



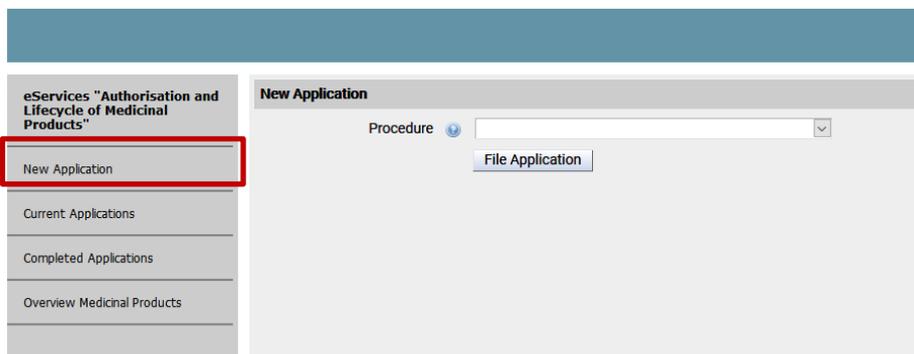
# User-Manual Application for a certificate

## 1. REQUEST A CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP)

To apply for a Certificate of a Pharmaceutical Product (CPP), select the relevant application in the "Procedure" field in the "New Application" area and start with "File Application"

The following applications may be submitted:

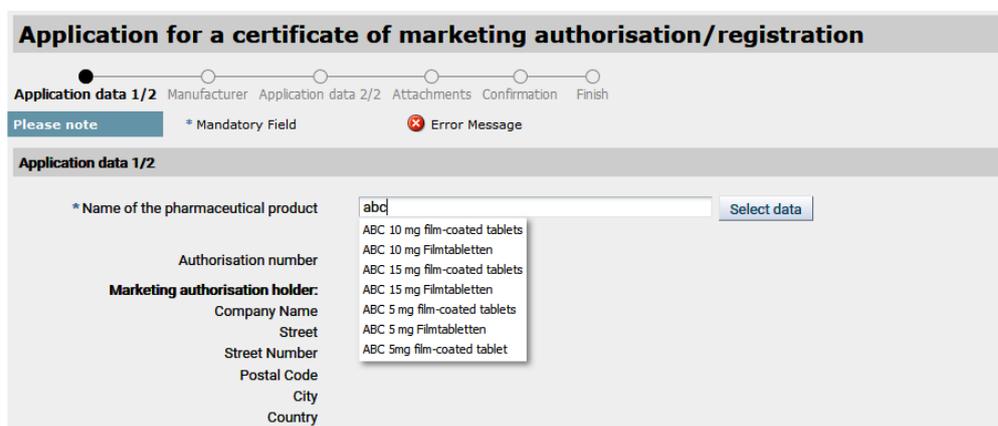
- Application for a certificate of marketing authorisation/registration
- Application for a certificate of the manufacture



### 1.1 CERTIFICATE FOR A MARKETING AUTHORISATION/REGISTRATION

On **page 1**, you have to select the medicinal product. The selection is restricted to the medicinal products that are listed in your "Overview Medicinal products". Is a product missing, please contact [cpp@basg.gv.at](mailto:cpp@basg.gv.at).

Please enter the name of the medicinal product in the search field. Select the medicinal product and click on "Select data" to fill in the fields marketing authorisation number and MAH incl. address.



Select the importing country from the catalogue and fill in the marketing and manufacturer data.

If the medicinal product is not marketed, please indicate the reason in the comments box on page 3.

The selection for manufacturer corresponds to categories a-e in form F\_M64.

* Importing Country	<input type="text"/>
* Is the medicinal product actually on the market in Austria?	<input type="radio"/> Yes <input type="radio"/> No
* Manufacturer	<input type="radio"/> The authorisation holder is the manufacturer of the dosage form. <input type="radio"/> The marketing authorisation holder is only involved in labelling and/or packaging. <input type="radio"/> The marketing authorisation holder is not involved in manufacture of the dosage form/labelling and/or packaging. <input type="radio"/> The marketing authorisation holder is manufacturer of the dosage form and further manufacturing sites for the finished dosage form may be involve. <input type="radio"/> The marketing authorisation holder is involved in manufacturing of the dosage form together with further manufacturing site.

Information on delivery is then required.

If "Other recipient" is selected, the data fields can be filled in, otherwise they are pre-filled or hidden for "Self pickup".

<b>Delivery</b>	
* Number of copies	<input type="text" value="1"/>
* Delivery should be sent to	<input type="radio"/> Marketing authorisation holder <input checked="" type="radio"/> Applicant <input type="radio"/> Self pickup <input type="radio"/> Other recipient
* Company Name	<input type="text" value="Q2-Testfirma"/>
* Street	<input type="text" value="Traisengasse"/>
* Street Number	<input type="text" value="5"/>
* Postal Code	<input type="text" value="1200"/>
* City	<input type="text" value="Wien"/>
* Country	<input type="text" value="Republic of Austria"/>

Please enter an invoice recipient and add the Purchase order number (PO-Nr.) if necessary.

If you select "Enter different invoice recipient" the data fields cab be filled in, otherwise they are pre-filled.

<b>Invoice Recipient</b>		
	<input checked="" type="radio"/> Applicant is invoice recipient <input type="radio"/> Enter different invoice recipient	
* Company Name	<input type="text" value="Q2-Testfirma"/>	
* Street	<input type="text" value="Traisengasse"/>	
* Street Number	<input type="text" value="5"/>	
* Postal Code	<input type="text" value="1200"/>	
* City	<input type="text" value="Wien"/>	
* Country	<input type="text" value="Republic of Austria"/>	
<b>Purchase order number (PO-Nr.)</b>		
Purchase order number (PO-Nr.)	<input type="text"/>	
<input type="button" value="Back"/>	<input type="button" value="Next"/>	<input type="button" value="Cancel"/>

On **page 2**, information on the manufacturer (name and address, as well as manufacturing activity in the filed Category" must be provide.

With the plus sign at the right margin further input blocks can be created, the minus sign deletes the blocks.

If on page 1, the 1<sup>st</sup> option (The authorisation holder is the manufacturer of the dosage form.) in the manufacturer section is selected, the data from the marketing authorisation/registration holder are pre-filled and only have to be completed with the manufacturing activity.

The screenshot shows the 'Manufacturer' section of the application form. At the top, a progress bar indicates the current step is 'Manufacturer'. Below the progress bar, there are instructions: 'Please note' with a blue background, '\* Mandatory Field' with a red asterisk, and 'Error Message' with a red 'x' icon. The form contains two identical 'Manufacturer' input blocks. The first block is empty, while the second block is pre-filled with the following data: Company Name: Q2-Testfirma, Street: Traisengasse, Street Number: 5a, Postal Code: 1200, City: Wien, Country: Republic of Austria, and Category: Processing of non-sterile mex. At the bottom of the form, there are three buttons: 'Back', 'Next', and 'Cancel'.

On **page 3**, indicate whether module 3.2.P.3.1 is already applicable at BASG in eCTD format, and if so, enter the sequence number containing the module. If no, module 3.2.P.3.1. is mandatory to upload on page 4.

Please indicate with part of the composition should be stated in the CPP and whether additional information will be uploaded in a cover letter on page 4.

Further comments for the processing of your application are optional.

The screenshot shows the 'Application data 2/2' section of the application form. At the top, a progress bar indicates the current step is 'Application data 2/2'. Below the progress bar, there are instructions: 'Please note' with a blue background, '\* Mandatory Field' with a red asterisk, and 'Error Message' with a red 'x' icon. The form contains the following fields: '\* Module 3.2.P.3.1 is available in eCTD format' with radio buttons for 'Yes' (selected) and 'No'; '\* Sequence number' with a text input field containing '0023'; '\* In the CPP should be stated' with radio buttons for 'Only the active substances' and 'The active substances and the excipients'; '\* Additional information about the medicinal product is included' with radio buttons for 'Yes' (selected) and 'No'; and 'Comments' with a text area containing 'enter text here'. At the bottom of the form, there are three buttons: 'Back', 'Next', and 'Cancel'.

On **page 4** supplementary documents can be uploaded to the application.

### Application for a certificate of marketing authorisation/registration

Application data 1/2   Manufacturer   Application data 2/2   **Attachments**   Confirmation   Finish

Please note   \* Mandatory Field   Error Message

#### Attachments

\* Document type:

\* File:  Keine Datei ausgewählt.

Comment:

Document type	File name	Comment	
Module 3.2.P. 1	M32P31.pdf		
Cover letter	Cover letter.pdf	please find additional information in the CL	
SmPC	SMPC.pdf	final common SmPC (IA/001)	
SmPC (national translation)	Fachinformation in EN.pdf	translated Fachinformation for attachment to CPP	

**Page 5** (Confirmation) is for your overview. Please note that you must confirm the accuracy and completeness of the information before the application can be sent.

I confirm the accuracy and completeness of the information.

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**Page 6** (Finish page) contains the procedure number, which you can use to find your application in the "Ongoing Application" section.

### Application for a certificate of marketing authorisation/registration

#### Finish

Your application for a certificate of marketing authorisation/registration has successfully been submitted. You will receive an email confirmation.

Procedure number 100025241

## 1.2 CERTIFICATE FOR MANUFACTURING

On **page 1**, you have to fill in the medicinal product name. Select the importing country from the catalogue and fill in the marketing and manufacturer data.

*The selection for manufacturer corresponds to categories a-e in form F\_M64.*

The screenshot shows a web form titled "Application for a certificate of the manufacture". At the top, there is a progress bar with five steps: "Application data 1/2" (active), "Manufacturer", "Application data 2/2", "Attachments", "Confirmation", and "Finish". Below the progress bar, there are two notes: "Please note" and "Mandatory Field" (with a red asterisk), and "ErrorMessage" (with a red error icon). The main form area is titled "Application data 1/2" and contains the following fields:

- \* Name of the pharmaceutical product: Text input field containing "Test tablet".
- \* Importing Country: Dropdown menu showing "Ukraine".
- \* Manufacturer: Radio button options:
  - The applicant is the manufacturer of the dosage form.
  - The applicant is only involved in labelling and/or packaging.
  - The applicant is not involved in manufacture of the dosage form/labelling and/or packaging.
  - The applicant is manufacturer of the dosage form and further manufacturing sites for the finished dosage form may be involve.
  - The applicant is involved in manufacturing of the dosage form together with further manufacturing site.

Information on delivery is then required.

If "Other recipient" is selected, the data fields can be filled in, otherwise they are pre-filled or hidden for "Self pickup".

The screenshot shows a web form titled "Delivery". It contains the following fields:

- \* Number of copies: Text input field containing "1".
- \* Delivery should be sent to: Radio button options:
  - Marketing authorisation holder
  - Applicant
  - Self pickup
  - Other recipient
- \* Company Name: Text input field containing "Q2-Testfirma".
- \* Street: Text input field containing "Traisengasse".
- \* Street Number: Text input field containing "5".
- \* Postal Code: Text input field containing "1200".
- \* City: Text input field containing "Wien".
- \* Country: Dropdown menu showing "Republic of Austria".

Please enter an invoice recipient and add the Purchase order number (PO-Nr.) if necessary.

If you select "Enter different invoice recipient" the data fields cab be filled in, otherwise they are pre-filled.

The screenshot shows a web form titled "Invoice Recipient". It contains the following fields:

- Radio button options:
  - Applicant is invoice recipient
  - Enter different invoice recipient
- \* Company Name: Text input field containing "Q2-Testfirma".
- \* Street: Text input field containing "Traisengasse".
- \* Street Number: Text input field containing "5".
- \* Postal Code: Text input field containing "1200".
- \* City: Text input field containing "Wien".
- \* Country: Dropdown menu showing "Republic of Austria".

Below the form, there is a section titled "Purchase order number (PO-Nr.)" with a text input field. At the bottom, there are three buttons: "Back", "Next", and "Cancel".

On **page 2**, information on the manufacturer (name and address, as well as manufacturing activity in the filed Category" must be provide.

With the plus sign at the right margin further input blocks can be created, the minus sign deletes the blocks.

**Application for a certificate of the manufacture**

Application data 1/2 **Manufacturer** Application data 2/2 Attachments Confirmation Finish

Please note \* Mandatory Field Error Message

**Manufacturer**

Company Name  
Street  
Street Number  
Postal Code  
City  
Country  
Category

Back Next Cancel

On **page 3** indicate whether additional information will be uploaded in a cover letter on page 4.

Further comments for the processing of your application are optional.

**Application for a certificate of the manufacture**

Application data 1/2 Manufacturer **Application data 2/2** Attachments Confirmation Finish

Please note \* Mandatory Field Error Message

**Application data 2/2**

\* Additional information about the medicinal product is included  Yes  No

Comments  
Comments on CPP

Back Next Cancel

On **page 4** supplementary documents can be uploaded to the application. Please note, that a composition and a proof of manufacturer (similar to module 3.2.P.3.1) is required

**Application for a certificate of the manufacture**

Application data 1/2 Manufacturer Application data 2/2 **Attachments** Confirmation Finish

Please note \* Mandatory Field Error Message

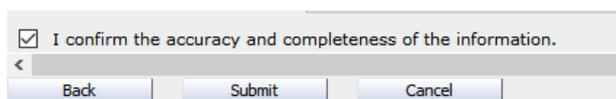
**Attachments**

\* Document type  
\* File  Keine Datei ausgewählt.  
Comment  
Add document

Document list  
Document type File name Comment  
No data available

Back Next Cancel

**Page 5** (Confirmation) is for your overview. Please note that you must confirm the accuracy and completeness of the information before the application can be sent.



A confirmation dialog box with a checked checkbox and the text "I confirm the accuracy and completeness of the information." Below the text is a left-pointing arrow. At the bottom are three buttons: "Back", "Submit", and "Cancel".

**Page 6** (Finish page) contains the procedure number, which you can use to find your application in the "Ongoing Application" section.



A "Finish" page titled "Application for a certificate of the manufacture". The text reads: "Your application for a certificate of marketing authorisation/registration has successfully been submitted. You will receive an email confirmation. Procedure number 100025248". At the bottom are three buttons: "Back", "Close", and "Cancel".

## 2. Application with application form

During the transition period, it is still possible to submit an application using the application form.

- Please send only one application per e-mail.
- Only use the application form below. (Can be found on the CPP official confirmation homepage).
- Any side information (e.g. which documents should be attached to the CPP, that the CPP will be picked up in person, etc.) is only to be written in the section provided for this purpose on the application form (comments). Do not send this information by e-mail.
- Please send all documents (application form, annexes to the CPP and, if applicable, information on the manufacturer) in one document.