

**MANUAL OF SUBMISSION OF APPLICATIONS FOR CERTIFICATES OF A
PHARMACEUTICAL PRODUCT – WHO MODEL AND STATEMENTS OF
PHARMACEUTICAL PRODUCTS**

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GLOSSARY

MA - Marketing Authorization

MHU - Medicines for Human Use

WHO - World Health Organization

DAM - Directorate for Drug Evaluation

SPC - Summary of Product Characteristics

PIL – Patient Information Leaflet

CPP - certificate of pharmaceutical product

MAH - Marketing Authorizations Holder

INTRDUCTION

Objective

This manual intends to describe and/or clarify the rules relating to the submission of applications for Certificate of a Pharmaceutical Product (WHO Model); Certificate of a Pharmaceutical Product not authorized but with a Marketing Authorization (WHO Model); Statement of Licensing status of Pharmaceutical product (WHO Model) and Statement of licensing status of Pharmaceutical product not Authorized but with Marketing Authorization.

The fulfilment of the present rules is of major importance as the quality of the information in the electronic application form depends mainly on the quality of the data initially inserted.

The technical requirements that must be followed for proper use of the program are:

- ✓ The application is optimized for 1280x800 resolution;
- ✓ The browsers that are possible are Internet Explorer 7 and higher (Internet Explorer 8, 9 and 10);
- ✓ The browsers that are possible are Google Chrome and Mozilla Firefox;
- ✓ The application was developed without taking into account the access via mobile devices. Access via tablet or smartphone can be done, however, and were not meant any tests, we can not guarantee full operability of the application SIOMS in mobile devices.
- ✓ The application session time is 20 minutes. After this time, and if session is not renewed (ie, if the user does not browse pages of SIOMS) application loses Login and prompts you to enter the access data again.

DEFINITIONS

Certificate of a Pharmaceutical Product – WHO Model (WHO certificate)

The certificate of pharmaceutical product (abbreviated: CPP or CoPP) is a certificate in the format recommended by the World Health Organization (WHO) and is issued for export or registration in countries outside the European Community. This certificate describes the characteristics of the medicinal product approved in the exporting country, includes information about the applicant of the certificate and is according with the model recommended by the World Health Organization and approved by “Deliberação n.º 2123/2001, de 28 de Outubro”.

For each medicinal product (Trade Name / Pharmaceutical Form / Strength) is issued a certificate stating the country to export.

These Certificates are issued to the marketing authorizations holders (MAH) for medicinal products (with valid MA) or their representatives, manufacturers (without MA and with manufacturing authorization valid) or wholesale distributor authorized by the MAH to consult the information for the (s) medicinal product(s).

Declaration annexed to the Certificate of a Pharmaceutical Product, Who Model related to a different name of the Pharmaceutical product

These declarations will be attached to CPP whenever required and inform that the medicinal product to which the certificate refers has a different name in the importing country, as stated by the applicant.

Statement of Licensing status of Pharmaceutical Product – WHO Model

This statement is intended for use by exporters to submit in international tenders. These statements indicate that the medicinal products mentioned in it are allowed to be marketed in the exporting country.

These Statements are issued to the MAH for medicinal products (with valid MA) or their representatives and wholesale distributors.

Statement on Manufacture Authorisation to Pharmaceutical Product(s) without Marketing Authorisation

These statements are issued for medicinal products without MA in Portugal, with a valid marketing authorization. It refers that the medicinal products are approved for exportation (as reported in Annex 8 of the manufacturing authorization).

These statements are issued to manufacturers of MHU without MA that hold a manufacturing authorization.

ACCESS

The portal for submission of applications for certificates of a pharmaceutical product and statement of licensing status of pharmaceutical product- who model is available on Infarmed, IP website in <http://sioms.infarmed.pt>

To request the documentation for exportation to foreign countries, the applicants must register first to use the application.

Access to request depending on the type of entity

The types of entities that may have access to the application can be summarized as follows:

Type of documentation	Applicant		
Certificate of a Pharmaceutical Product – WHO Model	<p>MAH For their own MHU</p>	<p>Manufactures For their own MHU without MA but with manufacturing authorization valid</p>	<p>Distributor As authorized by the MAH, and only possible for approved medicinal products</p>
Declaration annexed to the Certificate of a Pharmaceutical Product, Who Model related to a different name of the Pharmaceutical product	<p>MAH For their own MHU</p>	<p>NA</p>	<p>Distributor As authorized by the MAH, and only possible for approved medicinal products</p>
Statement of Licensing status of Pharmaceutical Product – WHO Model	<p>MAH For their own MHU</p>	<p>NA</p>	<p>Distributor For all medicinal products approved</p>
Statement on Manufacture Authorisation to Pharmaceutical Product(s) without marketing authorisation	<p>NA</p>	<p>Manufacturer For their own MHU without MA but with manufacturing authorization valid</p>	<p>NA</p>

Access to requests depending on the type of entity

- **MAH** - Can request all types of documentation.
- **Distributors** - Can request Certificates and Statements, WHO Model, for approved medicinal products. For each request of a Certificate of a Pharmaceutical Product– WHO Model, it will be required to attach the "Declaration of Representative".
- **Manufacturers** - Can request Certificates WHO Model and Statements for MHU without marketing authorisation.
- **Representative** - Can request Certificates and Statements, WHO Model, for approved medicinal products. For each request of a Certificate of a Pharmaceutical Product– WHO Model, it will be required to attach the "Declaration of Representative".

Login access

To make a new request for access, the user must access the homepage of the portal and click on the link "here" that is in the text "Click here to register the application".

Homepage > Login Page

First Page

The export of medicinal product is one of the key activities to ensure business growth of the pharmaceutical industry at national level. During the export process, several documents that prove the quality, effectiveness and safety of the medicinal product are requested. Thus, it is ensured that the company is exporting medicinal products already approved (through Marketing Authorisations or Manufacturing Authorisations) and therefore validated by the origin country of the medicinal product. The documents requested are: Certificate of a medicinal product - WHO Format; Statement on the Marketing Authorisation of Medicinal Products

Login:

Username:

Password:

[Recover Password](#)

• Click [here](#) to register in the application

In case of difficulties during the submission request of an certificate / statement, you may contact INFARMED IP by e-mail certificado.medicamento@infarmed.pt.

When you click this button, the application will forward the user to a new page:

New registration Help menu

Selected language:  English

New user registration

Type of entity

TIN:

Full company name

Email

Email confirmation

Contact person

Duty of the contact person

Telephone number of the contact person

Address:

Address

Postal code -

Country

District

County

Attaching files

All required documents should be attached:

Copy of updated Company Register Information : Nenhum ficheiro selecionado

Copy of the Identification Document: Nenhum ficheiro selecionado

Letter of authorization for communication on behalf of the MAH: Nenhum ficheiro selecionado

1. Select the type of the entity.

2. Fill in all fields on the form and attach the following documents:

- Copy of updated Company Register Information
- Copy of the Identification Document (referring to the person indicated in the area “Representative information”);
- 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 SIOMS)

NOTES:

1) 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.

2) 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 proof of establishment (i.e. the Company Register Information) of both the MAH and the company, as well the corresponding letters for authorisation for communication on behalf of the MAH must be attached.

3. If the system detects that the Taxpayer Identification Number (TIN) and / or e-mail address already entered into the system, the applicant will be alerted to this situation by displaying a warning "The TIN is not valid." and / or "The email address already exists in the system." In such case, the applicant must send an email to certificado.medicamento@infarmed.pt to request cancellation of the previous registration.
4. Select the Liability waiver.
5. Click in the "Create registration" button.
6. It will be appear the message "Your access request was successfully registered in the application and awaits for approval. Thank you."
7. After validation of the data submitted by the Infarmed, the applicant will receive an e mail with your access data.
8. You may recover the password, for that clicks in the "Recover Password "button and fill with your e-mail registration. You'll receive an email with a new password.

NOTES:

- 1) If the e-mail address associated with the entity is no longer active, you should send an email to certificado.medicamento@infarmed.pt to request to change to your new e-mail address.
- 2) If it is necessary to attach more than one registration in each category, you will be required to attach all registration into a single document for each category.

Change "Password"

In the box "My Account" select "Change Password". Enter the current password, the new password and click Change. You will receive a confirmation email of the password change.


SIOMS
Certification of Medicines for Human Use


[My requests](#) | [Certificate of a Pharmaceutical Product](#) | [Statem. of a Pharmaceutical Prod.](#) | [Help menu](#) | [My account](#)

Homepage > My requests Username: E000000016
Name: abcdefg Selected language: Logout

My requests

Search:

 Request type: State: Goal: Submission date: from

 Medicinal product: INN: Pharmaceutical form: Dosage:

Results: [Export data](#)

Type of Request	Identification of Applicant	Country	Purpose	Medicinal product information	Status	Creation date	Submission date	Conclusion date	Delivery Date	
Certificate of a Medicinal product (WHO Format) - Authorised Human Medicinal Products	abcdefg (Marketing Authorizathion Holder; Manufacture; Distributor; Representative Entity;)			Med: Castilium Dct: Clobazam FF: Tablet Doz:	In fulfillment	12-07-2013				See Request Delete

In case of difficulties during the submission request of an certificate / statement, you may contact INFARMEID IP by e-mail certificado.medicamento@infarmed.pt.




SUBMISSION OF APPLICATIONS FOR CERTIFICATES OF A PHARMACEUTICAL PRODUCT – WHO MODEL AND STATEMENTS OF PHARMACEUTICAL PRODUCTS


SIOMS
Certification of Medicines for Human Use


[Help menu](#)

Homepage > Login Page Selected language: English

First Page

The export of medicinal product is one of the key activities to ensure business growth of the pharmaceutical industry at national level. During the export process, several documents that prove the quality, effectiveness and safety of the medicinal product are requested. Thus, it is ensured that the company is exporting medicinal products already approved (through Marketing Authorisations or Manufacturing Authorisations) and therefore validated by the origin country of the medicinal product. The documents requested are: Certificate of a medicinal product - WHO Format; Statement on the Marketing Authorisation of Medicinal Products

Login:

Username:

Password:

[Recover Password](#)

• Click [here](#) to register in the application

In case of difficulties during the submission request of an certificate / statement, you may contact INFARMEID IP by e-mail certificado.medicamento@infarmed.pt.




Requests for a Certificate of a Pharmaceutical Product (WHO Model) - Authorised Human Medicinal Products

1. Enter the main page of the application with your username and password.

2. In the main menu, position the mouse in the "Certificate of a Pharmaceutical Product".
3. Select with the mouse the Sub-Menu "Certificate of a Pharmaceutical Product (WHO Model) – Authorised Human Medicinal Products".

The screenshot displays the SIOMS web application interface. At the top, there are logos for 'infarmed' (Autoridade Nacional de Medicamentos e Produtos de Saúde I.P.) and 'GOVERNO DE PORTUGAL' (MINISTÉRIO DA SAÚDE). The main header reads 'SIOMS Certification of Medicines for Human Use'. Below the header, there is a navigation menu with three tabs: 'My requests', 'Certificate of a Pharmaceutical Product', and 'Statem. of a Pharmaceutical Prod.'. The 'Certificate of a Pharmaceutical Product' tab is active, and a sub-menu is open showing 'Certificate of a Pharmaceutical product (WHO model) - Authorised Human Medicinal Products'. The main content area is titled 'Step 1 - Selection of a Pharmaceutical Product' and contains a search form with the following fields: 'Name of the medicinal product', 'PT registration codes', 'INN' (with a dropdown menu set to 'Select INN'), 'Pharmaceutical Form' (with a dropdown menu set to 'Select the pharmaceutical form'), and 'Strength'. There are 'Search' and 'Clear' buttons, and a 'Next >>' button. At the bottom, there is a footer with contact information: 'In case of difficulties during the submission request of an certificate / statement, you may contact INFARMED IP by e-mail certificado.medicamento@infarmed.pt'.

4. Perform a search by filling out the field(s) identified(s) and select 'Search'. Optionally, you can click directly on the "Search" button that returns all medicinal products associated with your entity.
5. In the table of the results, you have to choose the medicinal product through the "Select medicinal product" button.
6. After selecting the medicinal product, click on the "Next" button.
9. Fill out the information requested on the application form, including: importing country; if you want the statement of the name in the importing country; the purpose for which the certificate is required; if you want the qualitative and quantitative composition of the medicinal product and if you want the SPC and / or PIL.
10. Attach the "Proof of payment" by using the "Search" button (the document already stored on your computer) and then press the button "Attach".
11. It should be identified how do you want to receive the documents issued by answer the question "Do you wish the document to be sent by post?".
12. Save the information and view the message "Operation successfully completed".
13. If you consider that all information is correct, click on the "Submit" button and view the message "Operation successfully completed".
14. The status of the request changes from "In fulfilment" to "Submitted".

NOTES:

- 1) The request can be saved until submission to obtain all the information and documentation necessary.
- 2) After submission of the request, it is impossible to make further changes to the information previously loaded and each submission can only contain a reference to one medicinal product.

Requests for a Certificate of a Pharmaceutical product (WHO Model) - Human Medicinal Products with Manufacturing Authorisation

1. Enter the main page of the application with your username and password.
2. In the main menu position the mouse in the "Certificate of a Pharmaceutical Product".
3. Select with the mouse the Sub-Menu "Certificate of a Pharmaceutical product (WHO Model) - Human Medicinal Products with Manufacturing Authorisation".

The screenshot shows the SIOMS web application interface. At the top, there is a header with the 'infarmed' logo (Autoridade Nacional de Medicamentos e Produtos de Saúde I.P.), the text 'SIOMS Certification of Medicines for Human Use', and the 'GOVERNO DE PORTUGAL' logo (MINISTÉRIO DA SAÚDE). Below the header is a navigation menu with tabs: 'My requests', 'Certificate of a Pharmaceutical Product', and 'Statem. of a Pharmaceutical Prod.'. The 'Certificate of a Pharmaceutical Product' tab is active, and a sub-menu is open showing 'Certificate of a Pharmaceutical product (WHO model) - Authorised Human Medicinal Products' and 'Certificate of a Pharmaceutical product (WHO model) - Human Medicinal Products with Manufacturing Authorisation'. The latter is selected. The main content area displays a form titled 'Medicinal product information' with the following fields: 'Name of the medicinal product' (text input), 'Pharmaceutical form: Select the pharmaceutical form' (dropdown menu), 'INN: Select INN' (dropdown menu), and 'Strength' (text input). The page also includes a 'Help menu' and 'My account' link, and user information: 'Username: E000000016', 'Name: abcdefg', and 'Selected language: English'.

4. Fill out all the fields requested on the application form, including: medicinal product information, medicinal product composition, production chain, packing information and additional data.
5. The fields "medicinal product composition"; "production chain" and "packing information" (which are mandatory) must be filled with complete information. You have to press "Enter" button after completing each line.
6. In the field "production chain" you should include all manufactures: manufacturer of the active substance; bulk manufacturer; immediate packaging and outer packaging.
7. In the field "packing information", the required fields are: Primary packaging; Package sizes; Shelf life; Temperature and Storage conditions.

8. Attach the "Proof of payment" by using the "Search" button (the document already stored on your computer) and then press the button "Attach".
9. It should be identified how do you want to receive the documents issued by answer the question "Do you wish the document to be sent by post?".
10. Save the information and view the message "Operation successfully completed".
11. If you consider that all information is correct, click on the "Submit" button and view the message "Operation successfully completed".
12. The status of the request changes from "In fulfilment" to "Submitted".

NOTES:

- 1) The selection range of years in the field "Date of the Manufacturing Authorisation" is 10 years, so for years prior to that are displayed, you should select the earliest year and reopen this tab as many times as necessary until you see the desired year.
- 2) The request can be saved until submission to obtain all the information and documentation necessary, however the required fields must be filled.
- 3) After submission of the request it is impossible to make further changes to the information previously loaded and each submission can only contain a reference to one medicinal product.

Requests for a Statement of Licensing Status of Pharmaceutical Product(s) (WHO Model)

1. Enter the main page of the application with your username and password.
2. In the main menu position the mouse in the "Statem. of a Pharmaceutical Prod.".
3. Select with the mouse the Sub-Menu "Statement of Licensing Status of Pharmaceutical Product(s)".

4. Fill out the name of the importing country.
5. For loading the PT registration codes may make it by manual loading or by data file loading.

6. **Manual loading**

- a) Filing one PT registration code per line.
- b) After filing all PT registration codes press the button "Validate PT registration codes".
- c) If there are any PT registration codes invalid, in order to proceed, you should correct it.

7. **File data loading**

- a) First you must download the template, by using the "Download the template" and save it on your computer with the extension '.csv' (do not change the file extension).

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	1.11E+08												
2	2.22E+08												
3	3.33E+08												
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													

- b) You must put in the first column of the template the PT registration codes of the medicinal products for which you want the statement and save the document (do not change the file extension).
- c) Press the button "Search" and search in your computer the file in which you saved the PT registration codes of the medicinal products.
- d) Click in the button "Load file data" and in the table will appear all PT registration codes of the medicinal products that were in the file.

- e) Press the button "Validate PT registration codes."
- f) If there are any PT registration codes invalid, in order to proceed, you should correct it.
- 8. It should be identified how do you want to receive the documents issued by answer the question "Do you wish the document to be sent by post?".
- 9. Attach the "Proof of payment" by using the "Search" button (the document already stored on your computer) and then press the button "Attach".
- 10. Save the information and view the message "Operation successfully completed".
- 11. If you consider that all information is correct, click on the "Submit" button and view the message "Operation successfully completed".
- 12. The status of the request changes from "In fulfilment" to "Submitted".

NOTES:

- 1) The request can be saved until submission to obtain all the information and documentation necessary.
- 2) After submission of the request it is impossible to make further changes to the information previously loaded.

Requests for a Statement on Manufacturing Authorisation to Pharmaceutical Product(s) without Marketing Authorisation

- 1. Enter the main page of the application with your username and password.
- 2. In the main menu position the mouse in the "Statem. of a Pharmaceutical Prod.".
- 3. Select with the mouse the Sub-Menu "Statement on Manufacturing Authorisation to Pharmaceutical Product(s) without Marketing Authorisation".

The screenshot shows the SIOMS (Sistema de Informação de Medicamentos) web application. At the top, there are logos for 'informed' (Autoridade Nacional do Medicamento e Produtos de Saúde I.P.), 'SIOMS Certification of Medicines for Human Use', and 'GOVERNO DE PORTUGAL' (MINISTÉRIO DA SAÚDE). The main navigation bar includes 'My requests', 'Certificate of a Pharmaceutical Product', 'Statement of a Pharmaceutical Prod.', 'Help menu', and 'My account'. The breadcrumb trail reads: 'Homepage > Statement on Manufacturing Authorisation to Pharmaceutical Product > Statement of Licensing Status of Pharmaceutical Product(s)'. The current page title is 'Statement on Manufacturing Authorisation' with a sub-header 'Statement on Manufacturing Authorisation to Pharmaceutical Product(s) without Marketing Authorisation'. User information shows 'Username: E000000016' and 'Name: abcdefg'. A language dropdown is set to 'English'. The form contains the following fields:

- Name of the medicinal product:
- Pharmaceutical form:
- INN:
- Strength:
- Number of the Manufacturing Authorisation:
- Date of the Manufacturing Authorisation:
- Importing Country:
- MA holder:
 - Name:
 - Address:

4. Fill out all the fields requested on the application form.
5. Attach the "Proof of payment" by using the "Search" button (the document already stored on your computer) and then press the button "Attach".
6. It should be identified how do you want to receive the documents issued by answer the question "Do you wish the document to be sent by post?".
7. Save the information and view the message "Operation successfully completed".
8. If you consider that all information is correct, click on the "Submit" button and view the message "Operation successfully completed".
9. The status of the request changes from "In fulfilment" to "Submitted".

NOTES:

- 1) The selection range of years in the field "Date of the Manufacturing Authorisation" is 10 years, so for years prior to that are screened, you should select the earliest year and reopen this tab as many times as necessary until you see the desired year.
- 2) The request can be saved until submission to obtain all the information and documentation necessary, however the required fields must be filled.
- 3) After submission of the request it is impossible to make further changes to the information previously loaded.

MY REQUESTS

1. Enter the main page of the application with your username and password.
2. In the main menu position the mouse in the "My Requests" and it will show all requests of the entity.
3. For the applications in the status "In fulfilment" it is possible to delete or edit the request.

a) **Delete the request:**

- In the desired request (status 'In fulfilment') press the button "Delete".
- Answer OK to the question "Are you sure you want to proceed with the requested operation?"
- View the message "Operation successfully completed" and on the screen of my requests that that request is deleted from the list.

b) **Edit the request:**

- In the desired request (status 'In fulfilment') press the button "See Request".
- Edit the fields that you want.
- Save the information and view the message "Operation successfully completed".

CONCLUSION OF REQUEST

After Infarmed has validated all information contained in the application form, you will receive an email informing that it is ready to be lifted and/or sent by post.

CORRECTION REQUEST

If you check that it is necessary to correct the documents that have been delivered, you can request the correction.

1. Enter the main page of the application with your username and password.
2. In the main menu position the mouse in the "My Request".

3. Select the medicinal product for which you want to correct the document and click on "See Request".
4. Press in the button "Correction request".
5. Identify very clearly the corrections that must be performed referring the section(s) that need correction stating the information that should be included in it.
6. Save the information pressing the button "Save correction request" and after viewing the warning message "Correction request successfully inserted" click "OK".
7. Click in the button "Close" to exit the window.
8. After Infarmed has validated the request for correction and issued a new document, you will receive e-mail informing that it is ready to be lifted and/or sent by post.

NOTE: You can only apply for correction of documents in the status "Delivered".