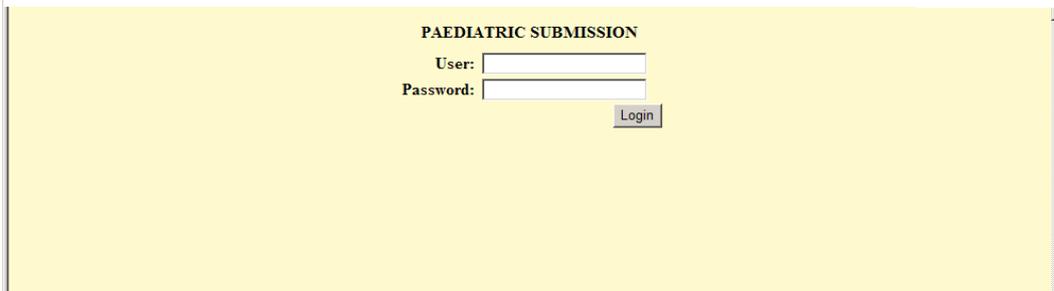


## Paediatric Submission Tool

### *Instructions for use*

- 1- You need to Login into the Paediatric Submission Tool by using the Password and Username that was sent to you by INFARMED.



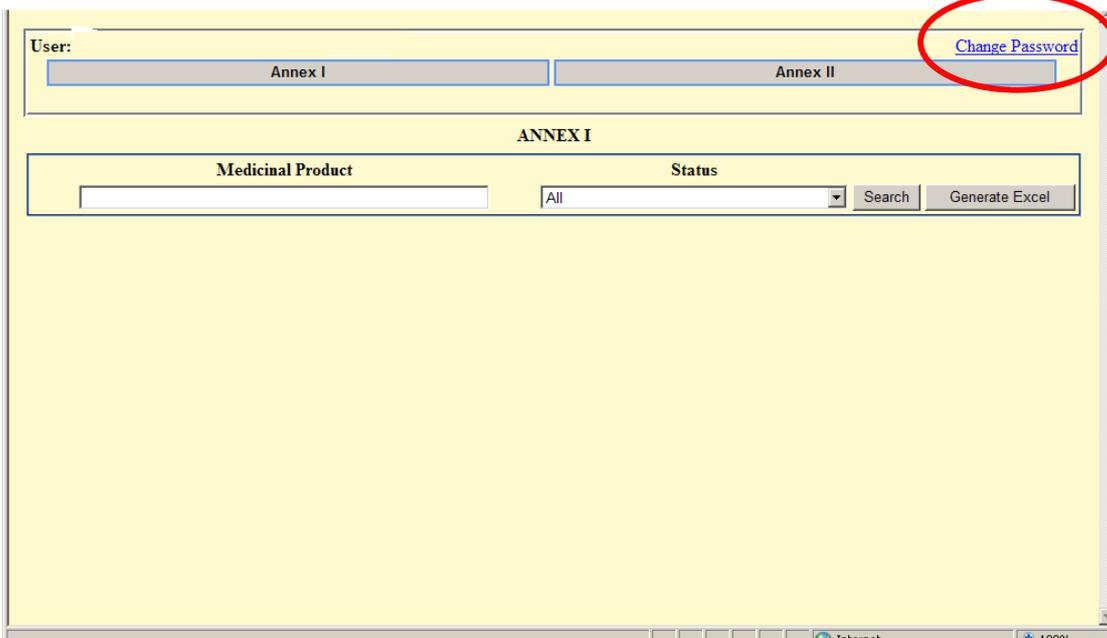
PAEDIATRIC SUBMISSION

User:

Password:

Login

- 2- The first time you access the Paediatric Submission Tool, it is advised that you change your Password ( button on the Upper Right Handside)



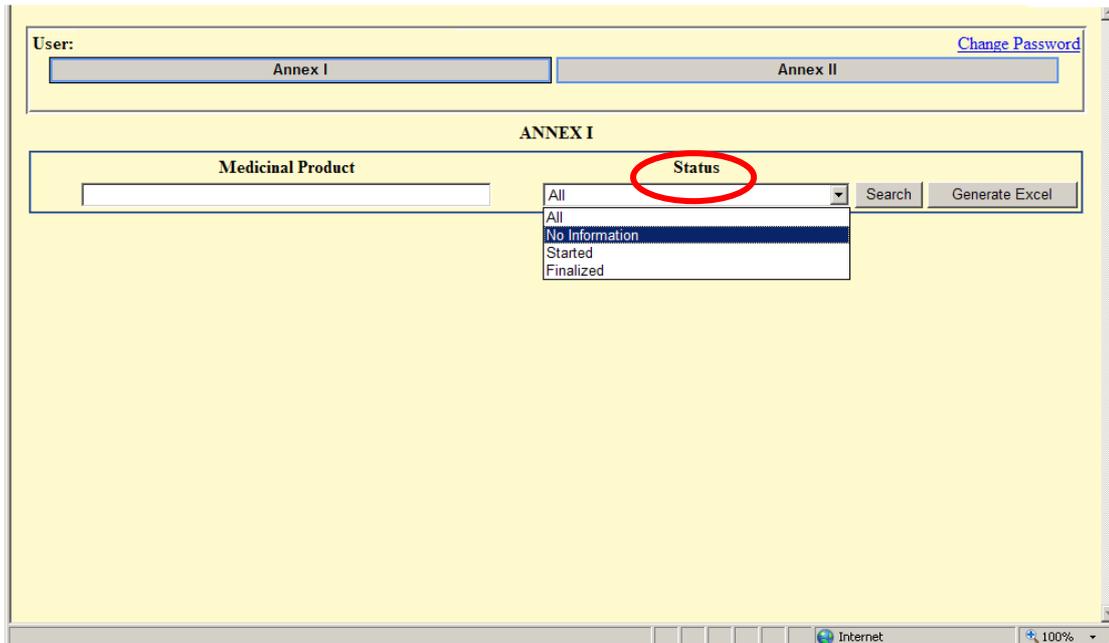
User:  [Change Password](#)

Annex I  Annex II

ANNEX I

Medicinal Product  Status  Search

- 3- By default, the starting screen is for completion of the Line listing.
- 4- In the Status dialog box, several possibilities exist :



- **All** : lists all your medicinal products, regardless of having or not already some information inserted.
- **No Information** : lists those medicinal products for which you have not inserted any information yet.
- **Started**: list those medicinal products for which some information has already been filled in, but that you still want to add some more .
- **Finalized** : lists the medicinal products for which you have already inserted all the relevant information.

This Status dialog box allows you, at any moment, to have a list of all your medicinal products according to the status of completion of the information.

- 5- When you are starting the application, choose the option **All** from the Status, and click on the Search button next to it. You will obtain a list of all the medicinal products for which you are the marketing authorisation holder

The screenshot shows the application interface with a table of medicinal products. The table has the following columns: Medicinal Product, Pharmaceutical Form, Strength, Authorization Number, and Status. The 'Status' column for all products is 'No Information', which is circled in red.

Medicinal Product	Pharmaceutical Form	Strength	Authorization Number	Status
Test 1	Capsule, hard	100 mg	MRP XYZ	No Information
Test 2	Syrup	3 mg/ml	Nat 123	No Information

The Status, for all the products on this initial list will appear as **No Information**

- 6- In order to insert the relevant information, you need to edit the information on each medicinal product.
- When you click on the name of one medicinal product, the fields to be completed appear on the lower part of the screen:

User:   [Change Password](#)

**ANNEX I**

Medicinal Product:  Status:  Search

Medicinal Product	Pharmaceutical Form	Strength	Authorization Number	Status
Test 1	Capsule, hard	100 mg	MRP XYZ	No Information
Test 2	Syrup	3 mg/ml	Nat 123	No Information

Paediatric Use:

Studies already submitted if yes provide a declaration:  Yes  No

Studies not yet submitted if yes complete the next 2 fields below:  Yes  No

Finalized:

Study Title:

Study Number:

7- You can either choose to fill the complete information in one session or more. If you have filled in some information but want to come back later to complete it, you can click on the Save button (line blue, in the picture above). The status of this medicinal product will then be **Started**.

Whenever you want to add the rest of the remaining information to this medicinal product, you search for medicinal products with the **Started** Status.

8- The instructions to complete these forms are exactly the same as to complete the paper versions.

9- When all the relevant information has been completed, you have to put a tick in the Finalized box, and Save the information

Paediatric Use:

Studies already submitted if yes provide a declaration:  Yes  No

Studies not yet submitted if yes complete the next 2 fields below:  Yes  No

Finalized:

Study Title:

Study Number:

10- In order to generate the Excel file, the Status for **all the medicinal products** will have to be **Finalized**.

11- First, check if all your medicinal products have the Status as **Finalized**.

Then, click on the "Generate Excel" button

User:   [Change Password](#)

**ANNEX I**

Medicinal Product:  Status:  Search

Medicinal Product	Pharmaceutical Form	Strength	Authorization Number	Status
Test 1	Capsule, hard	250 mg	MRP XYZ	Finalized
Test 2	Capsule, hard	100 mg	Nat 123	Finalized
	Syrup	3 mg/ml		Finalized
	Film-coated tablet	1 mg		Finalized
	Film-coated tablet	70 mg		Finalized
	Tablet	70 mg		Finalized

12- You need to save the resulting Excel generated (Line listing) into your computer

13- Regarding Annex II, the procedure is very much the same. When you enter the Paediatric Submission Tool, you must click on the Annex II button

User:   [Change Password](#)

**ANNEX I**

Medicinal Product:  Status:  Search

User:   [Change Password](#)

**ANNEX II**

Medicinal Product:  Status:  Search

Medicinal Product	Pharmaceutical Form	Strength	Authorization Number	Status
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14- When you then click on any of the medicinal products listed, the following fields will appear at the bottom of the screen:

SPC-Wording 4.1

SPC-Wording 4.2

Specific age groups (neonate, infant, child, adolescent)

From [years]  To [years]

Finalized

15- The Status attributed to each medicinal product is the same as for the line listing (please see number 4), as well as the Finalization and generation of the Excel file (please see number 9 and 11).

16- You need to save the resulting Excel file generated for the Line listing, together with the Annex I (Declaration), and eventually, and with the Excel file generated for the Annex II.

17- The resulting Excel files generated (Line listing and Annex II), together with the Annex I (Declaration), will be attached to the email that must be sent to the EMEA and INFARMED I.P.

**If you need any further information, please contact:  
Paediatric.studies@infarmed.pt**