Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

BASG/BBSG
Traisengasse 5, 1200 Wien

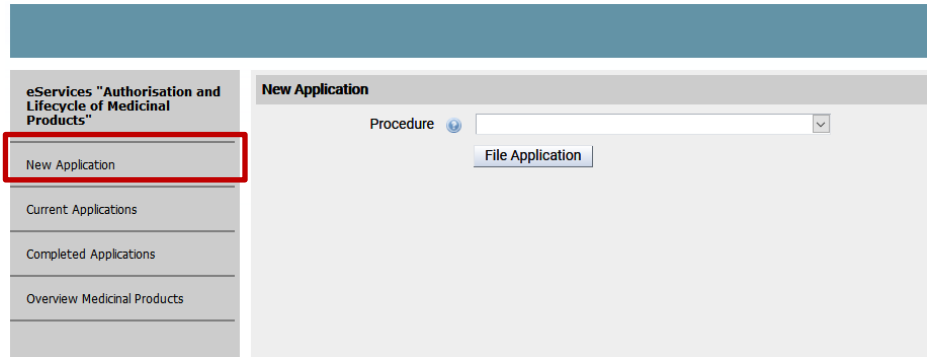
User-Manual Application for a certificate

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:

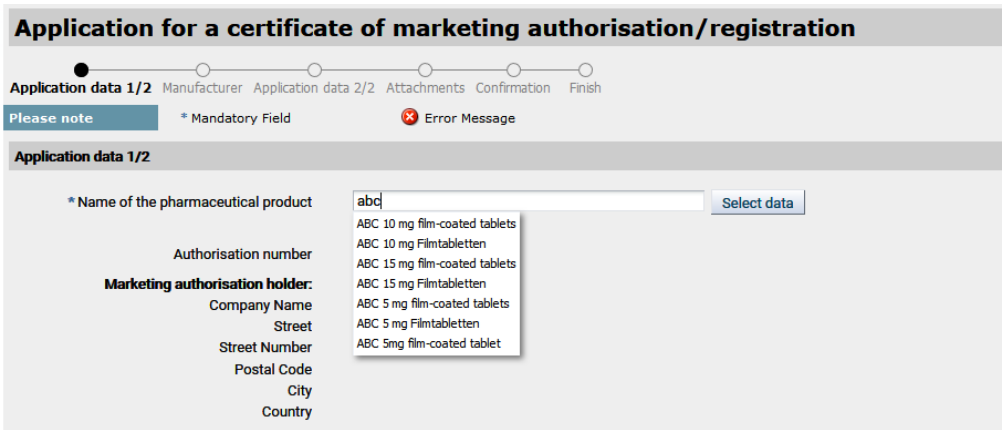
- Application for a certificate of marketing authorisation/registration
- Application for a certificate of the manufacture



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.

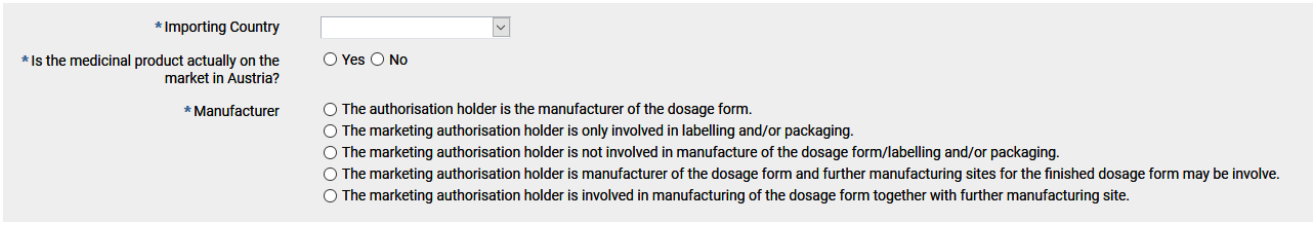
Please enter the name of the medicinal product in the search field. Select the medicinal product and click on "Select data" to fill in the fields marketing authorisation number and MAH incl. address.



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

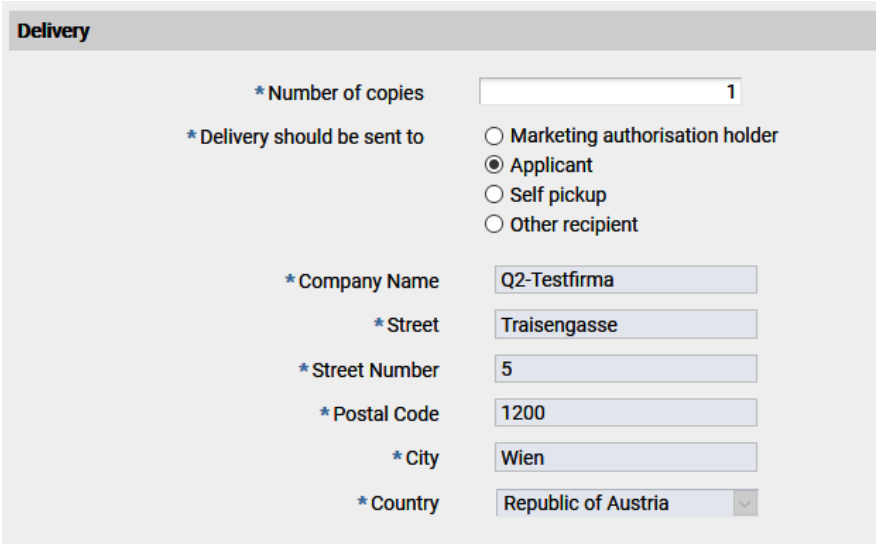
If the medicinal product is not marketed, please indicate the reason in the comments box on page 3.

The selection for manufacturer corresponds to categories a-e in form F_M64.



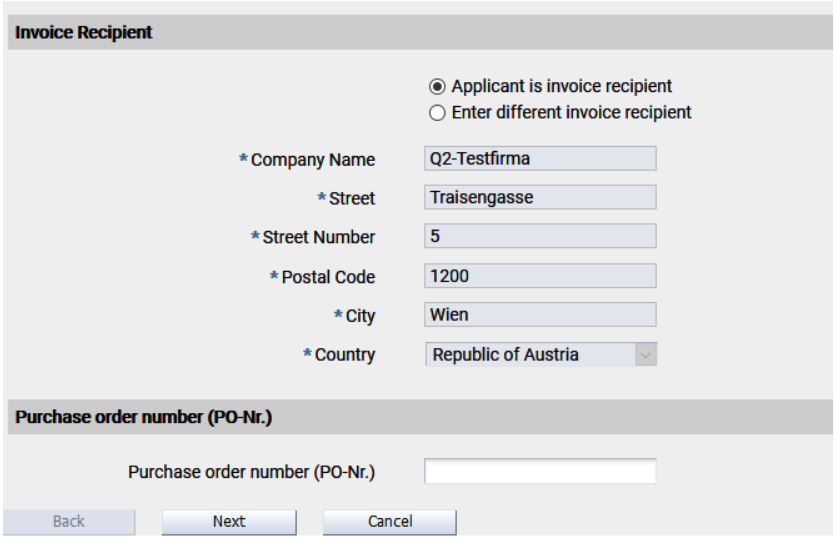
Information on delivery is then required.

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



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

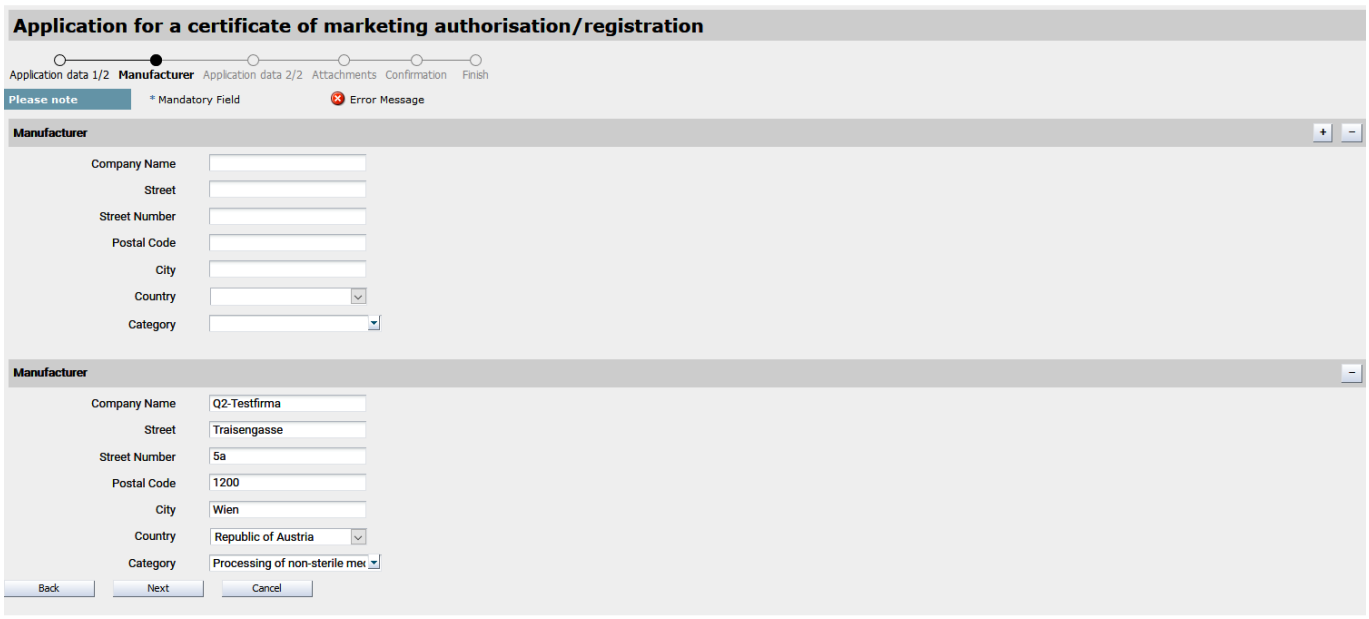
If you select "Enter different invoice recipient" the data fields cab be filled in, otherwise they are pre-filled.



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.

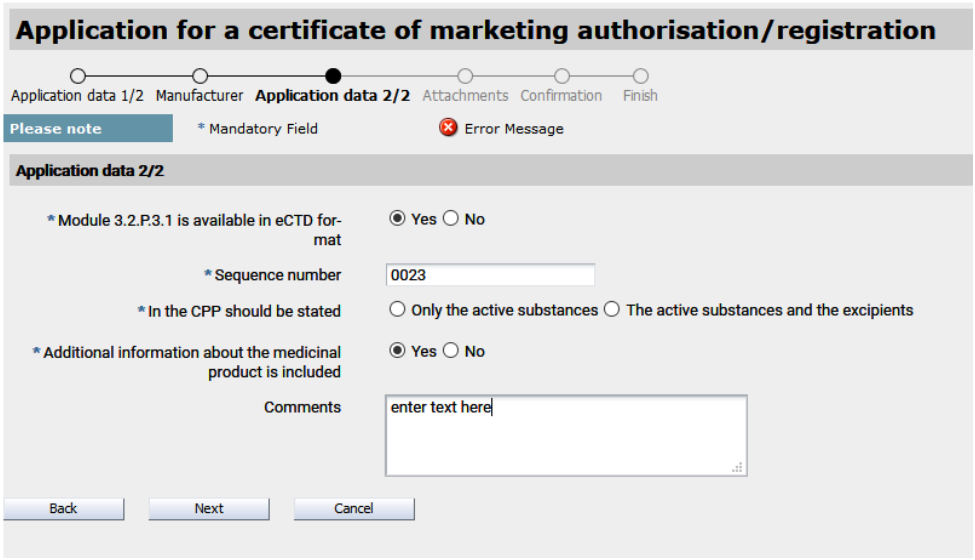
If on page 1, the 1st option (The authorisation holder is the manufacturer of the dosage form.) in the manufacturer section is selected, the data from the marketing authorisation/registration holder are pre-filled and only have to be completed with the manufacturing activity.



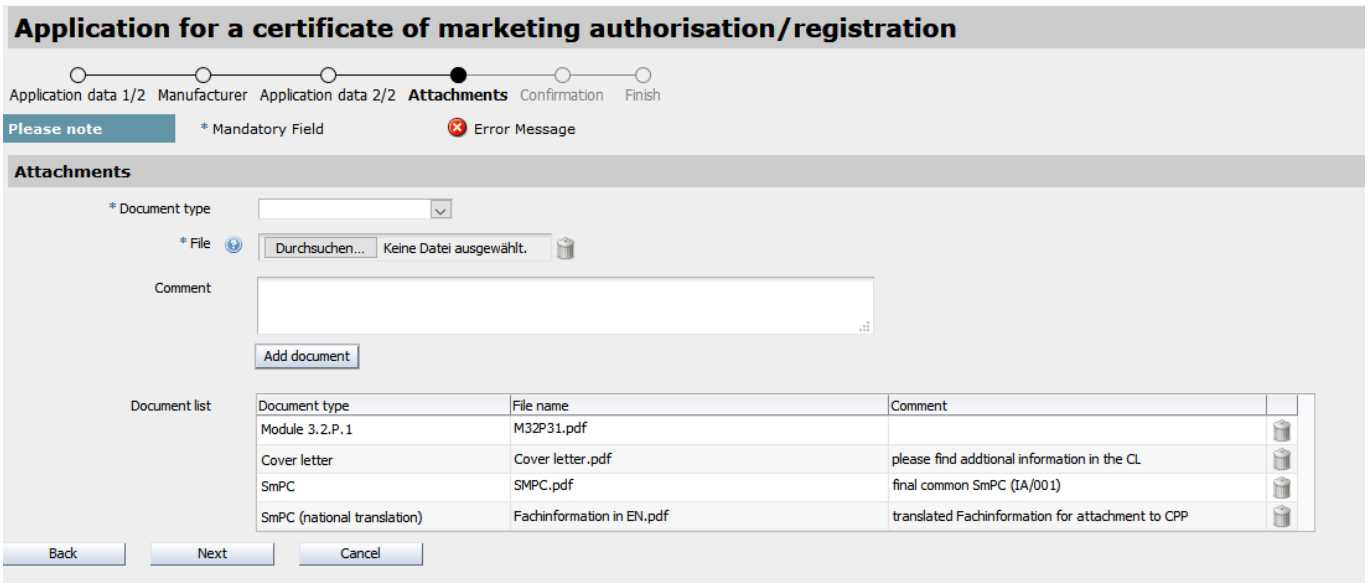
On **page 3**, indicate whether module 3.2.P.3.1 is already applicable at BASG in eCTD format, and if so, enter the sequence number containing the module. If no, module 3.2.P.3.1. is mandatory to upload on page 4.

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.

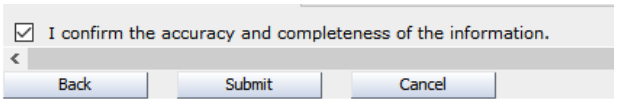
Further comments for the processing of your application are optional.



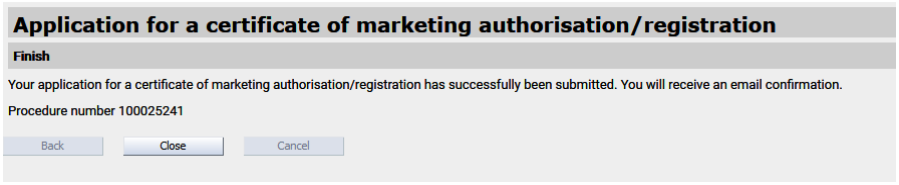
On **page 4** supplementary documents can be uploaded to the application.



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.



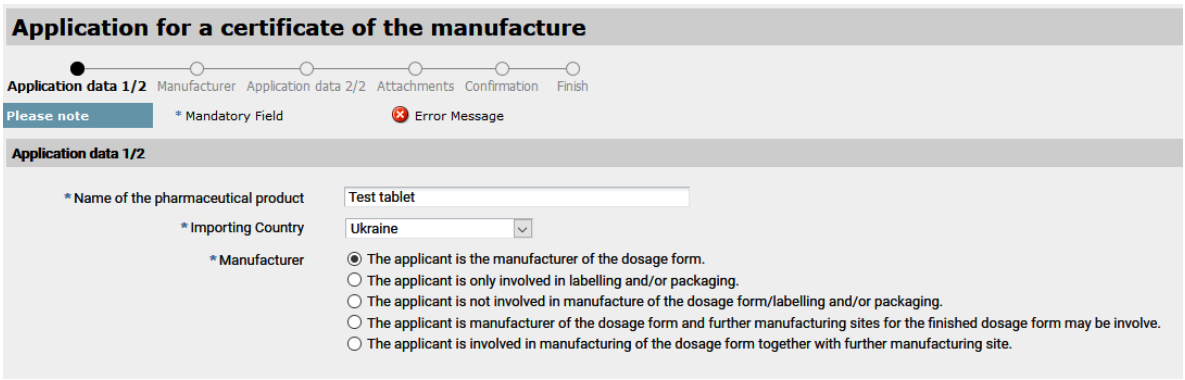
Page 6 (Finish page) contains the procedure number, which you can use to find your application in the "Ongoing Application" section.



1.2 CERTIFICATE FOR MANUFACTURING

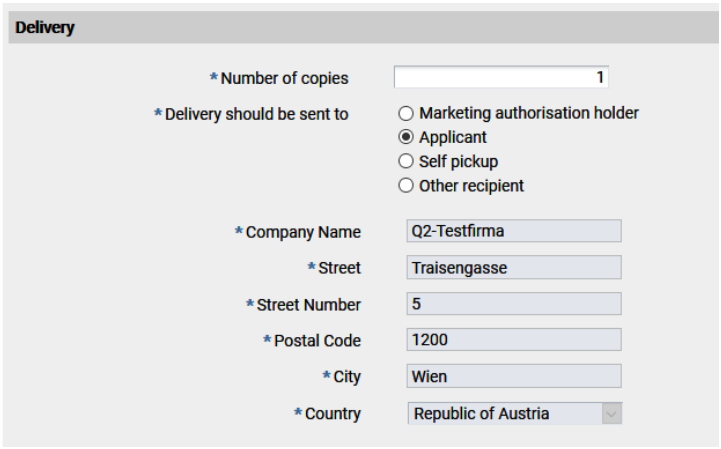
On **page 1**, you have to fill in the medicinal product name. Select the importing country from the catalogue and fill in the marketing and manufacturer data.

The selection for manufacturer corresponds to categories a-e in form F_M64.

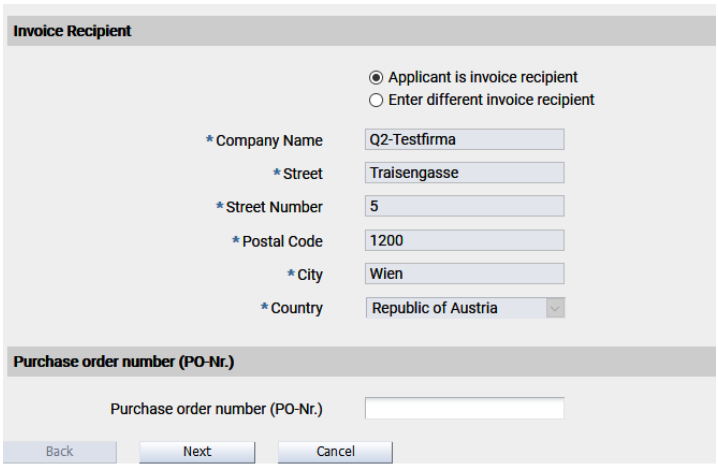


Information on delivery is then required.

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

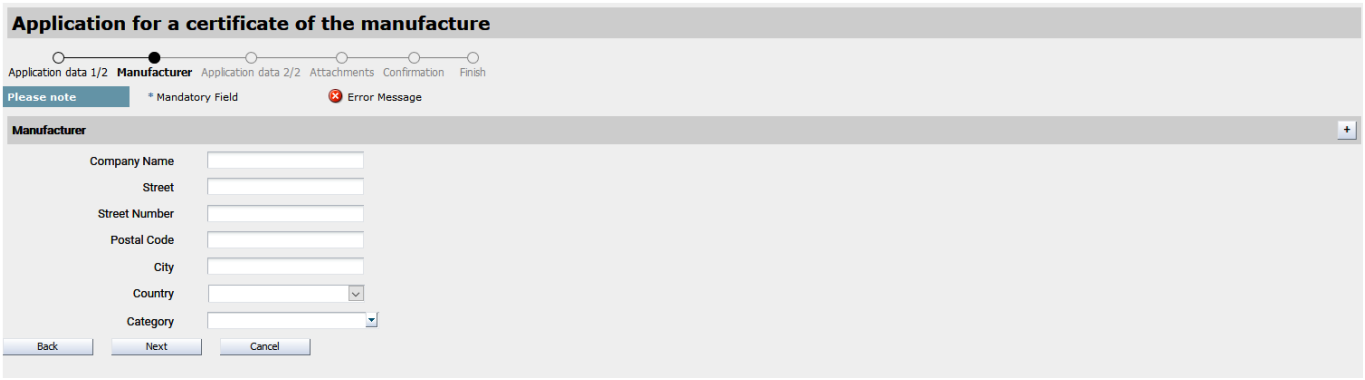


Please enter an invoice recipient and add the Purchase order number (PO-Nr.) if necessary.
If you select "Enter different invoice recipient" the data fields cab be filled in, otherwise they are pre-filled.



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

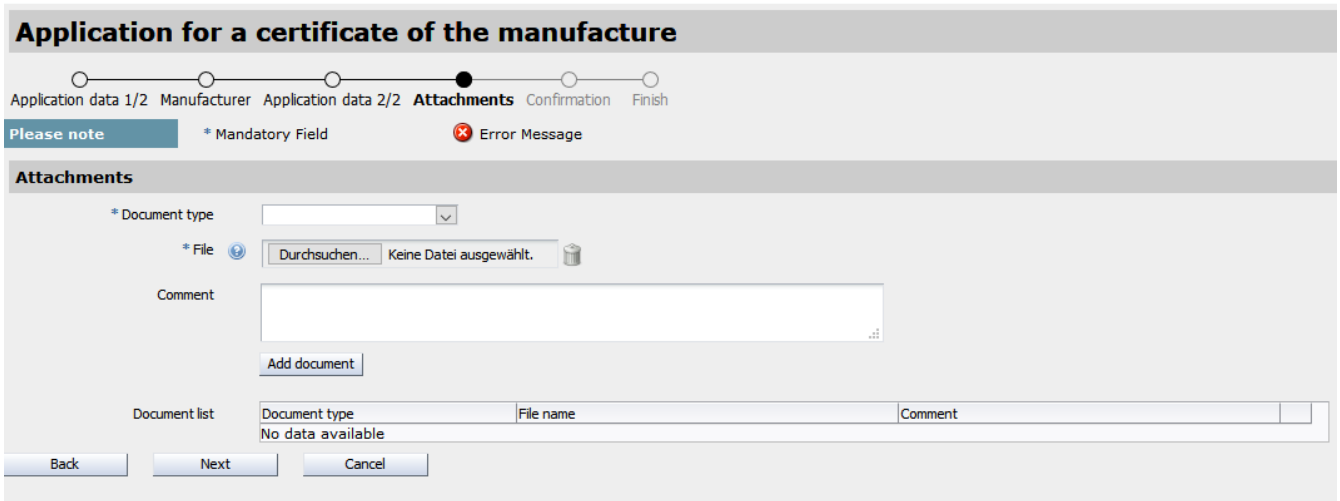
With the plus sign at the right margin further input blocks can be created, the minus sign deletes the blocks.



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.

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



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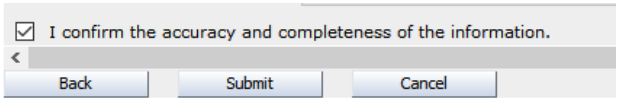

Page 6 (Finish page) contains the procedure number, which you can use to find your application in the "Ongoing Application" section.

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.