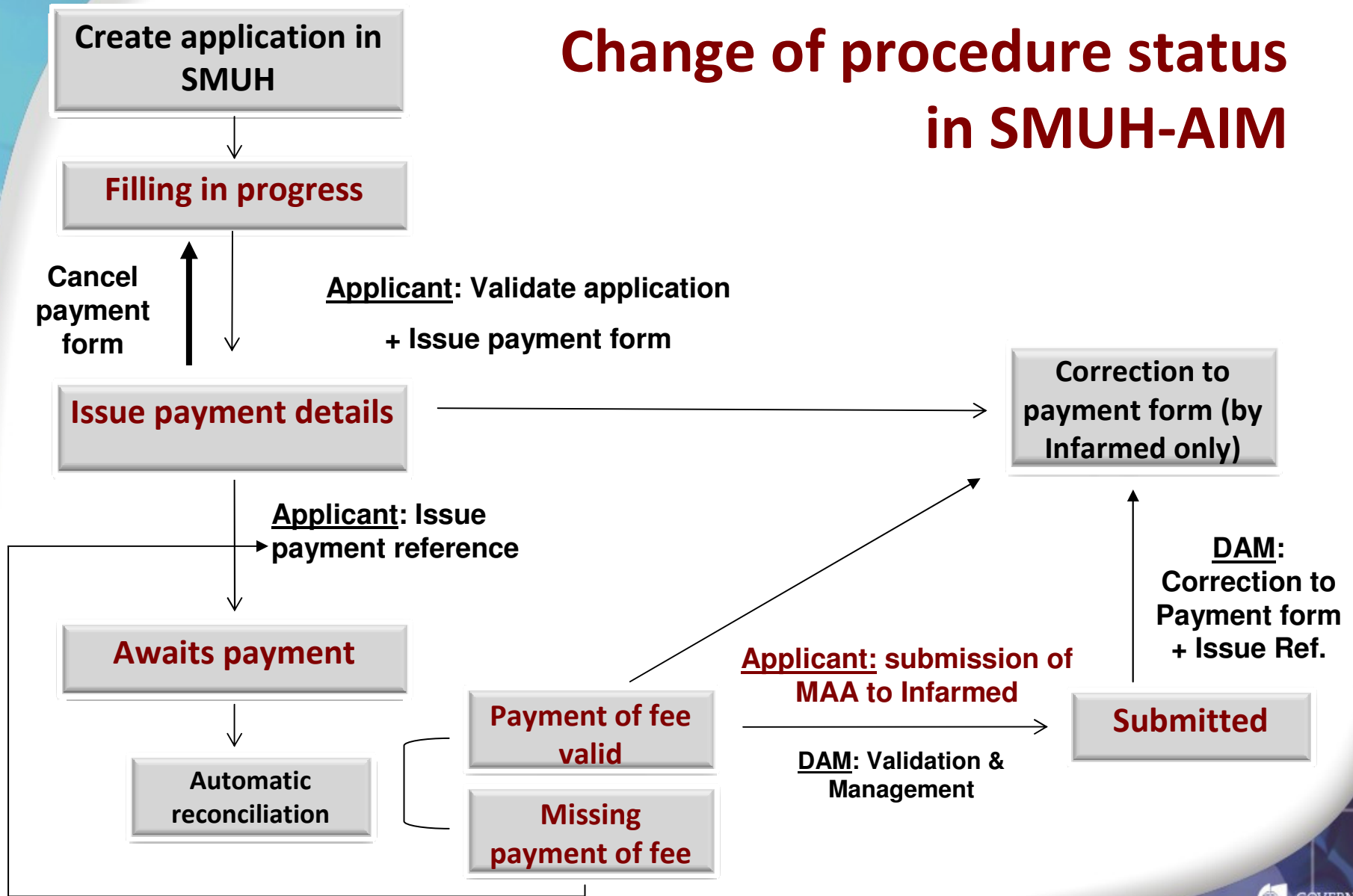


## MAA by NP/MRP/DCP

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

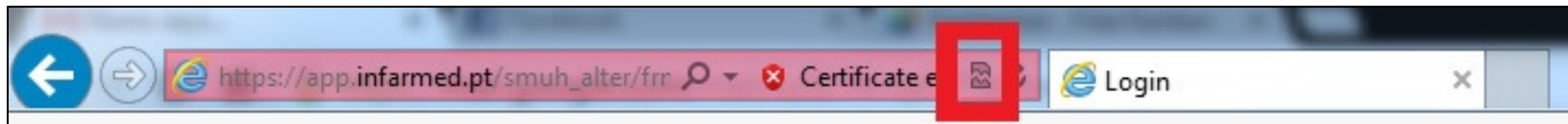
NOTE: applicants providing payment from abroad must contact [tesouraria@infarmed.pt](mailto:tesouraria@infarmed.pt) after issuing reference for payment in the portal

# Change of procedure status in SMUH-AIM



## 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

A screenshot of a web browser window. The address bar shows the URL `http://iis-interno-testes/smuh_alter/frmPesquisaAlterA.as`. A red box highlights the compatibility mode icon in the address bar, with a red arrow pointing to the text "Compatibility mode is not active, click to activate". The page content includes a header with "Utilizador: *username acesso*" and "Avaliador: *nome avaliador -> tipo avaliador*". Below this are several filter buttons: "Pesquisa Global", "Distribuidos sem PI ou PF", "Respondidos sem PI ou PF", and "Com Parecer Final". The main section is titled "PROCESSOS POR RESPONDER" and contains a table with columns: "Nome Comercial", "Titular AIM", "Alteração", and "Estado". The "Estado" column has a checkbox for "Em Avaliação" and a "Pesquisar" button. A "Limpa" button is also present.

A screenshot of the same web browser window. The address bar shows the same URL. A red box highlights the compatibility mode icon, with a red arrow pointing to the text "Compatibility mode active". The page content is identical to the previous screenshot, but the "Pesquisa Global" button is highlighted with a red border.

A close-up screenshot of the browser address bar. The URL `http://iis-interno-testes/smuh_alter/frmPesquisaAlterA.as` is visible. A red box highlights the compatibility mode icon, which is a blue square with a white 'A' and a blue lightning bolt.

## 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

SEARCH

Procedure Number	Medicinal Product Name	Status	
<input type="text"/>	<input type="text"/>	All	<input type="button" value="Search"/>

- 1.1 Enter the page for creation of new applications using the button **“New application”**



# 1. Create new application (cont.)

<b>Procedure Type</b>	
<input checked="" type="radio"/> National	<input type="radio"/> MR / DC
<b>MRP/RUP where PT – RMS</b>	<b>Medicinal Product</b>
<input type="text" value="No"/>	<input type="text"/>
<b>National procedure includes fee for subsequent MRP</b>	<b>RMS</b>
<input type="text" value="No"/>	<input type="text"/>
<b>MARKETING AUTHORISATION APPLICATION DETAILS</b>	
<b>Proposed (Invented) Name</b>	<b>Strength</b>
<input type="text"/>	<input type="text"/>
<b>ATC Classification</b>	<b>CFT Classification</b>
<a href="#">Insert</a>	<a href="#">Insert</a>
<b>Pharmaceutical Form</b>	<b>INN/Active Substance</b>
<input type="text"/>	<input type="text"/>
<b>Legal Status</b>	
<input type="text" value="Not subject to MP"/>	
<b>Routes of Administration</b>	
<a href="#">Insert</a>	
<b>CONTAINER</b>	
<a href="#">Insert</a>	
<b>Shelf life</b>	
<a href="#">Insert</a>	
<b>QUALITATIVE AND QUANTITATIVE COMPOSITION (ACTIVE SUBSTANCE AND EXCIPIENTS)</b>	
<b>Pharmaceutical Product</b>	
<a href="#">Insert</a>	
<b>Composition</b>	
<a href="#">Insert</a>	
<input type="button" value="Save"/> <input type="button" value="Back"/>	

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

User: [Change Password](#) [PT/EN](#) [Logout](#) [Alerts \(25 new\)](#)

SEARCH

Procedure Number:  Medicinal Product Name:  Status:

	Select	Procedure Number	Medicinal Product Name	Pharmaceutical Form	Strength	Submission Date	Status	Payment Form		
<a href="#">Delete</a>		<a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<a href="#">Validate Request</a>
<a href="#">Delete</a>	<input type="checkbox"/>	<a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<a href="#">Validate Request</a>
<a href="#">Delete</a>	<input type="checkbox"/>	<a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<a href="#">Validate Request</a>

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

User: [PT/ EN](#)  
[Logout](#)  
[Alerts \(25 new\)](#)  
[Change Password](#)

SEARCH

Procedure Number:  Medicinal Product Name:  Status:

Select	Procedure Number	Medicinal Product Name	Pharmaceutical Form	Strength	Submission Date	Status	Payment Form		
Delete	<a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<input type="button" value="Validate Request"/>
Delete	<input type="checkbox"/> <a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<input type="button" value="Validate Request"/>
Delete	<input checked="" type="checkbox"/> <a href="#">RS/H/0000/</a>	<a href="#">RS</a>	Bath additive	100		Filling in progress	Open	<a href="#">Copy Application</a>	<input type="button" value="Validate Request"/>

**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.)

User:

**CONTACT PERSON**

Name:

Telephone:

Email:

(This email will be used for the exchange of information related with this payment of the fees)

**PENDING APPLICATIONS**

**APPLICATION TO INCLUDE IN THE PAYMENT FORM**

Medicinal Product Name	Pharmaceutical Form	Strength	INN
RS_	Bath additive	100	Acetylsalicylic acid
RS_	Bath additive	100	Acetylsalicylic acid

Further to issuing the payment form you must issue a reference for payment of fee (please use the link Open in the column Payment form). In case of payment made from abroad, please contact the Human, Financial and Property Resources Department by email [tesouraria@infarmed.pt](mailto:tesouraria@infarmed.pt) further to issuing the payment form

### 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”**

Health Ministry National Authority of Medicines and Health Products, I.P.

APPLICANT IDENTIFICATION		
Fiscal Identification Number:		
Name:		

CONTACT PERSON		
Name: 123		
Telephone: 123		
Email: 123@12.pt		

APPLICATION		
Procedure Type: MR/DC		
Application Type: Article 8(3) application		
Line Extension: YES		
National procedure includes fee for subsequent MRP: NO		
Ongoing Applications:		
Medicinal Products		
RS/H/0000/	- RS_	- Bath additive - 100 - Acetylsalicylic acid

View previous versions of the payment form:

PAYMENT FORM		
Payment Form ID: 387		
Issuing Date: 22-10-2013		
Payment Date:		
Payment Status: Issue Payment Details		
Period for Payment:		
ATM Reference Payment:		
(In case of payment made from abroad, please contact the Human, Financial and Property Resources Department by email tesouraria@infarmed.pt)		
Cost: 3166.19 €		

FEES		
Legal basis	Fee Description	Value
EN_Portaria 377/2005	5 - o) For each extension concerning changes to the strength, pharmaceutical form or administration route: i) Including one strength and one pharmaceutical form	3166.19 €
TOTAL: 3166.19 €		

**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 Department by email [tesouraria@infarmed.pt](mailto: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

PROCEDURE INFORMATION			
Procedure Type	MR / DC		
MRP/RUP where PT-RMS	NO		
Medicinal Product			
National procedure includes fees			
RMS			
Procedure Number			

MARKETING AUTHORISATION APPLICATION DETAILS			
ID	370070		
Proposed (Invented) Name	RS_		
INN/Active Substance	Acetylsalicylic acid		
Strength	100 ..		
Pharmaceutical Form	Bath additive		
Legal Status	Not subject to MP		
	rfs		
	rfs 1		
	rfs		
	rfs 1		
	rfs 1		
	rfs@as.pt		
	OLISM		

CONTAINER			
Primary Packaging	Units	Quantity	Hospital Package
Ampoule - Alu	1	1 %	Non Hospital Package
Shelf life			
Unopened - 1 Second(s) - less than 0°C - Do not refrigerate			

MANUFACTURERS				
Manufacturing Operation	Name of the Manufacturer			
Immediate Packaging	A	- 3010	St.	
Outer Packaging	A	- 3010	St.	
Manufacturer of the Active Substance - Spruce	- Plot No.			
Bulk Manufacturer	A	- 3010	St.	
Batch Control/Testing Site	A	- 3010	St.	
Responsible for Batch Release	A	- 3010	St.	

QUALITATIVE AND QUANTITATIVE COMPOSITION (ACTIVE SUBSTANCE AND EXCIPIENTS)		
Pharmaceutical Product		
Eye drops, tablet and solvent for solution		
Substance	Quantity	Ingredient Type
Spruce	12 %	Active

DOCUMENTS	
Document Type	File Name
Declaration form for the use of e-mail communications with INFARMED	20130218_teste

Print

Save as HTML

Close

Applicants may access the screen for viewing submitted application using the link under “Procedure number” or “Medicinal product name” in the initial 15 screen