

**ELECTRONIC PRE-SUBMISSION OF
MAA
INSTRUCTIONS MANUAL**

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INTRODUCTION

Objective

This manual intends to put out the way of filling the electronic application form for the submission of Marketing Authorization Applications. Applicants must fill in the application form ahead of submitting the dossier.

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 data management by DAM/UIIM should consist only in a quality assurance mechanism and should not be understood as a systematic review of the inserted data, which would consist a doubling of efforts.

GENERAL RULES OF FILLING THE ELECTRONIC APPLICATION FORM

Text fields

- * Write the first letter of each word with capital letter and the remaining ones with small letters
- * Do not leave more than one space between each word
- * To write the greek letter "μ" (micro) push down the key "Alt" and while pressing this key write "0181"

Selection fields

- * The fields consist of pre-defined list from which a selection has to be made (they are not free text fields)
Finding a term is done by writing part of the intended term and selecting between the options presented. Results show all the existing terms with the sequence of letters, independently from where they stand in the word. You should restrict your search as much as possible,
E.g.: if you search for a the pharmaceutical form by writing *oral*, all pharmaceutical forms containing oral will be shown (see Marketing Authorization Application Particulars – V) pharmaceutical form.

Lists for the selection of entities Listas que envolvam a selecção de entidades
E.g. MAA, manufacturers

- * In case de desired entity is not found on the list or if it is not updated select the option OUTROS

Lists for the selection of substances

E.g. qualitative and quantitative composition in terms of the active substances and the excipients

- * If the desired substance is not found on the list you should ask DAM to add it to the list. The e-mail dam@infarmed.pt, is available for this situation. A monography of the substance should be attached to the e-mail.

Lists for the selection of Standard Terms

Dosage forms; Containers, closures and delivery devices, Routes and methods of administration.

TYPE OF APPLICATION

(selection fields)

Legal basis

Content of the table:

- * This list is according to Directive 2001/83/CE

* The options are:

Completo (Article 8(3) application)

Genérico (generic application)
Híbrido (hybrid application)
Uso bem estabelecido (well-established use application)
Nova associação fixa (fixed combination application)
Consentimento informado (informed consent application)

If one of the legal basis generic, hibrid or informed consent is chosen, the reference medicine or the original medicine fields must be filled.

MARKETING AUTHORIZATION PARTICULARS

I) Proposed invented name

(text field - 80 charactes)

Filling:

- * Put the cursor in the beginning of the text field (do not leave any space).
- * Write the first letter with capital letter and the next ones with small letters.

CARACTERIZAÇÃO DO PEDIDO	
Nome proposto para o medicamento	Dosagem
Fluoxitina Titular	20 mg

- * If the proposed invented name is composed by two names, start each word with capital letter.

CARACTERIZAÇÃO DO PEDIDO	
Nome proposto para o medicamento	Dosagem
Amoxicilina + Ácido Clavulânico Titular	1000 mg + 200 mg

II) Strength

(text field – 30 characters)

Use:

- * Use this field to fill in the quantitative composition in terms of the active substance by pharmaceutical unit, expressed in INN.

Filling:


- * Put the cursor in the beginning of the field (do not leave any space)
- * Leave one and no more than one space between the quantity and the unit measurement.
Correct: 15 mg
Incorrect: 15 mg
- * Use commas and not dots, without leaving any space between figures
Correct: 1,5 mg
Incorrect: 1. 5 mg
- * The active substance quantity should be expressed in INN.
Correct: INN/quantity – Amoxicilin – 500 mg
Incorrect: Active substance /quantity – Amoxicillin trihydrate – 574 mg

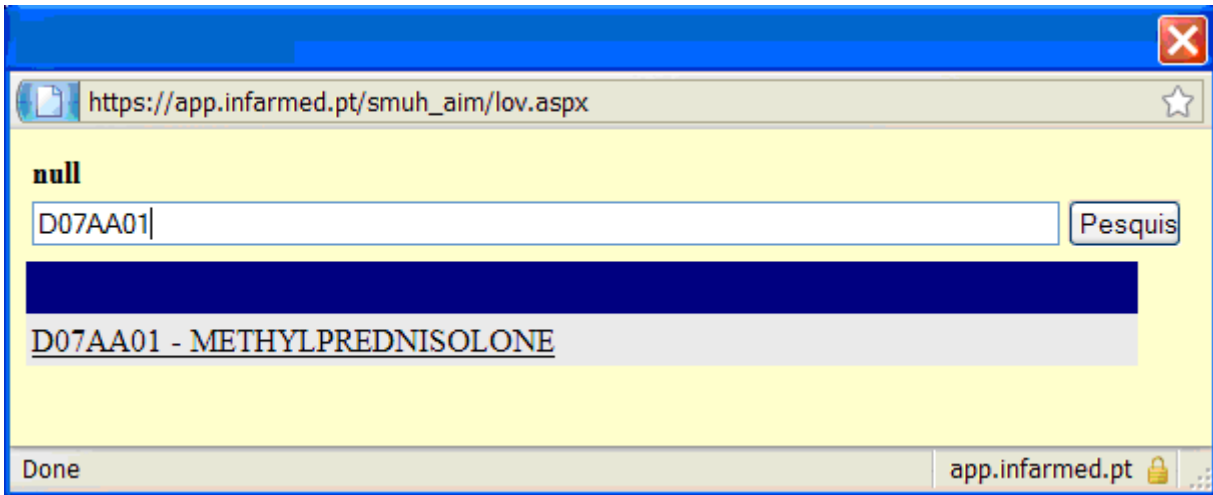
Filling in the field Strength and the pharmaceutical form

	Dosagem
Single-dose solid pharmaceutical forms Capsule, Tablet, Lozenge, Cachet; Suppository (blister; strip; Sachet; Tablet container etc.)	Total of the active – mass 20 mg
Multi-dose solid pharmaceutical forms Granules (in bottle)	Concentration of the active substance – mass/mass 50 mg/g
Single-dose liquid pharmaceutical forms Eye drops, solution, solution for injection, oral solution (ampoule, sachet, vial)	Quantity of the active substance in the administered volume – mass/adm. volume 25 mg/5 ml
Multi-dose liquid pharmaceutical forms Syrup, Oral solution, eye drops, solution (in bottle)	Concentration of the active substance – mass/total volume 500 mg/ml
Single-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (cannula, tube)	Quantity of active substance in the administered mass – mass/adm. mass 20 mg/5 mg
Multi-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (cannula, tube)	Concentration of the active substance – mass/mass 50 mg/g
Concentrates Concentrate for solution for injection	Concentration of the active substance before dilution – mg/ml 20 mg/ml
Impregnated dressing, implanter, Intrauterine delivery system and Transdermal system	Preferred -> Medim strength per unit time 50 mg/24 h
Aerosol	Preferred -> Quantity of active substance per dose 50 µg/inalação
Powders for reconstitution (single-dose) With reconstitution volume Without reconstitution volume or variable reconstitution volume	Quantity of the active substance in the administered volume – mass/adm. volume 50 mg/10 ml Total of active substance – mass 50 mg
Powders for reconstitution With reconstitution volume Without reconstitution volume or variable reconstitution volume	Concentration of active substance – mass/total volume 5 mg/ml Total of active substance – mass 50 mg

III) ATC Code

Searching and filling in
(selection field)

* Select the key **Inserir** and click  afterwards. In the new window write the ATC code and click “Pesquisar”. The ATC code is made of different levels represented by capital letters and numbers, Do not leave any space between the letters and numbers. *E.g.:* D07AA01



* Select from the list the intended ATC code.

* The ATC code is shown in the main window,. Click “Adicionar”.

* If the ATC code is not found, choose an upper level code


E.g: If the code A01AA03 cannot be found choose A01AA.

- **Several ATC codes can be selected for the same medicine.**

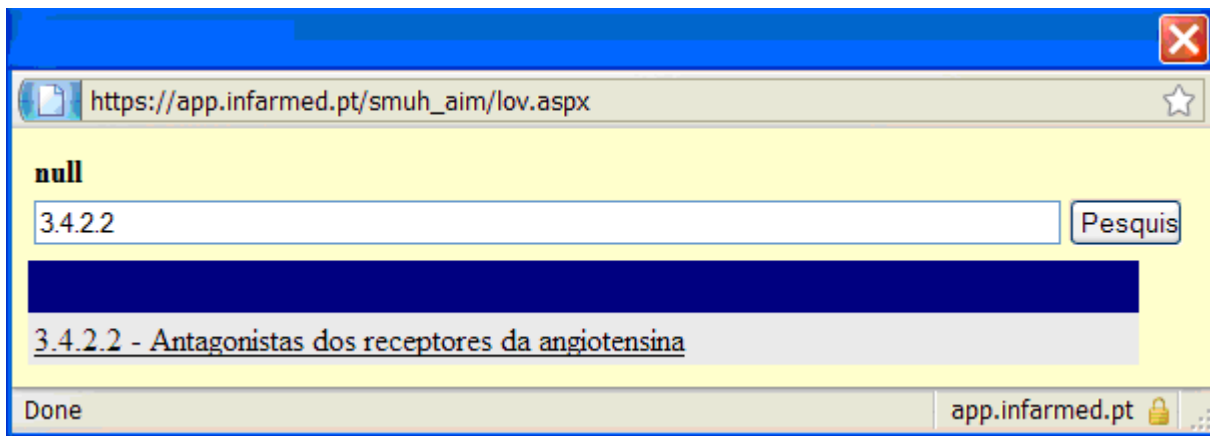
Classificação ATC		
	Código ATC	Descrição
<u>Apagar</u>	D07AA01	D07AA01 - METHYLPREDNISOLONE

IV) CFT Classification

Searching and filling in:
(Selection field)

* Select the key **Inserir** and click  afterwards. In the new window write the CFT code and click “Pesquisar”.

The CFT code is made of numbers separated by dots.
E.g.: 3.4.2.2



- * Select from the list the intended CFT code.
- * The CFT code is shown in the main window. Click “Adicionar”.
- **Several CFT codes can be selected for the same medicine.**

Classificação CFT		
	Código CFT	Descrição
<u>Apagar</u>	3.4.2.2	3.4.2.2 - Antagonistas dos receptores da angiotensina

V) Pharmaceutical Form


(selection field)

Table content:

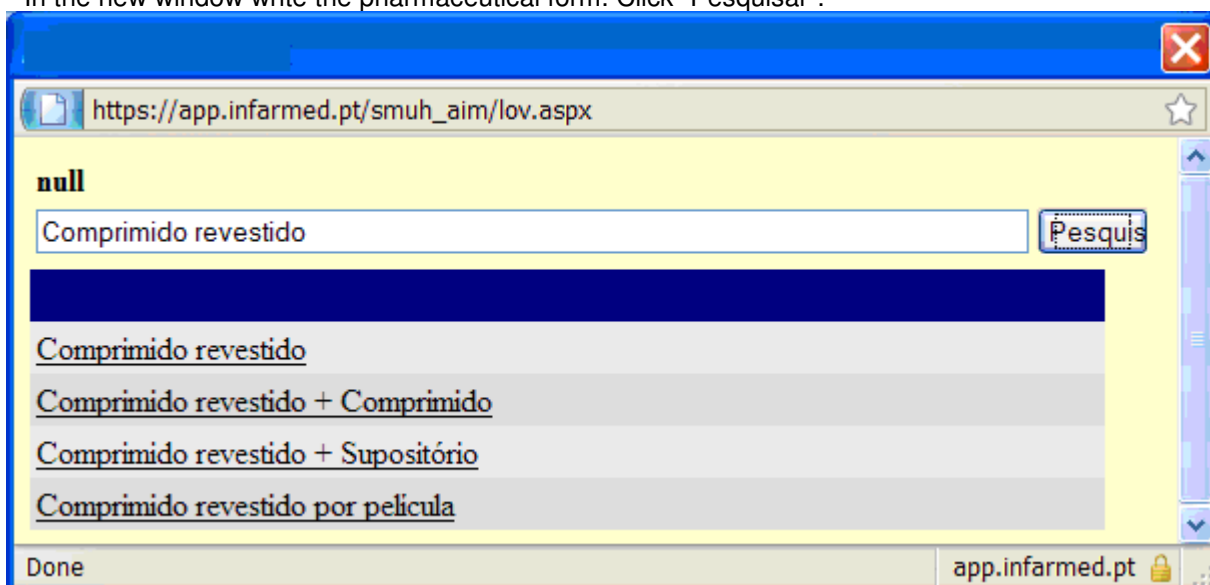
* "STANDARDS TERMS - Pharmaceutical dosage forms" - European Pharmacopoeia.

Searching and filing in:

(Selection field)

* Click the key 

* In the new window write the pharmaceutical form. Click “Pesquisar”.



- * Select from the list the intended pharmaceutical form.
- * The pharmaceutical form is shown in the main window.

Forma Farmacêutica

Comprimido revestido por película

- Only one pharmaceutical form can be selected per medicine.

VI) INN/Generic name

- * Information regarding the INN of the active substances in Portuguese.

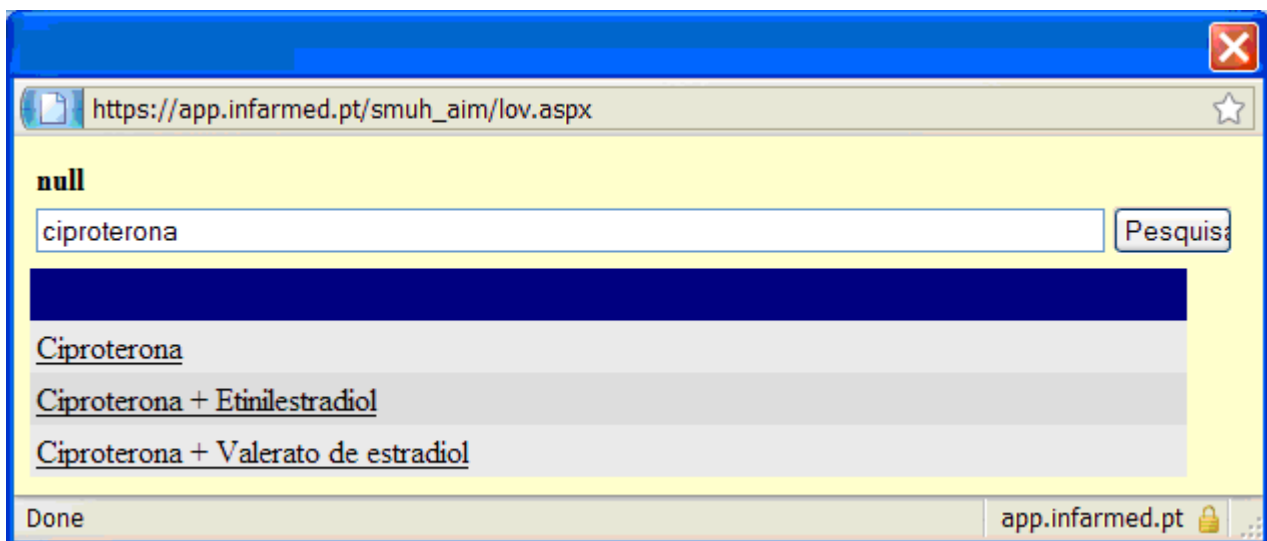
Searching and filing in:

- * When the medicine has more than one active substance the combined term for the active substances should be used.

- Only one INN/combined INN can be choosed per medicine.

E.g.: Ciproterona + Etinilestradiol should be used instead of Ciproterona and Etinilestradiol appart.

- * Click the key
- * In the new window write the INN/combined INN and click “Pesquisar”.



- * * Select from the list the intended INN/combined INN
- * If a INN/combined INN cannot be found choose the option “OUTROS”
- * The INN/combined INN is shown in the main window

DCI / Nome Genérico

Ciproterona + Etinilestradiol

VII) Dispensing Classification

(selection field)

* The list is based on the Decreto de Lei n.º 176/2006 de 30 de Agosto.

Filling in: choose from the table.

- Only one dispensing classification can be selected per medicine.


VIII) Routes of Administration

Table content:

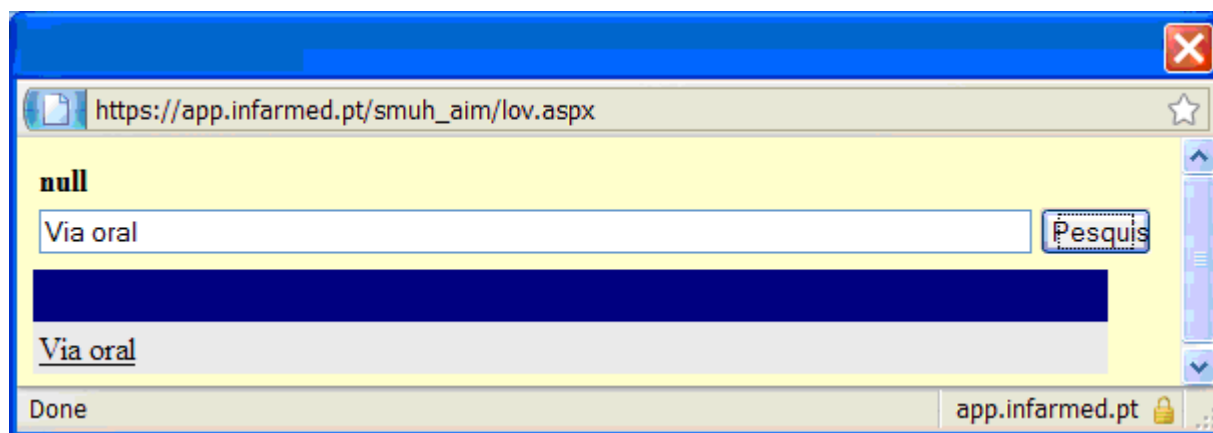
* STANDARDS TERMS – Routes of Administration" - European Pharmacopoeia.

Searching and filling in:

(selection field)

* Click the key **Inserir** and click  afterwards..

* In the new window write the route of administration and click “Pesquisar”.



E.g.: the search should be as strict as possible. IF the administration route would be *intradérmica* the search term should be *intradérmica*.

* Select from the list the intended route of administration.

* The route of administration is shown in the main window Click “Adicionar”.

* The inserted route of administration can be removed afterwards using the key “Apagar”.

- Several routes of administration can be selected per medicine.

Vias de Administração	
Vias de Administração	
Apagar	Via oral

REQUESTED PRESENTATIONS

I) Primary Packaging

Table content:


* "STANDARDS TERMS - Containers" - European Pharmacopoeia.

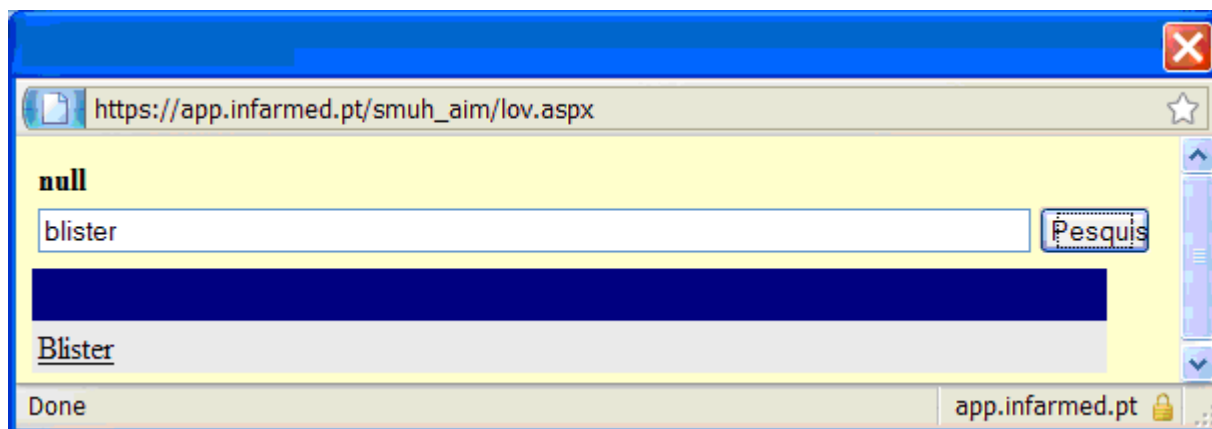
Filling: choose from the table

* Always indicate the primary packaging (*E.g.*: blister).

* In case of medicines for reconstitution, for which there is more than one recipient within the secondary packaging, the primary packaging to be indicated should be the one containing the active substance.

* When the active substances are in more than one recipient, the primary packaging to be described should be the one needing more information (fields) to be well defined.. The remaining information will be validated by INFARMED afterwards.

* Select the key **Inserir** and click  afterwards. In the new window write the packaging material and click "Pesquisar".



* Select the primary packaging from the list.

* The primary packaging is shown in the main window. Click "Adicionar".

II) Description

(selection field)

Use:

* Type of packaging material

Material	Abreviaturas
Aluminium	Alu
Polivinil chloride	PVC
Polivinilidene chloride	PVDC
Polyethylene	PE
Polypropylene	PP
High density Polyethylene	HDPE
Low density Polyethylene	LDPE
Type I glass	Vidro tipo I
Type II glass	Vidro tipo II
Type III glass	Vidro tipo III
Type IV glass	Vidro tipo IV
Paper + Aluminium	Papel/Alu
PVC + Aluminium	PVC/Alu
Aluminium + Aluminium	Alu/Alu
PVDC + Aluminium	PVDC/Alu
Vinyl polyacetate	EVAC
Politereftalato ethylene	PET
Polyethylene + Aluminium	PE/Alu
Polypropylene + Aluminium	PP/Alu
High density Polyethylene + Aluminium	HDPE/Alu
Low density Polyethylene + Aluminium	LDPE/Alu
PVC + PVDC	PCV/PVDC
PVC + Aluminium e PVC + PVDC	PVC/Alu-PCV/PVDC
Other	Outros

E.g.:

PVC/Aluminium blister

Description: PVC/Alu

Filling:

* Select the options related with the field “Descrição”

III) Number of units

* Fill this field with the number of units only.

IV) Quantity

(numeric field / selection field)

Filling:

See the following table.

Filling of the Packaging fields according with the pharmaceutical form

	Packagings
<p>Single-dose solid pharmaceutical forms Capsule, tablet, lozenge, Cachet; Suppository (In blister; strip; Sachet; Tablet container etc.)</p>	<p>Number of units Quantity – in white</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>10 % <input type="checkbox"/></p>
<p>Multi-dose Solid pharmaceutical forms Granules (In bottle)</p>	<p>Number of units Quantity – total mass <i>E.g.</i> Units 1 Quantity 250 g</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>1 250 g <input type="checkbox"/></p>
<p>Single-dose liquid pharmaceutical forms Eye drops, solution , solution for injection, oral solution (in ampoule, sachet, , vial)</p>	<p>Number of units Quantity – volume of liquid <i>E.g.</i> Units 10 Quantity 1ml</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>10 1 ml <input type="checkbox"/></p>
<p>Multi-dose liquid pharmaceutical forms Syrup, oral solution, Eye drops, solution (In bottle)</p>	<p>Number of units Quantity – volume of liquid. <i>E.g.</i> Unit 1 Quantity 150 ml</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>1 150 ml <input type="checkbox"/></p>
<p>Single-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (In cannula, tube)</p>	<p>Number of units Quantity – total mass <i>E.g.</i> Units 2 Quantity 1 g</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>2 1 g <input type="checkbox"/></p>
<p>Multi-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (In cannula, tube)</p>	<p>Number of units Quantity – total mass <i>E.g.</i> Units 1 Quantity 10 g</p> <p>Unidades Quantidade Emb. Hosp.</p> <p>1 10 g <input type="checkbox"/></p>

<p>Concentrates Concentrate for solution for infusion</p>	<p>Number of units Quantity – volume of liquid <i>E.g.</i> Units 10 Quantity 2 ml</p> <table border="1" data-bbox="735 297 1409 465"> <thead> <tr> <th data-bbox="735 297 1023 365">Unidades</th> <th data-bbox="1023 297 1326 365">Quantidade</th> <th data-bbox="1326 297 1409 365">Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td data-bbox="735 421 1023 465">10</td> <td data-bbox="1023 421 1326 465">2 ml</td> <td data-bbox="1326 421 1409 465"><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	10	2 ml	<input type="checkbox"/>
Unidades	Quantidade	Emb. Hosp.					
10	2 ml	<input type="checkbox"/>					
<p>Impregnated dressing, implant, Intrauterine delivery system e transdermal system</p>	<p>Number of units Quantity – in white</p> <table border="1" data-bbox="735 539 1409 707"> <thead> <tr> <th data-bbox="735 539 1023 607">Unidades</th> <th data-bbox="1023 539 1326 607">Quantidade</th> <th data-bbox="1326 539 1409 607">Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td data-bbox="735 663 1023 707">10</td> <td data-bbox="1023 663 1326 707"></td> <td data-bbox="1326 663 1409 707"><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	10		<input type="checkbox"/>
Unidades	Quantidade	Emb. Hosp.					
10		<input type="checkbox"/>					
<p>Aerosols</p>	<p>Number o units Quantity – number of inhalations or, if unknown, volume of liquid (in case of solutions) <i>E.g.</i> Units 1 Quantity 200 doses</p> <table border="1" data-bbox="735 904 1409 1072"> <thead> <tr> <th data-bbox="735 904 1023 972">Unidades</th> <th data-bbox="1023 904 1326 972">Quantidade</th> <th data-bbox="1326 904 1409 972">Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td data-bbox="735 1028 1023 1072">1</td> <td data-bbox="1023 1028 1326 1072">200 dose(s)</td> <td data-bbox="1326 1028 1409 1072"><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	1	200 dose(s)	<input type="checkbox"/>
Unidades	Quantidade	Emb. Hosp.					
1	200 dose(s)	<input type="checkbox"/>					

<p>Powders for reconstitution (single-dose) - With reconstitution volume</p> <p>- Without reconstitution volume</p>	<p>Number of units Quantity –reconstitution volume./ solvent volume</p> <p><i>E.g.</i> Units 10 Quantity 2 ml</p> <table border="1"> <thead> <tr> <th>Unidades</th> <th>Quantidade</th> <th>Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="10"/></td> <td><input type="text" value="2"/> <input type="text" value="ml"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table> <p>Number of units Quantity – in whyte</p> <table border="1"> <thead> <tr> <th>Unidades</th> <th>Quantidade</th> <th>Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="10"/></td> <td><input type="text"/> <input type="text"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	<input type="text" value="10"/>	<input type="text" value="2"/> <input type="text" value="ml"/>	<input type="checkbox"/>	Unidades	Quantidade	Emb. Hosp.	<input type="text" value="10"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>
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Unidades	Quantidade	Emb. Hosp.											
<input type="text" value="10"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>											
<p>Powders for reconstitution (multi-dose) - With reconstitution volume</p> <p>- Without reconstitution volume</p>	<p>Number of units Quantity – reconstitution volume/ solvent volume</p> <p><i>E.g.</i> Units 1 Quantity 150 ml</p> <table border="1"> <thead> <tr> <th>Unidades</th> <th>Quantidade</th> <th>Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="1"/></td> <td><input type="text" value="150"/> <input type="text" value="ml"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table> <p>Number of units Quantity – in whyte</p> <table border="1"> <thead> <tr> <th>Unidades</th> <th>Quantidade</th> <th>Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="10"/></td> <td><input type="text"/> <input type="text" value="ml"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	<input type="text" value="1"/>	<input type="text" value="150"/> <input type="text" value="ml"/>	<input type="checkbox"/>	Unidades	Quantidade	Emb. Hosp.	<input type="text" value="10"/>	<input type="text"/> <input type="text" value="ml"/>	<input type="checkbox"/>
Unidades	Quantidade	Emb. Hosp.											
<input type="text" value="1"/>	<input type="text" value="150"/> <input type="text" value="ml"/>	<input type="checkbox"/>											
Unidades	Quantidade	Emb. Hosp.											
<input type="text" value="10"/>	<input type="text"/> <input type="text" value="ml"/>	<input type="checkbox"/>											
<p>Powders for reconstitution - With variable reconstitution volume</p> <p><i>E.g.:</i> variable volume of 6 ml</p>	<p>Number of units Quantity – in whyte</p> <table border="1"> <thead> <tr> <th>Unidades</th> <th>Quantidade</th> <th>Emb. Hosp.</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="10"/></td> <td><input type="text"/> <input type="text"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	Unidades	Quantidade	Emb. Hosp.	<input type="text" value="10"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>						
Unidades	Quantidade	Emb. Hosp.											
<input type="text" value="10"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>											

* Click “Adicionar” to finish.

APRESENTAÇÃO REQUERIDAS				
	Acondicionamento Primário	Unidades	Quantidade	Embalagem Hospitalar
<u>Apagar</u>	<u>Blister - PVC/Alu</u>	10		Emb. Não Hospitalar

* To cancel the insertion of the presentation click “Cancelar”.

* To remove the presentation click “Apagar”

V) StatusEstado/ Shelf-life/ Storage conditions / Storage temperature

ATTENTION: TO FILL IN THESE FIELDS YOU HAVE TO SELECT FIRST THE COORRESPONDING PRIMARY PACKAGING MATERIAL (THIS WILL SHOW IN VIOLET) CLICK ON THE TYPE OF PRIMARY PACKAGING (UNDERLINED IN THE MAIN WINDOW).

Package status (selection field)

Table content:

* The options are:

- a) *Aberta* (open) - Shelf life after first opening container
- b) *Fechada* (closed) - shelf-life (mandatory option).
- c) *Reconstituída* (reconstituted or diluted) – shelf-life after reconstitution or dilution.

Filling in: choose from the table

* For each package different package status may be described.

Shelf-life (numeric field /selection field)

Use:

* Shelf-life of the medicine according with the rules set out for the SPc.

Filling in:

* Write the numeric value of the shelf-life.

* In the second field choose from the list the temporal unit.

E.g.: shelf-life 3 years

Field number - 3

Time measure unit – years

Storage conditions

* Special recommendations for storage

Filling in:

* From the table according with the Note for guidance on declaration of storage conditions:

Não refrigerar (Do not refrigerate)
Não congelar (Do not freeze)
Conservar na embalagem de origem (Store in the original package)
Manter bem fechado (Keep tightly closed)
Manter dentro da embalagem exterior (Keep in the outer carton)
Não necessita de precauções especiais de conservação (This medicinal product does not require any special storage conditions)
Proteger da luz (Protect from light)
Proteger da humidade (Protect from moisture)
Não aplicável (Not applicable)
Outros (Other)

Temperature conditions (selection field)

Use:

* Storage temperature for the medicine.

Filling in:

* From the table according with the Note for guidance on declaration of storage conditions:

:

1) Conservar a temperatura inferior a 25°C (Store below 25°C)

- 2) Conservar a temperatura inferior a 30°C (Store below 30°C)
- 3) Conservar no frigorífico (2°C – 8°C) (Store in a refrigerator (2°C – 8°C))
- 4) Conservar no congelador (Store in a freezer)
- 5) Não necessita de precauções especiais de conservação (This medicinal product does not require any special storage conditions)
- 6) Outros (Other)

* In case of any other storage temperature choose “Outros”.

Click [Inserir](#) and fill in each and every field. Click “Adicionar” afterwards.

- **Several presentations can be added per medicine.**

ATTENTION: THE MAIN WINDOW SHOWS THE INFORMATION FOR THE PACKAGE SELECTED IN THE PRIMARY PACKAGING. IF YOU CHOOSE ANOTHER PRIMARY PACKAGING THE INFORMATION CHANGES SHOWING THE DATA FOR THE NEW PACKAGE SELECTED..

QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCES AND THE EXCIPIENTS

* Insert in this screen the qualitative and quantitative composition in terms of the active substance and excipients of the pharmaceutical form. It is possible to differentiate between the several pharmaceutical products that might exist within the same packaging.

* Insert the data for each pharmaceutical product according to the following instructions and repeat for other pharmaceutical products.

I) Pharmaceutical Product

Table content:

* "STANDARDS TERMS - Pharmaceutical dosage forms" - European Pharmacopoeia.

Filling in: choose from the table


* Whenever possible it should be inserted the same pharmaceutical form selected in the Marketing Authorization Application Particulars.

* When the medicine has a combined pharmaceutical form, the composition of each pharmaceutical product has to be inserted.

E.g.: powder and solvent for solution for injection should be separated into two pharmaceutical products - “powder for solution for injection” and “solvent for parenteral use”

Produto Farmacêutico			
		Forma Farmacêutica	
Apagar	Pó para solução injectável		
Apagar	Solvente/Veículo para uso parentérico		
Inserir			
Composição			
	Substância	Quantidade	Tipo de Ingrediente
Apagar	Água para preparações injectáveis	1 ml (q.b.p.)	Solvente / Veículo

Searching and filling in:
(selection field)

* Click the key [Inserir](#) and  afterwards. In the new window write the pharmaceutical form and click “Pesquisar”.

- * Select the pharmaceutical product from the list.
- * The pharmaceutical product is shown in the main window. Click “Adicionar”.

II) Substance


(selection field)

For each substance the following data must be added:: Substance, Amount (and number of units), Type of substance.

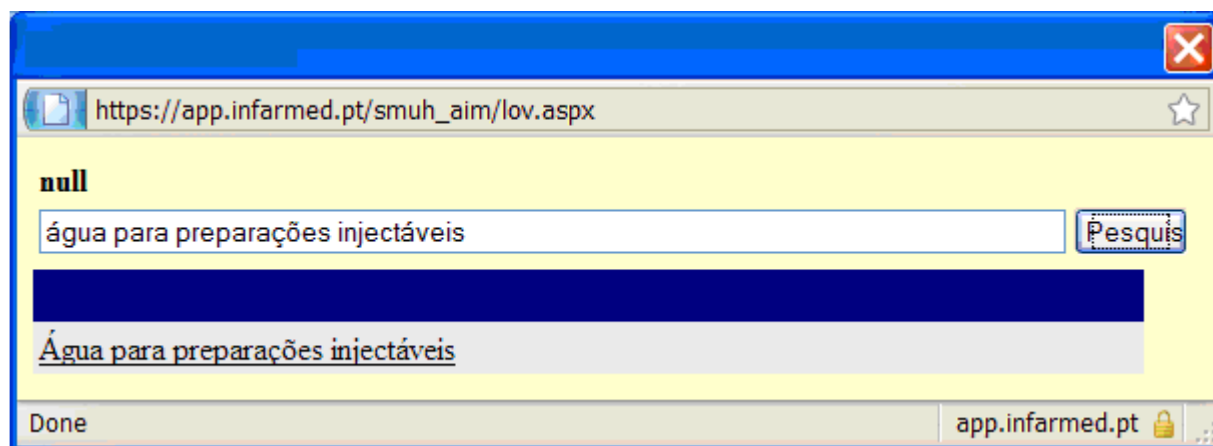
ATENÇÃO: TO FILL IN THE COMPOSITION THE MATCHING PHARMACEUTICAL PRODUCT MUST BE SELECTED FIRST (THIS WILL SHOW IN VIOLET). TO DO THIS CLICK ON THE PHARMACEUTICAL FORM..

ATENÇÃO: THE MAIN WINDOW SHOWS THE DATA FOR THE PHARMACEUTICAL FORM SELECTED. IF YOU CHOOSE ANOTHER PHARMACEUTICAL FORM THE INFORMATION CHANGES SHOWING THE DATA FOR THE NEW PHARMACEUTICAL FORM SELECTED.

Filling in: choose from the tale

- * Select the key [Inserir](#) and click  afterwards. In the new window write the name of the substance and click “Pesquisar”.

- * Select from the list the intended substance.



- * The substance is shown in the main window.

Note: search should be as equal as possible to the name of the substance.
E.g.: If you want to search for magnesium stearate, search for stearate.

III) Quantity and Units

(numeric field /selection field)

Use:

- * For inserting the quantity of the substance.
- * Select substances as they are present within the formula (e.g. salt or hydrate)
- * Choose **N.D** if the substance is not present in the final product (substances inserted with reagent in the Type of substance).
- * Overages are not to be mentioned in the formula.
- * For radionuclides the unit to be used is becquerel
- * In case of vaccines, active substances should be mentioned in biologic units.
- * For pH, if the value is mentioned, insert the number (e.g.: 3) and choose pH (q.b.p.)

* You should avoid using %

Filling in:

* In the field **Quantity**, write the numeric quantity of the substance (use dots and never commas).

* Do not place zeros after the last number (e.g. 10,02 mg instead of 10,020 mg)

* The field **Units** is a selection list

E.g.: Quantity of a given substance = 15,3 mg

Quantity – 15,3 (wright)

Quantity – 15.3 (incorrect)

Quantity – 15,30 (incorrect)

Units - mg

Units – mg

Units - mg

E.g.: Quantity of a given substance = q.b.p 1 ml

Quantity – 1

Units – ml (q.b.p.)

Filling in the field Composition according to the pharmaceutical forms

	Composição
Single-dose solid pharmaceutical forms Capsule, Tablet, Lozenge, Cachet; Suppository (blister; strip; Sachet; Tablet container etc.)	Substance quantity – mass 20 mg
Multi-dose solid pharmaceutical forms Granules (in bottle)	Substance concentration – mass/total mass 50 mg/g
Single-dose liquid pharmaceutical forms Eye drops, solution, solution for injection, oral solution (ampoule, sachet, vial)	Substance concentration– mass/total volume 5 mg/ml
Multi-dose liquid pharmaceutical forms Syrup, Oral solution, eye drops, solution (in bottle)	Substance concentration – mass/total volume 500 mg/ml
Single-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (cannula, tube)	Substance concentration – mass/total mass 5 mg/g
Multi-dose semi-solid pharmaceutical forms Cream, paste, ointment, gel (cannula, tube)	Substance concentration– mass/total mass 50 mg/g
Concentrates Concentrate for solution for injection	Substance concentration <u>before</u> dilution – mg/ml 20 mg/ml
Impregnated dressing, implanter, Intrauterine delivery system and Transdermal system	<u>Preferred</u> -> substance quantity in each dressing – mass 50 mg
Aerosol	<u>Preferred</u> -> Follow the rules for the pharmaceutical form as if it weren't for inalation (e.g.: powder or solution for inhalation – mass 250 µg

Powders for reconstitution

Includes also powders and solvents. In this last case two lines will have to be inserted: one for the powder composition and the other for the solvent composition.

Powder – quantity of each substance inside the primary packaging (as for sachets)

Solvent – quantity of each substance in the primary packaging; the solvent is inserted as “q.b.p. x ml” (qs x ml) (reconstitution volume).

Single-dose powders for reconstitution - With reconstitution volume - Without reconstitution volume	Active substance concentration – mass : total volume Powder - 500 mg Solvent - 10 ml = total volume Active substance quantity - mass Powder – mg
Pós para reconstituição (multidose) - With reconstitution volume - Without reconstitution volume	Active substance concentration – mass : total volume 5 mg Active substance concentration – mass/mass 50 mg/g

IV) Type of substance

(selection field)

Use:

* Function of the formula components (substances):

- Active substances; excipients and coating components (e.g.: capsules)
Filling gases used in ampoules, aerosol propellants and others.

* For medicines radio-marked after supplying (kits), the active substance is the one that will be marked or will transport the radionuclide.

* For generators, the active substances are the original radionuclides and its degradation products.

Filling in: choose from the table

* The criteria to be used are:

- Activo (Active substance)
- Excipiente (Excipient)
- Revestimento (coating)
- Solvente (solvent)
- Reagente (reagent) – when the substance is not present in the final product
- Propelente (propellant)

Fill in the data for each substance and the click “Adicionar”.

MANUFACTURING CHAIN

The name, telephone, fax and e-mail of the contact person are mandatory.

General concepts:

* For every medicine the data about the manufactures must include: **Fabricante do produto a granel** (bulk manufacturer), **fabricante de Acondicionamento Primário** (primary packaging manufacturer), **fabricante de Acondicionamento Secundário** (secondary packaging manufacturer), **Fabricante da Substância Activa** (manufacturer of the active substance), **Responsável pela Libertação de Lote** (Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA) and **Local de Libertação do Lote** (batch control/testing site).

* When the same manufacturer is responsible for more than one step, the name of the manufacturer should be repeated for each function.

* One medicine may have more than one manufacturer for each manufacturing step. Each and every manufacturer should be inserted.



I) Type of manufacturer

Table content and instructions for use:

Content	When to use
Fabricante de fase intermédia (Intermediate step manufacturer)	Manufacturer of an intermediate step of the bulk product. Choose a manufacturer address - (Fab. xxxxx) after the name.
Fabricante do produto a granel (Bulk manufacturer)	Bulk manufacturer Choose a manufacturer address - (Fab. xxxxx) after the name.
Acondicionamento primário (Primary packaging)	Primary packaging manufacturer. Fill in also the bulk manufacturer and the secondary packaging manufacturer. Choose a manufacturer address - (Fab. xxxxx) after the name..
Acondicionamento secundário (Secondary packaging)	Secondary packaging manufacturer. Fill in also the bulk manufacturer and the primary packaging manufacturer. Choose a manufacturer address - (Fab. xxxxx) after the name.
Responsável pela libertação de lote (Responsible for batch release)	Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA . Choose a manufacturer address - (Fab. xxxxx) after the name. Mandatory
Local de libertação De lote (Batch control/testing site)	Site(s) in the EEA or in countries where an MRA or other Community arrangements apply, where batch control testing takes place. Choose a manufacturer address - (Fab. xxxxx) after the name Mandatory
Fabricante da substância activa (Active substance manufacturer)	Manufacturer of the active substance Mandatory Insert in “Substancia Fabricada” the substance manufactured. The options in this selection field are the active substances previously identified in the medicine composition. Choose a manufacturer address - (Fab. xxxxx) after the name
Fabricante de fase intermédia de substância activa (manufacturer of the active substance - intermediate step)	For manufacturers of intermediate steps of the active substance. Choose a manufacturer address - (Fab. xxxxx) after the name .
Empresa contratada para ensaios de biodisponibilidade ou bioequivalência (Contract company used for bioavailability or bioequivalence trials)	Whenever applicable insert: sponsor, responsible for the clinical phase, responsible for the analytical phase.

Content	When to use
Empresa contratada para a validação de derivados de sangue/vacinas (Contract company used for validation of blood product/vaccine manufacturing)	Whenever applicable.

Searching and filling in:
(selection field)



- * Select the key  and  afterwards. In the new window write the type of manufacturer and click “Pesquisar”.
- * Select from the list the type of manufacturer.
- * The type of manufacturer is shown in the main window.

II) Manufacturer (name and address)

Use:

- * Name of the manufacturer responsible for type of manufacturing previously indicated.

Searching and filling in:
(selection field)

- * Select the key  (if the type of manufacturer hasn't been inserted yet) and click  afterwards. In the new window write the name of the manufacturer and click “Pesquisar”.
- * Select the manufacturer from the list (manufacturer addresses have fab between parentheses).
- * The manufacturer is shown in the main window. Click “Adicionar”.

Note: search should be as exact as possible.

e.g.: if a manufacturer has Laboratory in the name do not use Lab.

Whenever an address concerns a manufacturer and there is the same name and address in two different options, choose the one with (Fab. xxxxx) after the name.


Note:

- * Always check if the name/address is the one intended. There may be very similar names/addresses in the list.

III) MAA holder

(Selection field)

Do not choose addresses containing (Fab. xxxxx) after the name, as these concern premises addresses.

- * Click the key . In the new window write the name of the MAA holder and click “Pesquisar”.
- * Select from the list the MAA.
- * The MAA is shown in the main window.

STATEMENT REGARDING RISK OF TRANSMISSION OF SPONGIFORM ENCEPHALOPATHIES

(selection field)

* Used to identify the annex in which the medicine is as regards the risk of transmission of spongiform encephalopathies.

Table content:

* The options are

Anexo 1

Anexo 2

Anexo 3

Raw material	Documents	Annex
With risk	with TSE_CertiPhEur	1
	one substance with TSE_CertiPhEur	2
without risk		3

A medicine is classified in annex 3 when either its composition, manufacturing of excipients, manufacturing of active substances, reagents and culture media do not have any risk material.

When there are risk materials in either composition, manufacturing of excipients, manufacturing of active substances, reagents and culture media:

1) If there is at least one risk material without a certificate of the European Pharmacopoeia, the annex 2 is applicable.

2) If all risk materials have a certificate of the European Pharmacopoeia, annex 1 is applicable

ATTACH MODULE 1.3.)

* The SPC, PL and Labeling should be attached to the application form on the section "Documentos". Click on the button [Insertir](#), then in "Browse". Select the document related to SPC, PL or Labelling as in the left selection list. It will appear the URL pathway for the file. Finally, click in "Adicionar" and the file will be attached.

It should be used Word files (maximum 500 Kb). If the file you need to attach is bigger than 500 Kb, please Zip the file in advance.

DELETE REQUEST

This tool allows you to delete the MA application, you have previously inserted. The sentence "*Tem a certeza que pretende apagar o registo?*" will be shown, warning you that the MA application will be removed from the system.

Be aware that once you delete the request, there is no turning back.

After, payment validation, you can't delete your MA application.

MAKING CHANGES TO THE MA APPLICATION ALREADY INTRODUCED

In case, you need to change a MA request already introduced in the system, you should access your area, where you can see the summary of all your previously submitted MA applications and click in the name of the medicinal product. It will be displayed the application form, which will allow you to make changes/corrections.

After, payment validation, you can't change your MA application.

SUBMIT MA APPLICATION

Finish filling out the application form

* Once you finish filling out the application form, select **Gravar**. It will be displayed a application form summary.

* In case, you made any mistake while you are filling out the form, you may click on “Rectificar” and made the amendments you need.

* If you want to keep a record of your application, you may click on “Imprimir”.

* You can save your application while you are filling the form. If you need to access to a MA application, you didn't finish yet, you should access your area and search for the name of the medicinal product.

While you are filling out your application form, the application status (“estado”) will be shown as “Em preenchimento”.

The application form can be saved and changed until the generation of the “nota de pagamento” (payment validation). Once, “nota de pagamento” is generated, you can't make further amendments.

Generating “nota de pagamento” (payment form) for new submissions

* Search the medicinal product in search screen.

* Below the column “Seleccionar”, select the verification boxes of the medicinal products that belong the same MA application.

NOTE: the points concerning the additional strenghts/pharmaceutical forms it will only be included in the “nota de pagamento” if you select all the medicinal products included in the same MA application as it is described below.

* Click **Gerar Nota Pagamento** in order to generate “nota de pagamento”.

Once you generate “nota de pagamento” the MA application status will change from “Em preenchimento” to **“Confirmar pagamento”**

Generating “nota de pagamento” (payment form) for applications of new strengths or pharmaceutical forms submitted afterwards

* Proceed firstly as mentioned in “Generating “nota de pagamento” for mew submissions”

* In the next window click on the name of the medicine (MAA) that is under assessment

Note: the new application and the MAA under assessment must have the same medicine name

* Click “nota pagamento”

Fee payment

The fee payment can be done at INFARMED's treasure house or by bank tranfer.

PAYMENT AT INFARMED'S TREASURE HOUSE

* Fill out the payment voucher (“guia de pagamento”) and add “nota de pagamento”

* Go to INFARMED's treasure house, and proceed the payment .

The INFARMED's treasure house will confirm the payment. The MA application status will change to "Pagamento validado".

From this moment on, the MA dossier can be delivered at INFARMED.

PAYMENT BY BANK TRANSFER

* The number of "nota de pagamento" should be identified in bank transfer

* Access "pré-submissão electrónica" of MA applications

* Search the MA application and select the option "**Confirmar pagamento**"

* Type the NIB, the cash value, date of payment and the reference number of the "data de pagamento".

The screen should show in "Total" the full amount of the fee for the application (sum of the fees for all strengths and pharmaceutical forms).

* Click "Confirmar pagamento"

The MA application status change for "**Validar pagamento**".

This procedure is made only once in one of the strengths of the MAA.

INFARMED, I.P. will confirm the payment within 3 working days by email. This email will be send to the contact person as it is stated in application form. After that, the MA application status become "**Pagamento validado/invalidado**".

Once the status become "Pagamento validado", wich will happen when the email is send, the MA application dossier can be delivered at INFARMED.