

**Online Registration of Users of the Electronic System for the
Management of Medicinal Products of Human Use of
INFARMED, I.P.**

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1 Introduction

The Online Registration of Users of the Electronic System for the Management of Medicinal Products of Human Use (SMUH) of INFARMED, I.P. allows Marketing Authorisation Holders (MAHs) to submit a request for registration as user of the system which includes the following portals:

- SMUH-AIM for pre-submission of Marketing Authorisation applications, including the portal for information on the status of MA applications (national procedure only)
- SMUH-ALTER for submission of variations to existing Marketing Authorisations
- Application for confirmation/update of flow chart of a medicinal product
- Information on the status of reimbursement application

Access to the online registration form is possible using the link available in the [website of Infarmed](#). In order to submit a request for user/password, MAHs must follow the link, accept the terms of use, fill in the online registration form and attach the required documents.

Submission of a user registration requires identification of the company requesting registration (current or future MAH) and identification of the person legally representing the company and submitting the request.

Validation of the request for user registration and assignment of user/password will be processed by the Medicines Evaluation Department (DAM) of Infarmed.

The online registration form also allows assigned users to request a new password to the portals.

Infarmed will only assign one user/password to each MAH, therefore submission of a request by a registered user will result in generation of a new password, without assignment of a new user.

The online registration form does not include any links to the portals SMUH. External access to the portals must be made using the links available in the website of Infarmed. The online registration form is available in English and Portuguese.

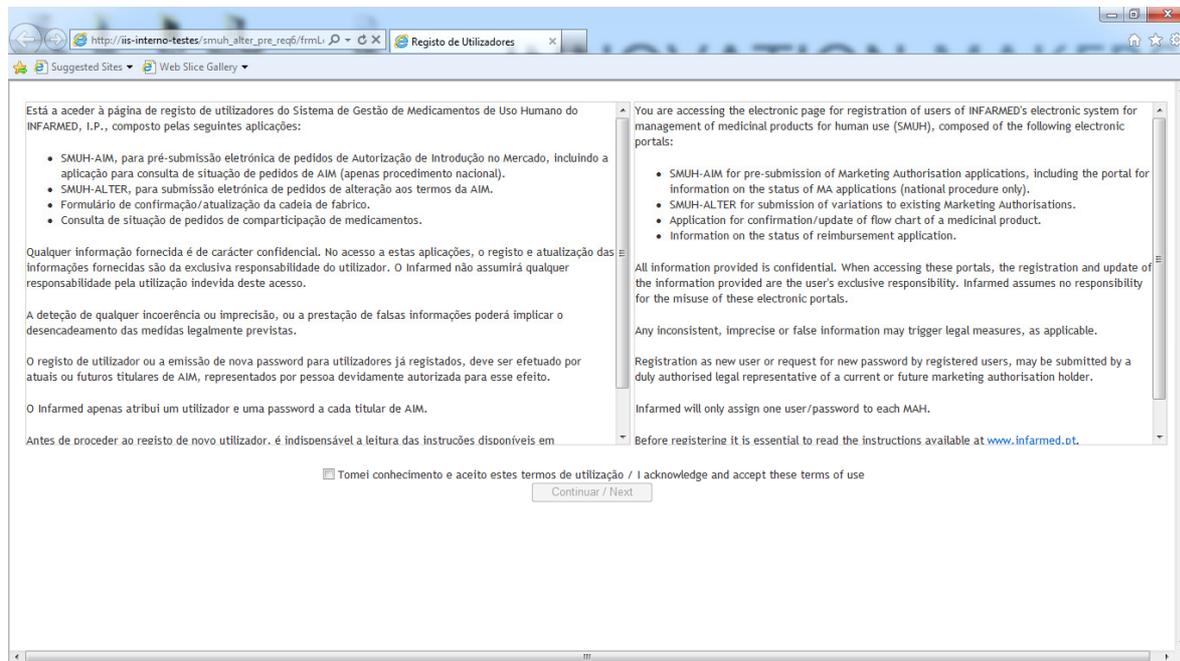
2 Using the Online Registration Form

The online registration is a two page platform where MAHs will first have to acknowledge and accept the terms of use, and then fill in a registration form and attach the required documents.

2.1 FIRST STEPS – TERMS OF USE

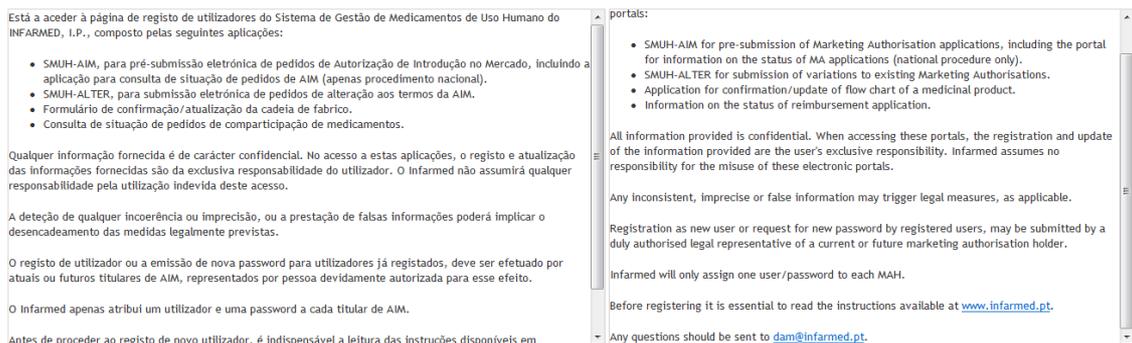
Access to the online registration for is made using the link available in the website of Informed. The link opens the page where the MAH has to acknowledge and accept the terms of use.

2.1.1 Layout



2.1.2 Areas and Features

Terms of Use



This area includes a text box with reference to the terms of use of the online registration form, in both Portuguese and English. It is possible to navigate up and down the text using the scroll bars on the right side of the text.

There is also reference to Infarmed's email to address any questions in relation with the user registration request.

Acceptance of the terms of use

Tomei conhecimento e aceito estes termos de utilização / I acknowledge and accept these terms of use

Continuar / Next

This area includes the following fields:

- **Check box** "tomei conhecimento e aceito estes termos de utilização/ I acknowledge and accept these terms of use", to be marked if the MAH accepts the terms of use;
- "Continuar/ Next", to confirm acceptance of terms and proceed to the next page;

The two fields have a combined function in order to assure that MAH confirm acceptance of the terms of use, i.e. the button "Next" is only available if the check-box is marked. MAHs have to mark the check-box and then press "Next", so a double and consent confirmation of acceptance of the terms is made. After pressing "Next" the user will be directed to the user registration form.

2.2 USER REGISTRATION FORM

The registration form is only available after acceptance of the terms of use.

In this page the MAH will fill in the information required and attach the necessary documents for submission of the request.

It includes the following áreas:

1. Informação do Titular/ MA Holder Information;
2. Informação do Representante/ Representative Information;
3. Documentos Necessários/ Required Documents;
4. Submeter/ Submit.

The followins actions are required:

- Fill in the information regarding the MAH;
- Fill in the information regarding the MAH legal representative;
- Attach the documents required;
- Submit the user/password request.

2.2.1 Layout

The screenshot shows a web form with two main sections. The first section, titled "Informação do Titular / MA Holder Information", contains input fields for Name, Address, Country, Telephone, Email, and NIF (Fiscal Identification Number). Below these fields are two radio buttons: "Nacional / National" and "Não nacional / Not national". The second section, titled "Informação do Representante / Representative Information", contains input fields for Full Name, ID Number or Passport Number, Telephone, Email for sending Username and Password, and Password. Below this section is a "Documentos Necessários / Required Documents" window. This window has a title bar and a scrollable area containing a list of required documents: "Certidão de Registo Comercial atualizada / Company Register Information", "Cópia do Documento de Identificação/Passaporte / Copy of the Identification Document/Passport", and "Carta de autorização para contacto em representação do Titular / Letter of authorization for communication on behalf of the MAH". Below the list is a section for "Documentos Anexados / Attached Documents" with a link "Anexar Novo Doc. / Attach New Doc". At the bottom of the form is a "Submeter / Submit" button.

2.2.2 Main Characteristics

Informação do Titular/ MA Holder Information

This image shows a detailed view of the "Informação do Titular / MA Holder Information" form. It includes input fields for Name, Address, Country, Telephone, Email, and NIF (Fiscal Identification Number). At the bottom, there are two radio buttons: "Nacional / National" and "Não nacional / Not national".

This area allows the user to fill in the information regarding the MAH and includes the following fields:

- “Nome/ Name”, it is mandatory to indicate the MAH name as registered in the Proof of establishment.
- “Morada/ Address”, it is mandatory to indicate the MAH name as registered in the Proof of establishment.
- “País/ Country”, it is mandatory to indicate the MAH country as registered in the Proof of establishment.
- “Telefone/ Telephone”, it is mandatory to indicate a telephone number;
- “Email”, it is mandatory to indicate the email address, preferably an institutional email address. It must include the symbol @ and a dot after @;
- “NIF/ Fiscal Identification Number”, it is mandatory to indicate the Fiscal identification number of the MAH;
- Radio Button “Nacional/ National vs. Não nacional/ Not national it is mandatory to indicate if MAH is a national or not national company.

Informação do Representante/ Representative Information;

Informação do Representante / Representative Information	
Nome Completo / Full Name	<input type="text"/>
Nº de Identificação / ID Number or Passport Number	<input type="text"/>
Telefone / Telephone	<input type="text"/>
Email para envio de Utilizador e Password / Email to send Username and Password	<input type="text"/>

This area allows the user to fill in the information regarding the person legally authorised to submit the user registration request on behalf of the MAH. It includes the following fields:

- “Nome Completo/ Full Name”, it is mandatory to indicate the full name of the person legally representing the MAH;
- “Nº de Identificação/ ID Number or Passport Number”, it is mandatory to indicate the identification number of the representative (ID Card number for national representatives or Passport number for non-national representatives);
- “Telefone/ Telephone”, it is mandatory to indicate the telephone number of the representative;
- “Email para envio de Utilizador e Password/ Email to send Username and Password”, it is mandatory to indicate the email address of the representative. **This email address will be used for sending the user/password details, if the registration request is accepted by Infarmed.** endereço de correio eletrónico do representante. It must include the symbol @ and a dot after @.

Documentos Necessários/ Required Documents;

Documentos / Documents
Certidão de Registo Comercial atualizada / Company Register Information
Cópia do Documento de Identificação/Passaporte / Copy of the Identification Document/Passport
Carta de autorização para contacto em representação do Titular / Letter of authorization for communication on behalf of the MAH
Documentos Anexados / Attached Documents
Apagar / Delete Retira Seleção / Remove Selection Anexar Novo Doc. / Attach New Doc

This area allows the user to attach the documents supporting the request for user registration. It includes the following links:

- “Anexar Novo Doc./ Attach New Doc”, opens a field for attaching the new document.
- “Apagar/ Delete”, for deleting documents listed in the Field “Documentos Anexados/Attached Documents”;
- “Retira Seleção/ Remove Selection” , for unselecting documents selected in the Field “Documentos Anexados/Attached Documents”;

All documents listed in the field “Documents” are mandatory:

- Certidão de Registo Comercial atualizada / Company Register Information (for confirmation of name, address, fiscal identification number and legal representatives of the company);
- Cópia do Documento de Identificação/ Passaporte/ Copy of the Identification Document/ Passport (referring to the person indicated in the area “**Representative information**”);
- Carta de autorização para contacto em representação do Titular/ Letter of authorization for communication on behalf of the MAH (**it should clearly state that the MAH, legally represented by person designated in the Company Register Information, authorizes the person indicated as Representative to contact with Infarmed in what concerns registration and assignment of user/password details for access to SMUH portals**).

If representation of the MAH is being delegated, it should also be attached a “Copy of the Identification Document/ Passport” of the person legally responsible for the company (as referred in the Company Register Information) and who is signing the Letter of authorization for communication on behalf of the MAH.

In what concerns the document “Letter of authorization for communication on behalf of the MAH”, MAHs may delegate representation in another company, however a person legally authorised for communication with Infarmed must always be identified in the area “Representative information”. In this case the **Company Register Information** of both the MAH and the other company, as well the corresponding letters for authorisation for communication on behalf of the MAH must be attached. The required documents should be attached individually further to selection of the applicable type as many times as required.

Documents may be attached as described below:

1. Select the type of document to be attached from the list available in the field

Tipo de Documento / Document Type

Ficheiro / File

2. Press “Browse” to select the corresponding file from the computed.
3. Press the *link* “OK” to confirm the attachment or the *link* “Cancelar/ Cancel” to clear the previous selection.

In the area “Attached documents” it is also possible to select a document attached using the link in the column “Document Type”. After selection it is possible to delete the document using the *link* “Apagar/ Delete” or remove the selection using the *link* “Retira Seleção/ Remove Selection”.

Documentos Anexados / Attached Documents	
Tipo Documento / Document Type	Nome Ficheiro / File Name
Cópia do Documento de Identificação/Passaporte / Copy of the Identification Document/Passport	Copy-ID.doc
Apagar / Delete Retira Seleção / Remove Selection Anexar Novo Doc. / Attach New Doc	

Submeter/ Submit

Submeter / Submit

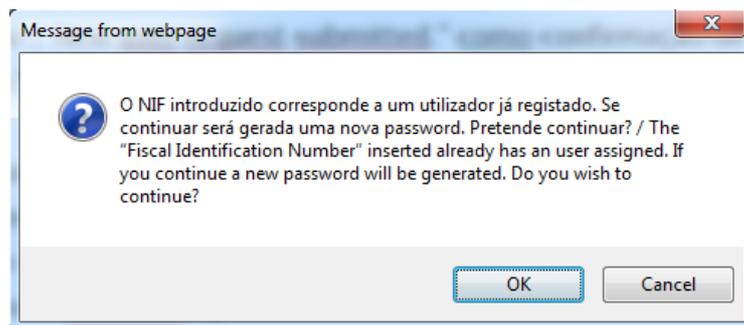
In this area MAHs may submit the user registration request.

2.2.3 Validation of the submission

In order to submit a user registration request the following steps must be taken:

1. Fill in all fiels in the area Informação do Titular/ MA Holder Information;
2. Fill in all fiels in the area Informação do Representante/ Representative Information
3. Attach all the required documents using the link "Anexar Novo Doc./ Attach New Doc". It is necessary to repeat attachment of the document for each of the mandatory documents listed;
4. Press  to submit the request
5. View the message "Pedido de registo de utilizador submetido com sucesso / New user request submitted." Confirming submission of the request

If the Fiscal Identification Number indicated in the area Informação do Titular/ MA Holder Information is referent to a MAH which is already registered, a message will be shown informing that if the request is submitted a new password for the user already assigned will be generated. A new user will not be assigned.



It is suggested to save screenshots of the filled registration form as well as confirmation of submission of the user request, in case it is necessary to follow-up on requests submitted with Infarmed.

2.3 RECEIPT OF ACCESS DETAILS (USER AND/OR PASSWORD)

The information and documents included in the registration request will be validated by DAM before assigning a user and/or password to the applicant.

In case the request is considered valid, the access details (user/password) will be sent to the address indicated in the field “Email para envio de Utilizador e Password/ Email to send Username and Password” in the area “Informação do Representante/ Representative information”. (**Example 1**)

In case the information and/or documents presented do not comply with the requirements for assigning new user and/or password for access to the SMUH portals, the registration request will be refused by Infarmed.

An email detailing the reasons for refusal will be sent to the address indicated in field “Email para envio de Utilizador e Password/ Email to send Username and Password” in the area “Informação do Representante/ Representative information”. (**Example 2**)

Exemplo 1 – Reply to User Registration Request:

- “Assunto Email”:
Resposta a Pedido de Registo Utilizador / Reply to User Registration Request;
- “Detalhes Corpo Email”;

Caro Representante do Titular [xxxxx],

Junto se envia utilizador e *password* de acesso às seguintes aplicações:

-SMUH-AIM, para pré-submissão eletrónica de pedidos de Autorização de Introdução no Mercado, incluindo a aplicação para consulta de situação de pedidos de AIM (apenas procedimento nacional)

-SMUH-ALTER, para submissão eletrónica de pedidos de alteração aos termos da AIM

-Formulário de confirmação/atualização da cadeia de fabrico

-Consulta de situação de pedidos de comparticipação de medicamentos.

Utilizador: [xx]

Password: [xx]

Esta *password* deverá ser alterada aquando da primeira utilização, podendo voltar a ser alterada sempre que for pretendido.

Esta mensagem foi gerada automaticamente por isso não responda a este *email*.

Qualquer questão deverá ser dirigida a dam@infarmed.pt

Dear Representative of the MAH [xxxxx],

Please find enclosed the user and password for access to the following electronic portals:

- SMUH-AIM for pre-submission of Marketing Authorisation applications, including the portal for information on the status of MA applications (national procedure only)
- SMUH-ALTER for submission of variations to existing Marketing Authorisations
- Application for confirmation/update of flow chart of a medicinal product
- Information on the status of reimbursement application

User: [xx]

Password: [xx]

This password must be changed upon first use, and may again be changed whenever desired.

This message was generated automatically so do not reply to this email.

Any questions should be send to dam@infarmed.pt

Exemplo 2 – Refusal of User Registration Request:

- “Assunto Email”:
Recusa de pedido de Registo Utilizador / Refusal of User Registration Request;
- “Detalhes Corpo Email” -
Caro Representante do Titular [xxxxx],

O pedido de registo de utilizador submetido em [dd-mm-aaaa] foi recusado pelo(s) motivo(s) abaixo descrito(s):

Por favor não responda a este email.

Qualquer questão deverá ser dirigida a dam@infarmed.pt

Dear Representative of the MAH [xxxxx],

The request for user registration submitted on [dd-mm-aaaa] has been refused for the following reason(s):

Please do not reply to this email.

Any questions should be send to dam@infarmed.pt