SIOMS - Certification of Medicinal Products for Human Use

March/2026

FO Application Manual

1. Introduction

INFARMED, I.P. shall, at the request of pharmaceutical companies, issue marketing authorisation holders, wholesale distribution authorisation holders or manufacturing authorisation holders, certificates (Certificate of a Pharmaceutical Product - CPP) or declarations, in the format of the World Health Organisation, for the purpose of export or registration in third countries.

The SIOMS - Certification of Medicinal Products for Human Use, allows the automatic issuance of these documents minimizing the context costs associated with the issuance of documents for export or registration processes, and streamlining their issuance.

Undertakings may independently apply, pay and issue the required certificate or declaration.

The documents issued by the platform are signed through the use of a Qualified Electronic Seal Certificate, associated with Infarmed. This qualified electronic seal allows the use of a certification associated with the Infarmed entity, with probative value and that ensures the reliability and integrity of the documents generated.

Each certificate generated has two unique codes (Application No and Certificate No) that will allow national and international entities involved in the export or registration process to verify the authenticity of the electronic certificate issued, on the Infarmed website, on a page made available for this purpose – https://extranet.infarmed.pt/SIOMS-fo/autenticarDocumento.

Marketing Authorisation Holders, Manufacturing Authorisation Holders or Wholesale Medicines Distribution Authorisation Holders wishing to apply for these certificates must register using https://extranet.infarmed.pt/SIOMS-fo.

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2. General information

2.1 About this document

This document aims to describe the functionalities implemented in **SIOMS** and serve as a practical guide for users.

The data displayed on the screens are test data and should be considered as illustrative only and may not make sense in the context in which they are being viewed/used.

Version registration

Date	Review #	Author	Description
29-01-2026	1.0	Infarmed	Version 1.0 - FO Application Manual
02-03-2026	2.0	Infarmed	Versão 2.0 - Inclusion of correction request functionalities and request duplication

2.2 Application/ System

Project name:	SIOMS – Certification of Medicinal Products for Human Use
Document title:	FO Application Manual
Reference:	Infarmed-SIOMS-ManualApplication-FO

Minimal requirements for using SIOMS:

Microsoft Edge 90 and higher
Mozilla Firefox 80 and higher
Google Chrome 80 and higher

2.3 Terms, abbreviations and acronyms

Term/Abbreviation/Acronym	Description
MA	Marketing Authorisation
MFA	Manufacturing Authorization
MUH	Medicinal product for human use
INN	International non-proprietary name
WHO	World Health Organization
DAM	Directorate for the Evaluation of Medicinal Products
DIL	Inspection and Licensing Directorate
USS	Availability Management Unit and for the Health System
SPC	Summary of Product Characteristics
PL	Package Leaflet

3. Access profiles

Access profiles allow you to define usage restrictions and/or permissions in order to apply these settings to each user or a set of users.

The entity has two types of user: main user and collaborator. The difference between these two types lies in the fact that only the main user has access to Employee Management, which allows adding and deleting employees and changing the main user. All other features are accessible to all employees.

Application area	*FrontOffice*
Navigation menu	Menu > My requests> Menu > Representatives management Menu > Employee management Menu > Messages Menu > Help
Functionalities all employees	*Login* Recover Password Consult/Edit User Information Change Password
	Search Requests submitted by the authority See Application information Request Certificate or Declaration Transfer issued documents (certificates or declarations) See User Manual Add and edit medicine representatives
Main User Features	Add and delete contributors Change main user

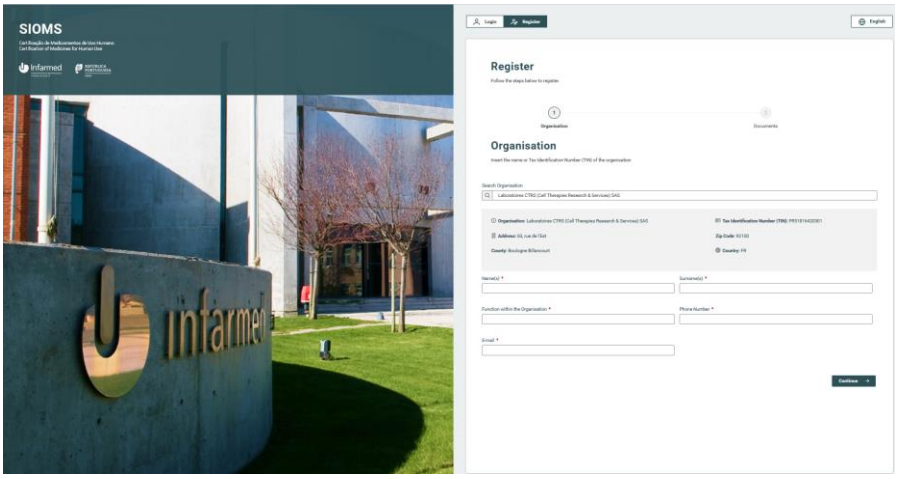
4. How to access SIOMS

Access the application through the address: https://extranet.infarmed.pt/SIOMS-fo.

4.1 Registration of the entity

1. In the **"New Registration"** area, search for the organisation using the Name or TIN. (The Password Manager feature may affect the display of the first Entity option displayed by the application.)

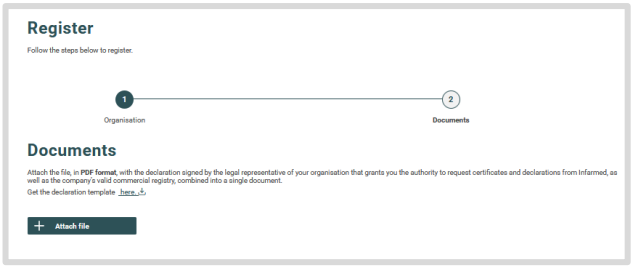
   Only Entities with eligible medicines, already registered in Infarmed, will be presented in the SIOMS Registration search field for selection.



2. Select the organisation to be registered and fill in the fields for the person registering and who will be registered as the main user of the authority – **Continue.**

   Note: Email fields must be unique to the primary user of each company. The phone number can be the same for the main user and other employees of the same company.

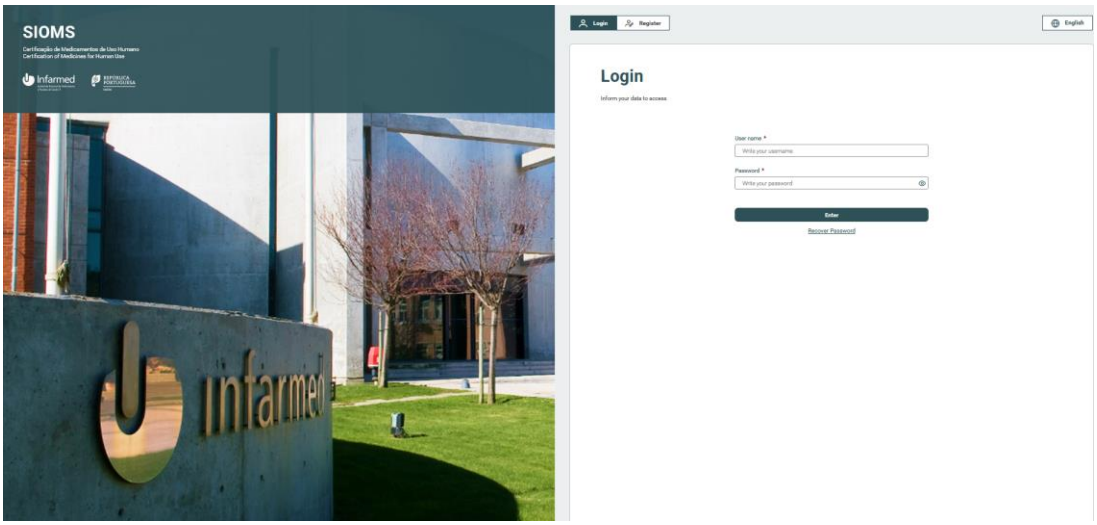
3. Insert the requested documentation and finish.



   The attached document should be a single pdf with the declaration duly signed by the legal representative of the organisation, together with the valid business registration certificate, and should not be larger than 20 MB.

4. After validation by Infarmed, access credentials will be sent to the email indicated.

4.2 Login



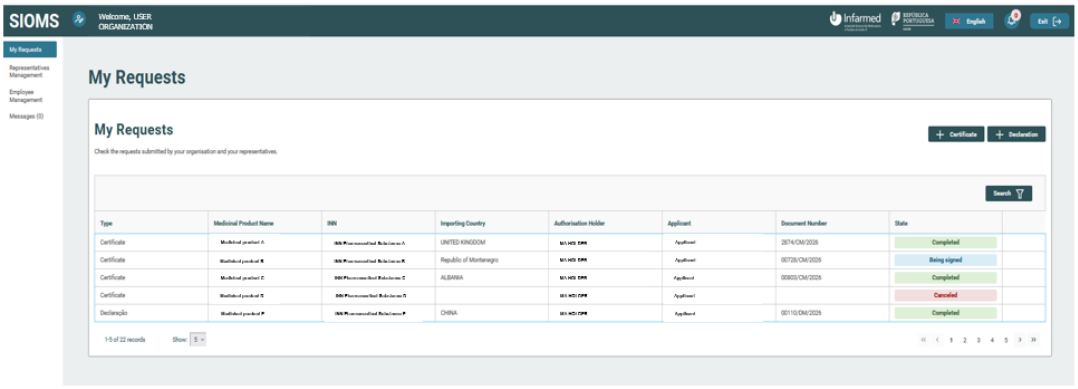
1. Enter the authentication data sent via e-mail after validation of the registration request by Infarmed.
2. This page allows you to access the platform and also retrieve the password. The assigned username cannot be changed. In the first access it is mandatory to change the password.
3. Select the “Enter” button.

5. Request management

5.1 My Requests

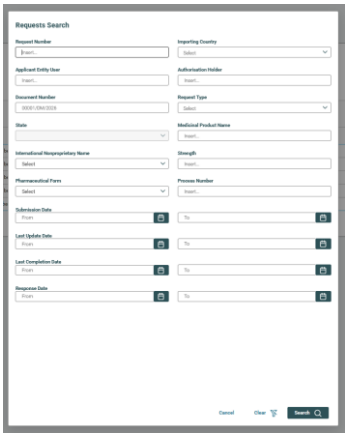
After logging in, the first screen of the system appears with

1. In the upper left field, the button allows access to the account information where you can edit the information and change the password.
2. In the upper right corner, the possibility to change the language (PT/ENG), the number of messages indicator and the exit button.
3. On the left, the main features menu: My requests|Representatives Management|Employee Management|Messages|Help.

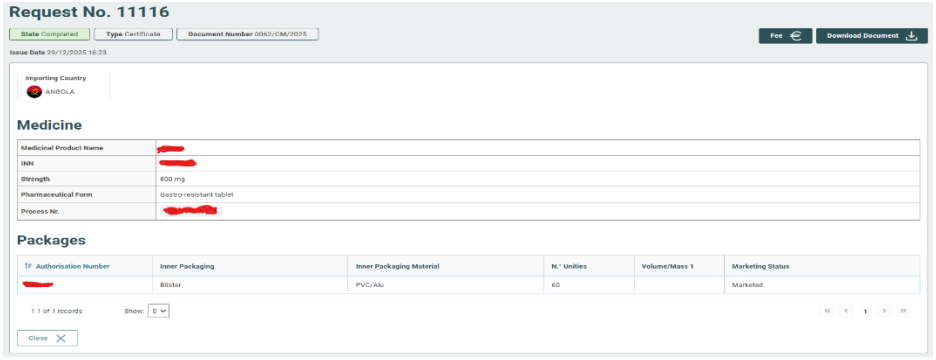


The My Requests screen allows:

1. View all applications for certificates or declarations and their status, in alphabetical order of the name of the medicinal product.
2. Search all requests submitted by your authority, or representing authorities, using different search criteria.



3. Consult the details of an application and, if in the Completed state, download the issued document and the invoice with the paid Fee value.



4. Consult the detail of a request that is in the status **In preparation** and resume the submission of the previously initiated and saved request.

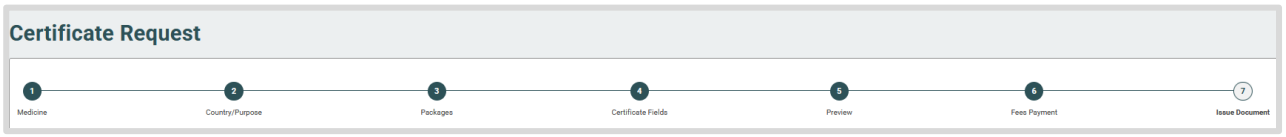
5. Request for new certificates or a new declarations using the **+Certificate** or **+Declaration** buttons.

6. Create a request from an already completed one (icon in the right column)

5.2 Application for a certificate

5.2.1 Application stages

The application for the issue of a certificate follows the flow identified in the image, with sequential insertion of the required information.



5.2.2 Applicant's options

During the preparation of the request, in any of the phases, it is possible to perform several actions, through the buttons in the footer.

Close - exit the request without saving the information.

Request correction - Make a correction request (See 5.3).

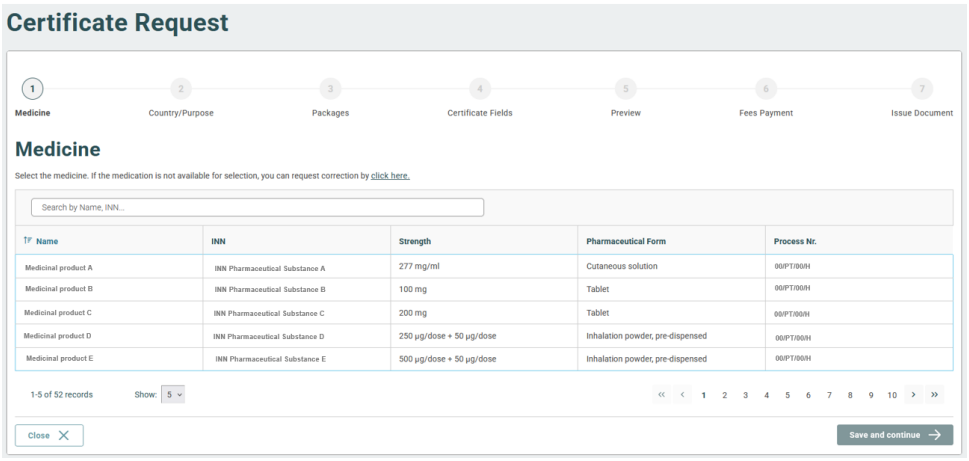
Cancel - delete the request; Once cancelled, it can no longer be reopened.

Back - go to the previous stage.

Save - save the entered information.

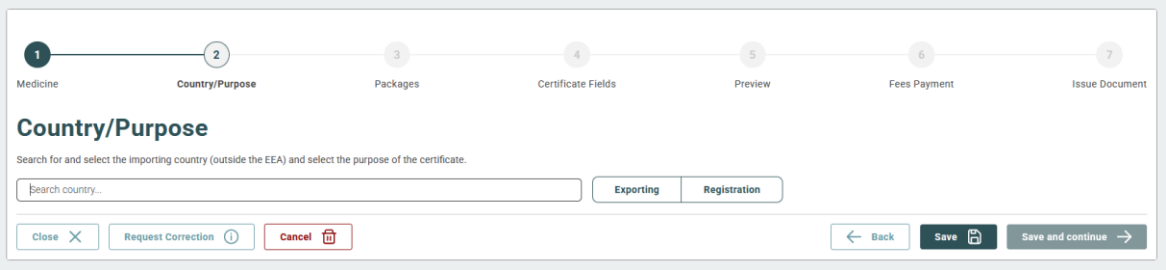
Save and continue - save the entered information and proceed to the next phase.

5.2.3 Medicinal product



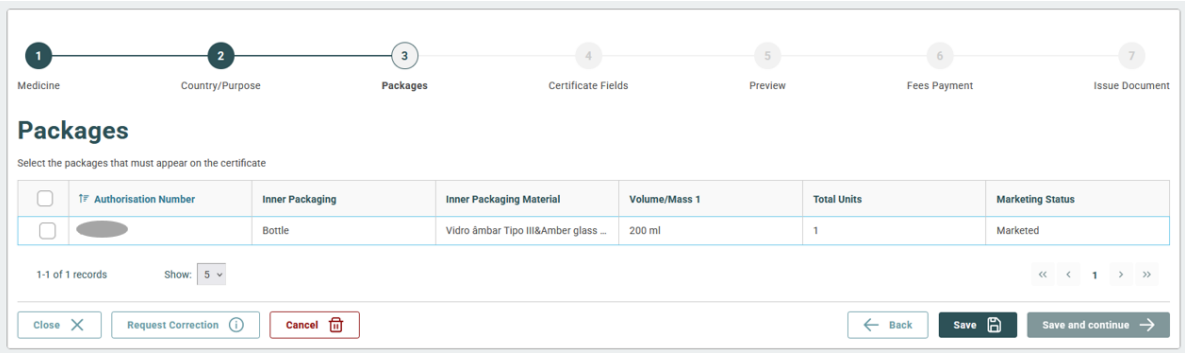
1. Display all medicinal products, associated with the applicant, for which a certificate, model WHO, may be issued.
2. Search by name, INN, strength, pharmaceutical form and process number of the medicinal product for which the certificate is sought.
3. Select the medicine.

5.2.4 Country/Purpose



1. Select the country for which the certificate is intended. To search, simply write the first 3 letters of the country you want.
2. Select the purpose for which the certificate is intended: exporting or registration.

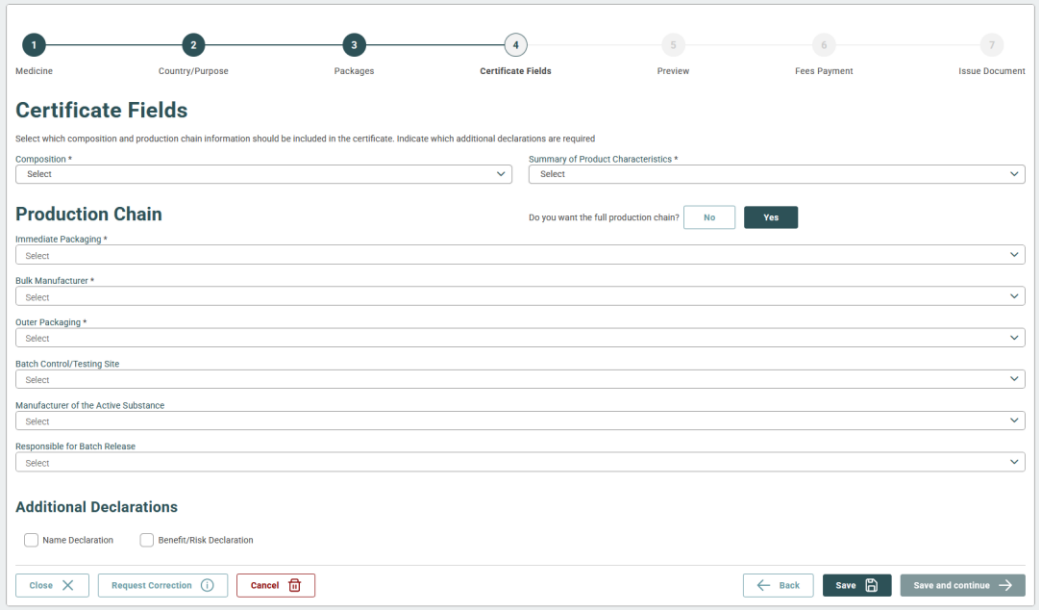
5.2.5 Packaging



1. Select the package(s) to be included in the certificate.

Note:
(1) One or more packages can be selected, regardless of the State of Marketing.
(2) If packaging in the state "temporarily **unavailable"** or on the "list **of packaging temporarily suspended for export" or on the "prior notification list" is** selected, the issuance of the document will be pre-assessed by Infarmed in order to ensure the availability of the medicinal product on the national market.

5.2.6 Certificate Fields



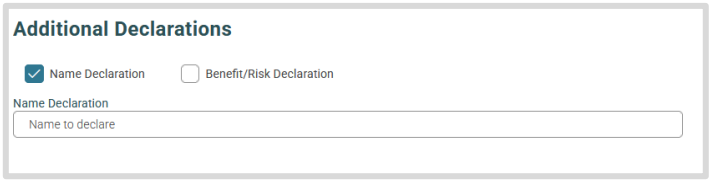
1. Please fill in the different selection fields:

- the type of **composition** you want to be listed in the Annex "Complete Composition" of the certificate (Qualitative and Quantitative Composition/Qualitative Composition/None). In the case of the "None" option, the Annex "Complete Composition" will only refer to the active substance(s) and their dosage(s) in the medicinal product.

- **information** you want attached to the certificate: SmPC (Summary of Product Characteristics)/PL (Package Leaflet) /SmPC and PL/None). For non-MA medicinal products only the option "None" is available.

- information from the **Manufacturers (complete/non-complete);** all the fields with the different types of manufaturers are filled in by the system with the entities authorised for this purpose; the user can delete those that he does not want to be indicated in the certificate. At least one manufacturer in the categories 'bulk manufacturer', 'immediate packaging manufacturer' and 'secondary packaging manufacturer' shall appear in the production chain.

- **additional declarations of Name and/or Risk/ Benefit;** the Risk/Benefit statement can only be selected for medicinal products with MA; if the name declaration is selected the field "Name" has to be filled in.



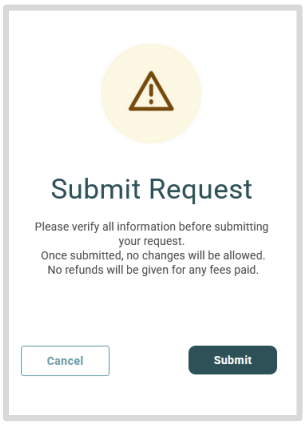
Note: INFARMED, I.P. does not evaluate the declared "Name" which is the sole responsibility of the Applicant.

5.2.7 Preview

1. Allows you to view the *draft* version of the Certificate to be issued.

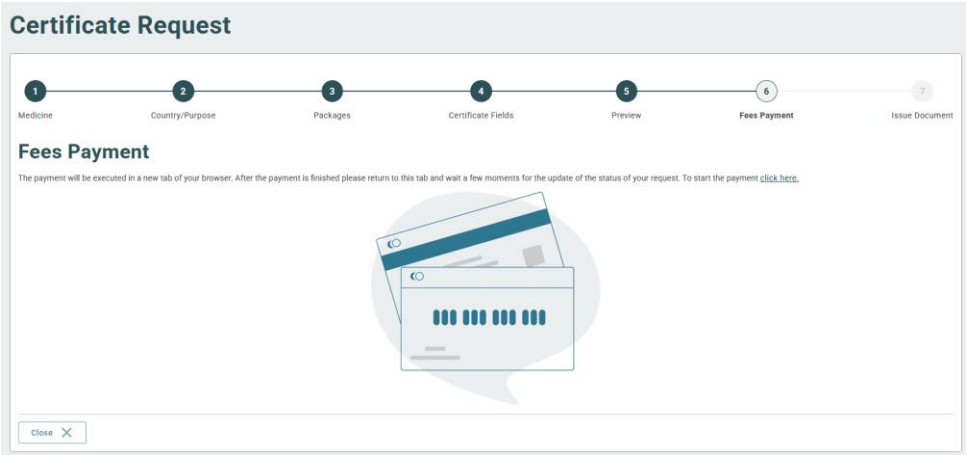
2. Validate the data and, if necessary, go back to change the information, or if you detect an error "request correction".

3. Submit the request.



Note: If packaging in the certificate is "temporarily **unavailable"** or is on the "list **of packaging for which export is temporarily suspended"** or on the "prior **notification list",** the issue of the document will be assessed in advance by Infarmed in order to ensure the availability of the medicinal product on the national market. You can only pay the fee after approval by Infarmed.

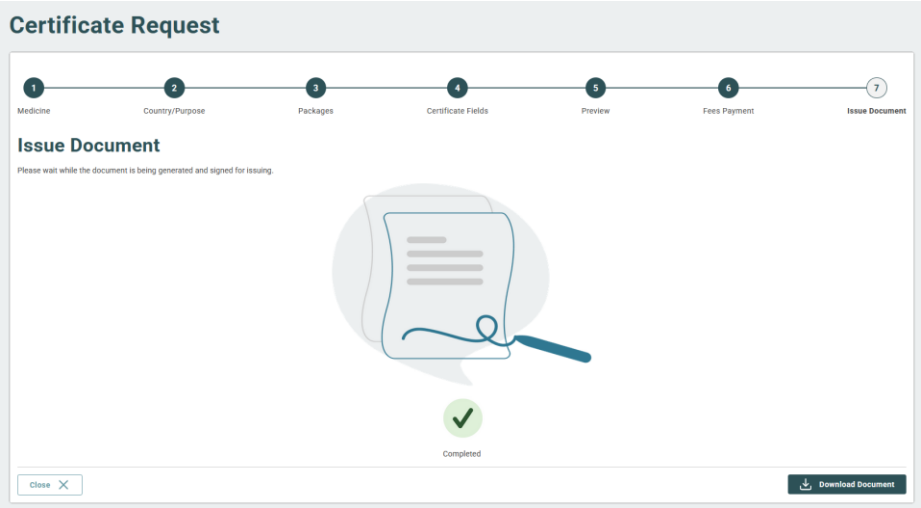
5.2.8 Fees payment



1. Initiate payment; the value is €30.69, regardless of the number of pages.
2. Comply with the instructions to make the payment of the order (Payment Gateway); this operation may take a few moments.
3. Once the payment has been made, return to the SIOMS tab in the browser and wait for the page to be automatically updated. The system detects that the payment has been successfully made and will automatically switch to the Step 7 – Issue Document screen.

Note:During the payment phase you can exit the SIOMS application. Systems communicate with each other without the need to keep SIOMS open.

5.2.9 Issue Document



1. The system automatically generates and signs the final document. The signature complies with national/European legislation and ensures that the information provided is validated at the date of issue of the certificate.
2. Download the certificate and declarations via the **Download Document button.**
3. Obtaining a compressed folder whose name corresponds to the certificate number, containing the corresponding documents in pdf format.

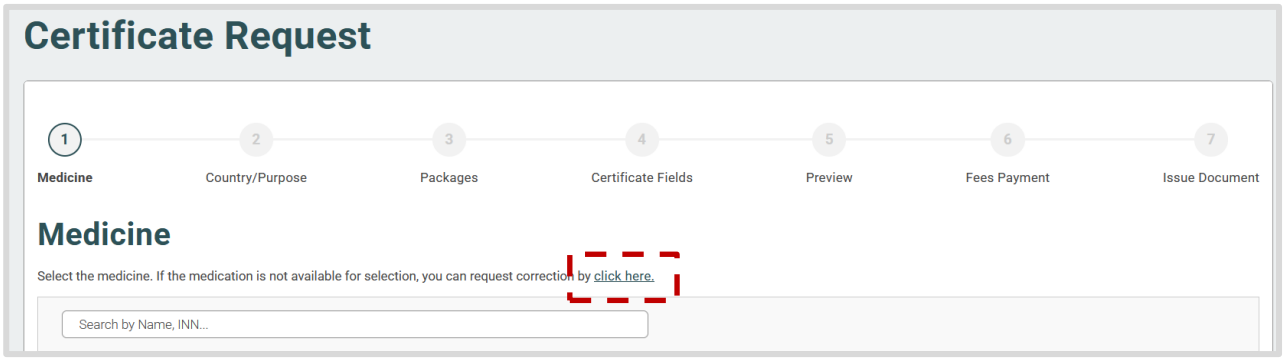
5.3 Requests for correction

5.3.1 Medicinal product not available for selection

Note: applicable only for MUH with manufacturing authorisation (without MA)

If the medicinal product for which the certificate is sought is not available for selection, the applicant may request the correction of this situation

1. In the product selection screen select the ‘click here’ option

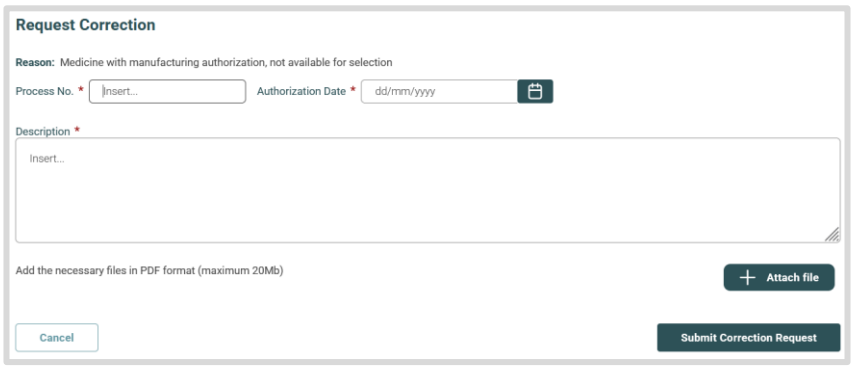


2. Display the screen to insert the information; the reason for this request is filled in with "Medicinal product with manufacturing authorisation, not available for selection".

3. Fill in the Nº Process, Authorization Date and Description fields.

4. Please attach the supporting documents that will be required for the assessment of this correction request.

5. Submit the request by selecting "Submit correction request".

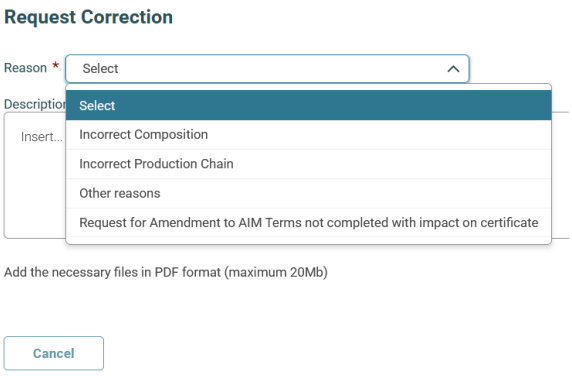


5.3.2 Correction of information

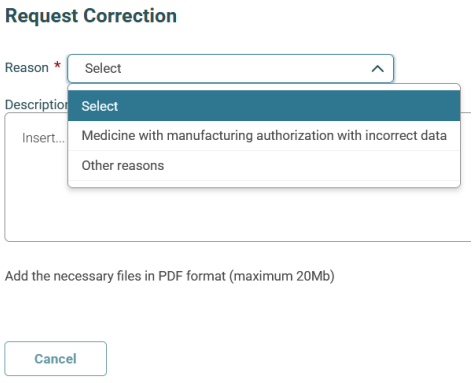
During the various stages of the application for a certificate, the applicant, if he detects any error in the information that the system returns, may request correction of the information by selecting the button "Request Correction" available in the footer.

The type of correction request to be selected in SIOMS depends on the medicine for which you are requesting the document and the content of the correction to be made, as illustrated in the following images

Medicinal product with MA

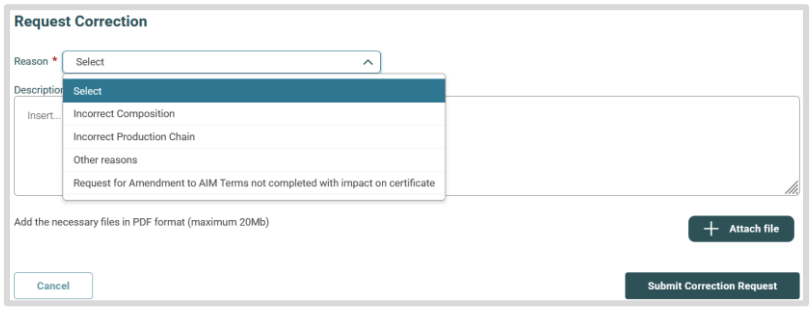


Medicinal product with MFA



5.3.3 Submission of the correction request

1. Select Reason



2. Insert a description and the procedure number of the variation (if the reason is "Request for variation to the terms of MA not completed with impact on the certificate").

3. Please attach, if necessary, the documents for the assessment of Infarmed's request for amendment. Please provide, at a minimum, the draft of the certificate.

4. After submission of the correction request, the status of the request becomes **"Awaiting correction"** and the applicant must wait for the reply from Infarmed before proceeding with the request.

5.3.4 Infarmed's reply to the correction request

Infarmed, evaluated the request for correction, can, always through the platform:

- ask for additional elements: the request status remains **"Awaiting correction"**;

- accept the correction: the request tatus becomes "In preparation", the applicant can complete the request and submit;

- refuse correction: the request status is changed to "In preparation"; the applicant may request a new correction, continue with the submission of the application for the issuance of the certificate with the original data, or cancel the application; the reason for the refusal is stated in the message.

All communications occur on the platform that generates messages with alerts for the new communication and simultaneously by email.

5.4 Application for the issue of a declaration

5.4.1 Application stages

The request of a declaration follows the flow identified in the following image, with sequential insertion of the information necessary for its issue.

5.4.2 Applicant's options

During the preparation of the request, in any of the phases, it is possible to perform several actions, through the buttons in the footer of the system.

Close - exit the request without saving the information.

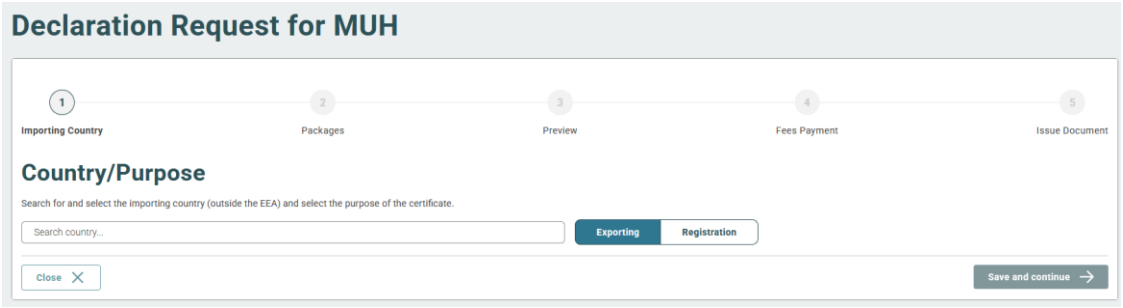
Cancel – delete the request; Once cancelled, it can no longer be reopened.

Back - go to the previous stage.

Save - save the entered information.

Save and continue - save the entered information and proceed to the next phase.

5.4.3 Country/Purpose

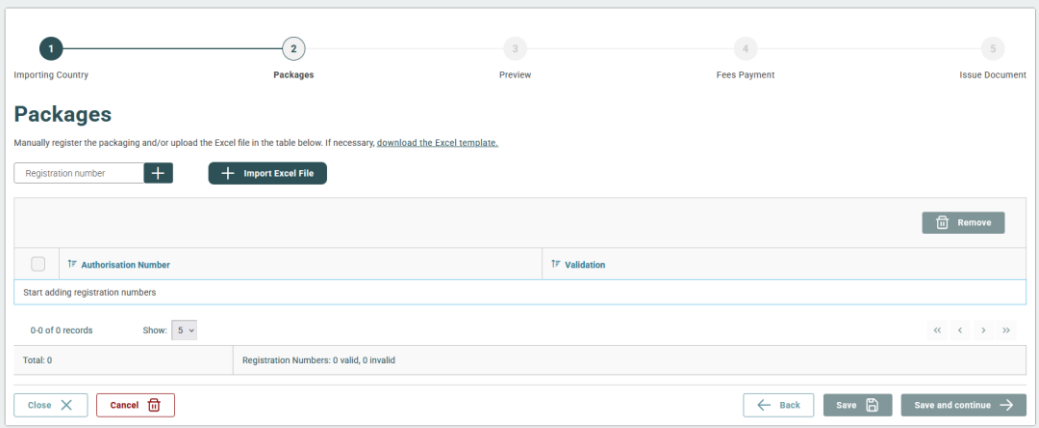


1. Select the country for which the declaration is intended. To search, simply type the first 3 letters of the country concerned.

2. Select the purpose for which the declaration is intended: export or registration.

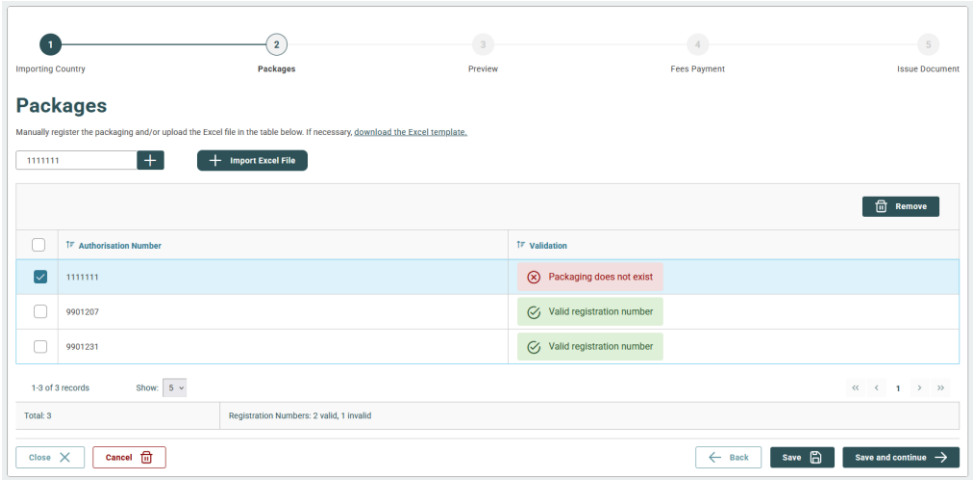
5.4.4 Packaging

The declaration shall be issued only for authorised packages and whose marketing status is "marketing confirmed by the MAH".

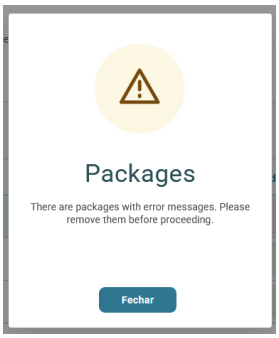


1. Insert the registration number of the packages of the MUH to be indicated in the declaration. This can be done either by direct manual recording or by uploading an excel file with the template provided under "download the excel template". The two means of inserting registration numbers at the same time may also be used.

2. The system validates the registration numbers and identifies those that are not valid by ticking the red 'Packaging does not exist', 'Packaging temporarily unavailable' or 'Packaging not marketed'.



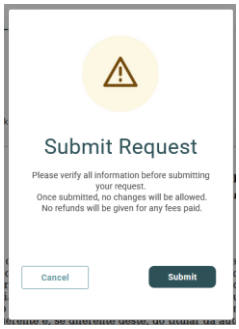
3. To continue to dispose of non-relevant packaging by selecting the packaging and using the remove button (including invalid records, non-marketed packaging and/or temporarily available packaging).



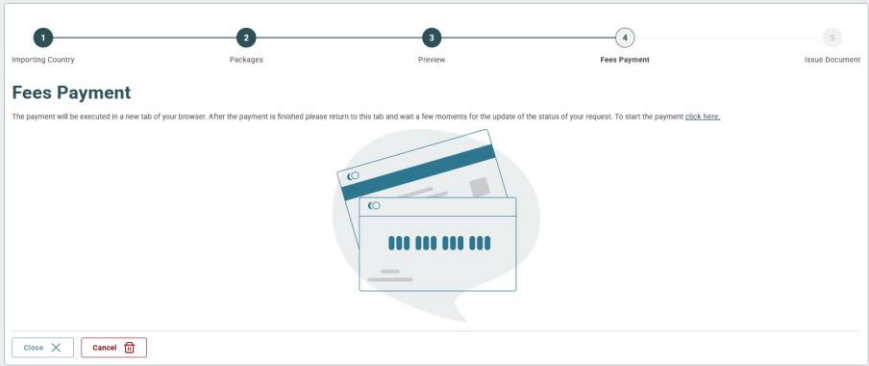
4. Once this selection is complete, you can proceed to the next step.

5.4.5 Declaration preview

1. View the draft version of the statement to be issued.
2. Validate the data and, if necessary, go back to change the information.
3. Submit the request.



5.4.6 Fees payment



1. Initiate payment ; the value is €30.69, regardless of the number of pages.
2. Comply with the instructions to make the payment of the order (Payment Gateway); this operation may take a few moments.
3. Once the payment has been made, return to the SIOMS tab in the browser and wait for the page to be automatically updated. The system will detect that the payment has been successfully made and will automatically switch to the Step 7 – Issue Document screen.

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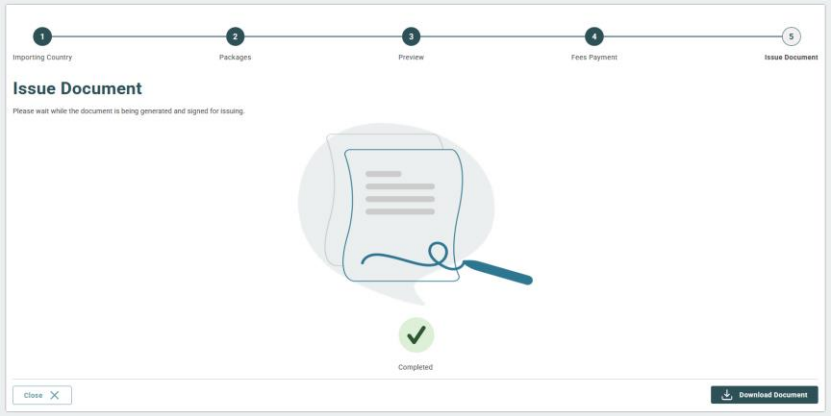
5.4.7 Issue Document



1. The system automatically generates and signs the final document.
2. Download the declaration via the **Download Document button.**
3. Obtaining the corresponding document in pdf format.

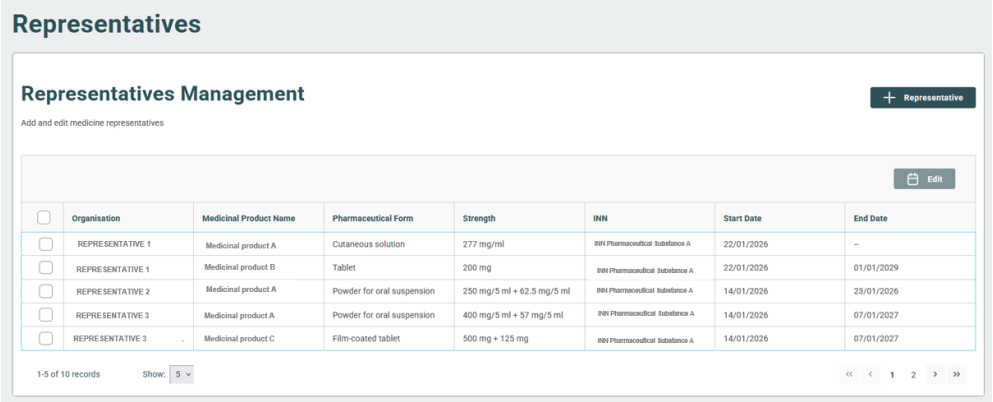
6. Management of representatives

MA and MFA Holders of medicinal products for Human Use may authorise third parties – **Representatives** – to request WHO model certificates and declarations for their medicinal products. This authorisation is carried out by autonomously in the SIOMS. The new representative will receive the access credentials through the email registered.

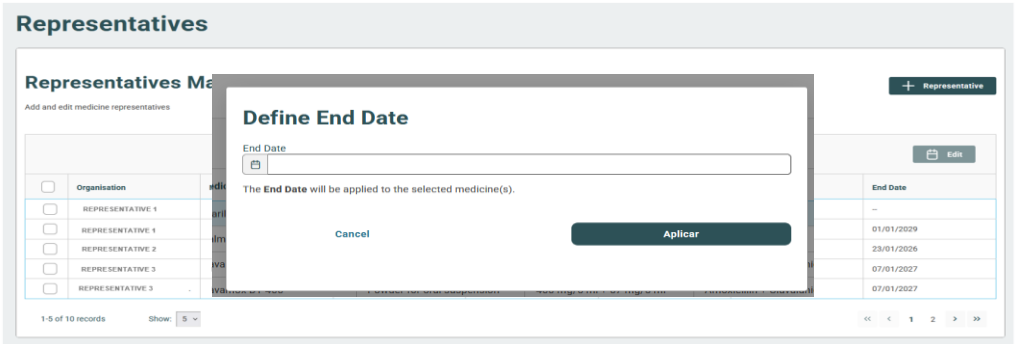
The Holder may select the universe of Medicinal products for which it gives access to its representative (all or specific ones) and may have more than one representative at the same time for the same medicinal product.

The Holder is responsible for managing access to information by other entities. All information on the medicinal product that is made available on a certificate is visible to its representatives.

6.1 Representatives management

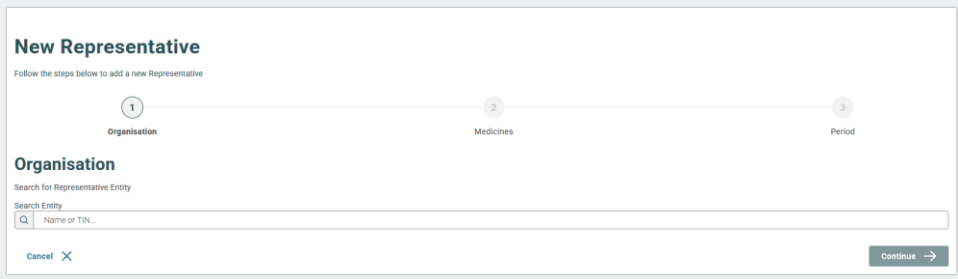


1. Manage current representations through the **Edit button.**
2. Select the medicine(s) for which you want to change the End Date.
3. Insert the new End Date. From this date the representative cannot issue documents for these medicinal products.

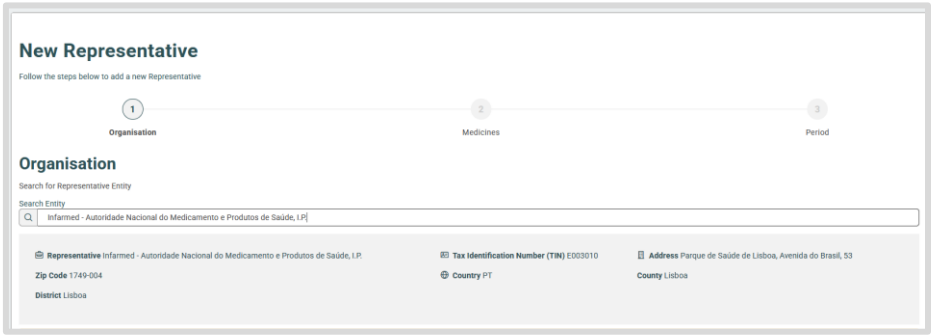


6.2 Add new representative - existing entity

1. Search through the name or TIN for the entity of the new representative.

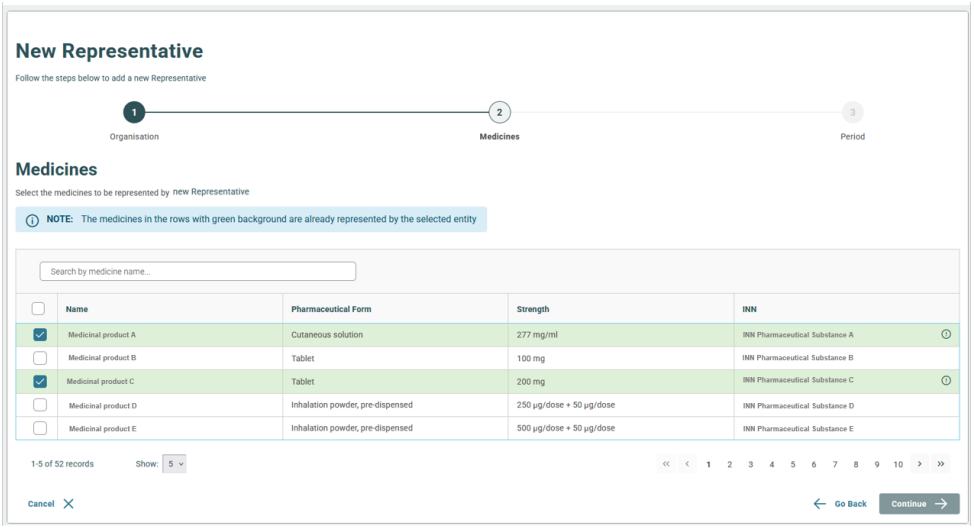


2. Select the authority and verify the information returned about the representative.



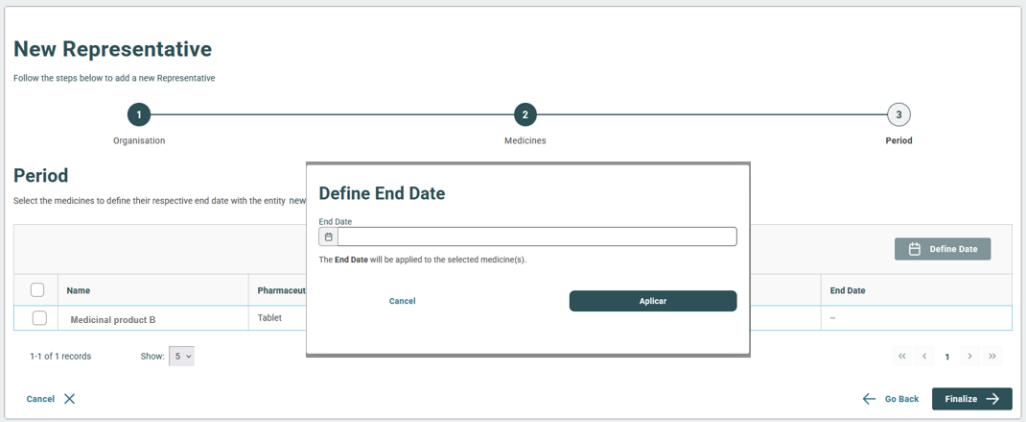
NOTE: The selected entity must exist in the Infarmed database and must be registered in SIOMS. If none of these conditions are met, you must request the creation of the entity in Infarmed or register it in SIOMS.
(See 6.3 Add representative - non-existing or non-registered entity in SIOMS).

3. Select the medicinal products for representation by the entity.



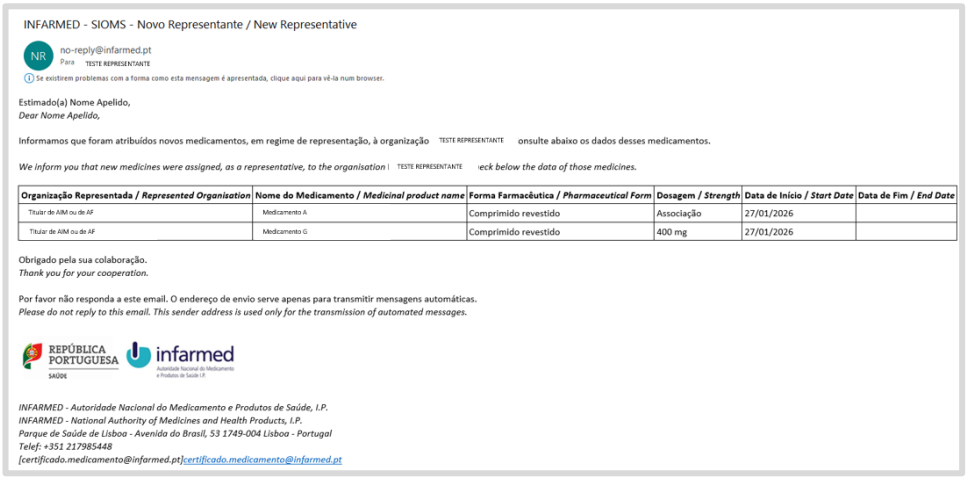
Note: Medicines that have already been assigned to the selected representative appear already selected and highlighted in green.

4. Define end date of the representation.



Note: The end date may be different for each selected medicine. If the representation does not have a defined conclusion, the date may be left blank.

Once this process is completed, the new representative will have access to the medicines assigned to him/her for the purpose of issuing the WHO certificate and model declarations, receiving an email with this information



INFARMED - SIOMS - Novo Representante / New Representative

NR no-reply@infarmed.pt
Para TESTE REPRESENTANTE

Se existirem problemas com a forma como esta mensagem é apresentada, clique aqui para vê-la num browser.

Estimado(a) Nome Apelido,
Dear Nome Apelido,

Informamos que foram atribuídos novos medicamentos, em regime de representação, à organização TESTE REPRESENTANTE onsulte abaixo os dados desses medicamentos.

We inform you that new medicines were assigned, as a representative, to the organisation TESTE REPRESENTANTE *eck below the data of those medicines.*

Organização Representada / *Represented Organisation*	Nome do Medicamento / *Medicinal product name*	Forma Farmacêutica / *Pharmaceutical Form*	Dosagem / *Strength*	Data de Início / *Start Date*	Data de Fim / *End Date*
Titular de AIM ou de AF	Medicamento A	Comprimido revestido	Associação	27/01/2026	
Titular de AIM ou de AF	Medicamento G	Comprimido revestido	400 mg	27/01/2026	

Obrigado pela sua colaboração.
Thank you for your cooperation.

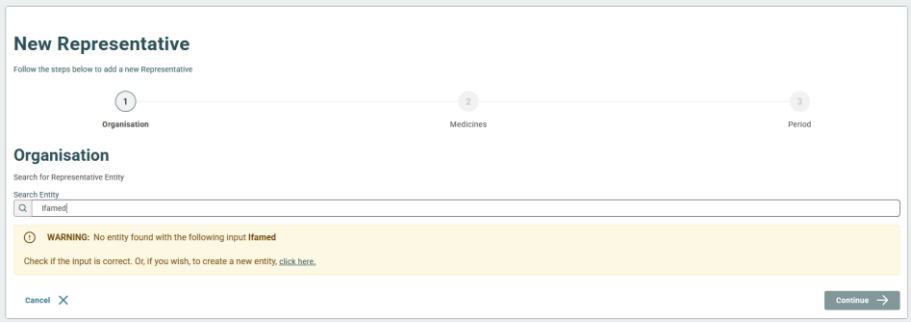
Por favor não responda a este email. O endereço de envio serve apenas para transmitir mensagens automáticas.
Please do not reply to this email. This sender address is used only for the transmission of automated messages.

REPÚBLICA PORTUGUESA SAÚDE infarmed

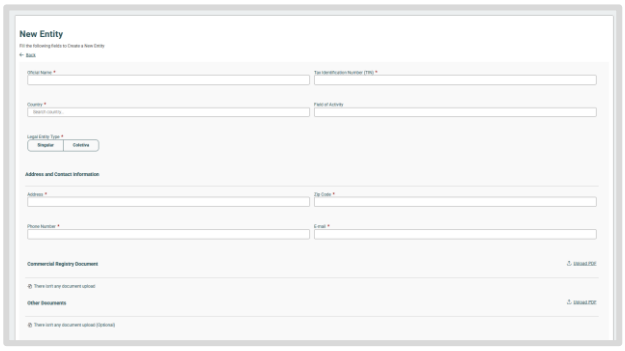
INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
INFARMED - National Authority of Medicines and Health Products, I.P.
Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa - Portugal
Telef: +351 217985448
[certificado.medicamento@infarmed.pt]certificado.medicamento@infarmed.pt

6.3 Add representative - non-existing or non-registered in SIOMS entity

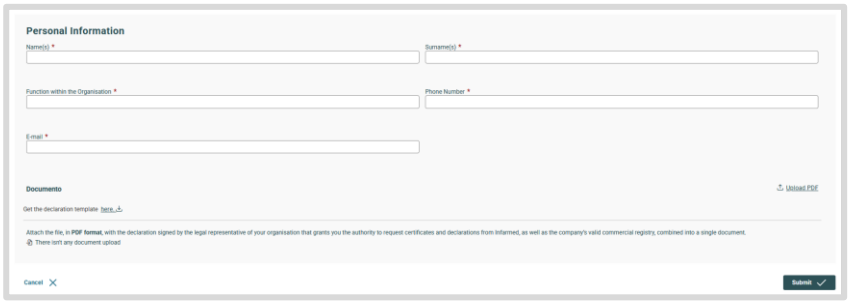
6.3.1 Request to create a new entity



1. Request the creation of a new entity.
2. Fill in the requested information on the new representative entity and enter its business register.

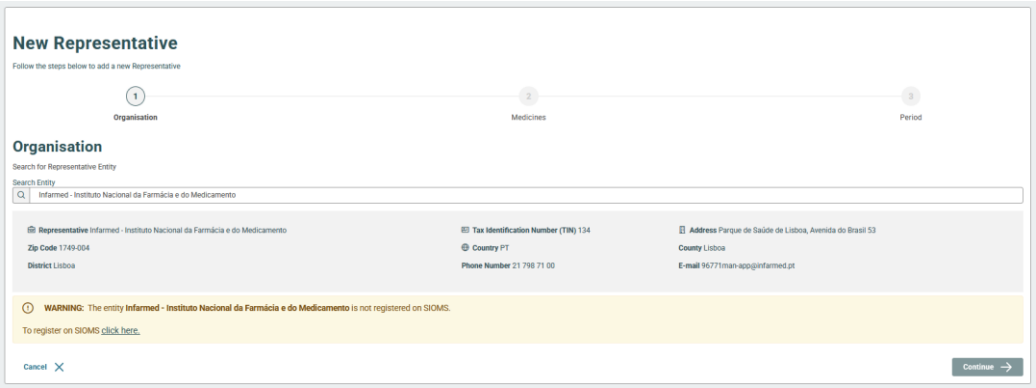


3. Fill in the details of the main user of the new entity and its declaration (according to the template available).



4. After the insertion of data select [Submit].
5. The request for the creation of an entity will be examined by Infarmed.
6. Infarmed's response will be sent to the entity's registration email.

6.3.2 Request for registration of entity in SIOMS



If the entity exists in the Infarmed database but is not registered in SIOMS, the entity that wishes to assign the representation should contact the future representative to follow the steps described in 4.1.1 Entity registration.

7. Employees – access management

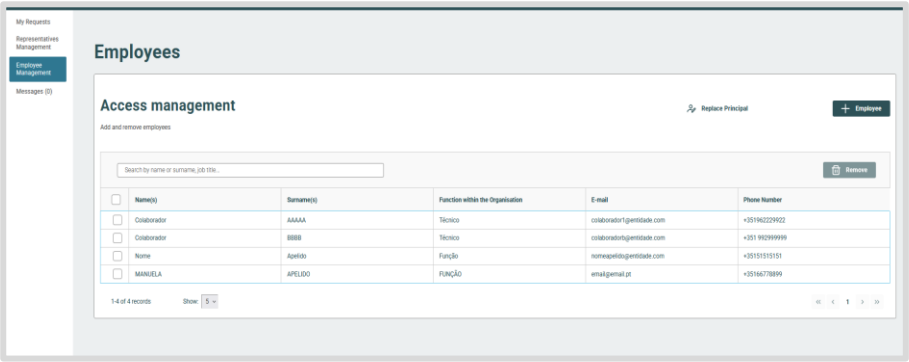
Each authority has 2 types of registered user profiles.

Principal User – first employee registered at the same time as the registration of the entity; can manage employees (add and remove). It is responsible for defining within the company who will have access to SIOMS.

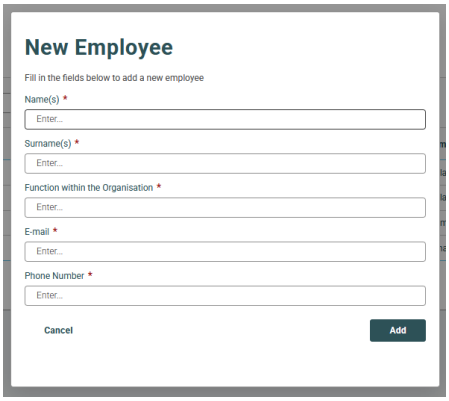
Employee – registered afterwards; registered by the principal user.

Application area	*FrontOffice*
Navigation menu	Menu > My requests> Menu > Representatives management Menu > Employee management Menu > Messages Menu > Help
Features of all employees	*Login* Recover Password Consult/Edit User Information Change Password
	Search Requests submitted by the organisation See Application information Request Certificate or Declaration Transfer documents (certificates or declarations) Add and edit representatives See User Manual
Exclusive features of the principal	**Add and delete employees** **Change principal user**

7.1 Add employee

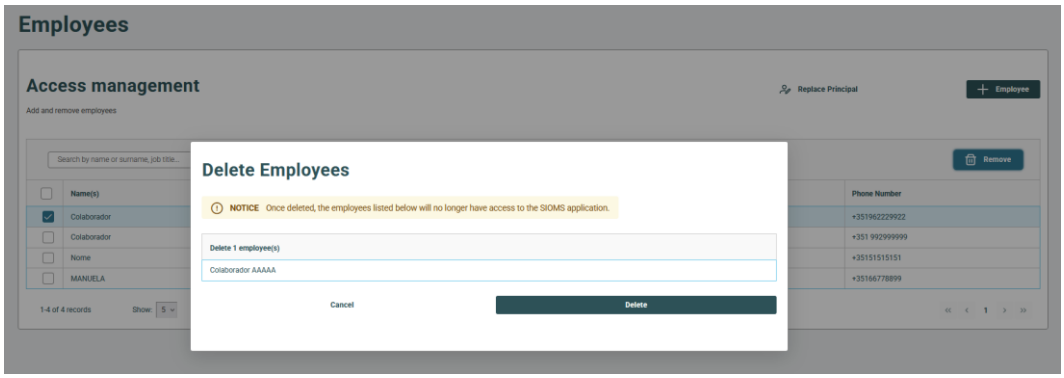


1. Select the **+ employee** option and fill in the details of the new employee.



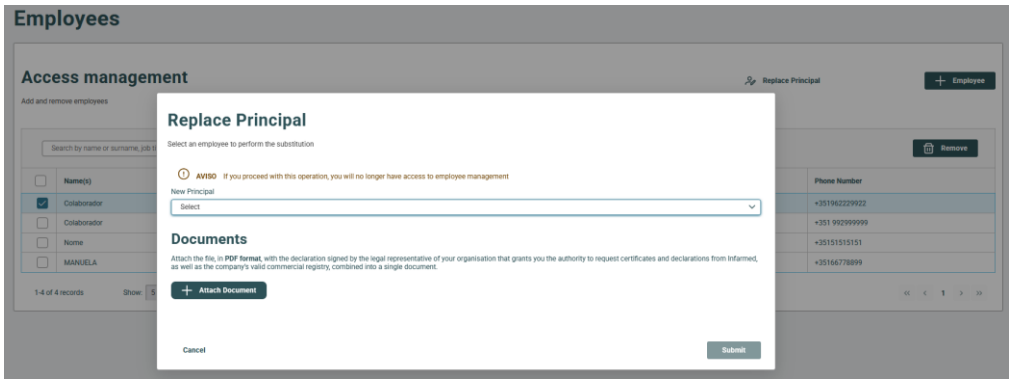
2. The access credentials of the new employee are sent to the email inserted in the registration data of the new employee.
3. The new employee will be included in the list of employees registered in SIOMS.

7.2 Delete employes



1. Select the employee(s) you want to delete.
2. Select the [Delete] button.
3. Confirm deletion.

7.3 Replace Principal

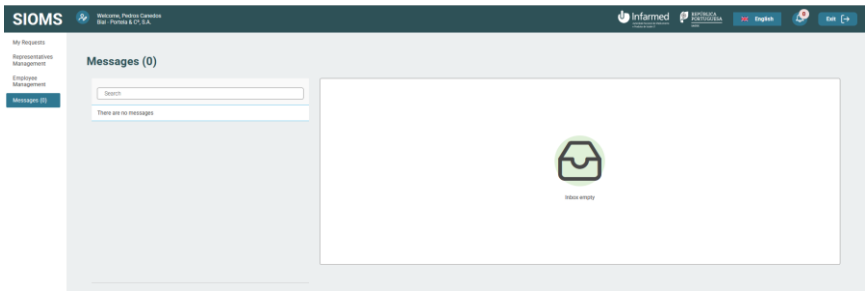


1. Select the [Replace Principal] button.
2. Select one of the registered employees.
3. Attach the declaration signed by the legal representative of the organisation granting authority to request certificates and declarations from Infarmed and the valid business register of the company, in a single PDF document and submit.
4. This action gives rise to a primary user replacement request that will be validated by Infarmed.

   Note: The main user remains, while the replacement request awaits a decision (acceptance or refusal) by INFARMED, I.P.. At this stage, you continue to manage access to the application, but you will not be able to delete the contact of the employee for whom you want to be replaced.

8 Messages

This area allows you to receive messages from Infarmed. The number in brackets informs about the number of new unread messages. This information is also indicated in the top right-hand corner.



9 Help

Through the Help button, the User Manual is displayed.

10 Final considerations

The information compiled in this document may be changed according to the future maintenance of the system/application.

Any inaccuracies that are detected between the application/system in its operational environment and the information described in this document should be reported to INFARMED, I.P., as well as any suggestions for improvement of the respective content, which we thank in advance.