User Manual for Marketing Authorisation and Lifecycle Management of Medicines

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1. General information

1.1 Login

https://eservices.basg.gv.at/

To access enter your user name and your password.

Click 'Zulassung und Lifecyle ASP' ('Authorisation and lifecycle MP').
1.2 Home
You can find the navigation area on the left side.

2. Current applications
To view your pending applications, click „current applications“. After you have submitted a dossier via CESP or CD/DVD it might take 1-2 days till your procedure is shown in the eService. In case you want to submit product information texts before the procedure has been activated please attach them in a MS-word format (*.doc, *.docx) as working documents to the dossier.
### Email addresses for notifications

Since November 2014 it is possible to enter individual Email addresses for each procedure.

Select one row and click the menu bar "Edit". A window, where you will be able to enter/change an email address, will open.

See also FAQ 7
2.1 New communication (procedure-specific)

Click the blue coloured number(s) in the column ‘Procedure Number’. The field ‘Communications’ then opens. If applicable, procedure-specific documents as provided by the BASG/AGES MEA are shown, such as deficiency letters or corrected product information texts. You can submit documents to the BASG/AGES MEA (e.g. the product information texts for AT) as well.

If you see an envelope symbol in the "Communications (All/Pending/Closed)" column, there are new communications for you. In addition, the date of the last additional message is shown in the column "latest message from BASG". This column is sortable. The envelope symbol is displayed until all lines in the procedure detail page have the value "closed" in the "Ext. Communication State" field (see Section 2.5).

To display the supplementary claim, click on the procedure number in this line.

Click the menu arrow that appears at the very left of the row.

Details of the new communication are then shown. To download the file, click the document name.
2.2 Reply to a communication

Open the details of the respective communication (as described in section 2.1). First, click the arrow of the menu bar 'Edit', then select Requested response'.

In the newly opened field 'Response: Add document', select the respective entries in the drop-down menus:

- In the menu 'to Object(s) of Consideration' select the name of the respective medicinal products
- Select a 'Document type'

Then click 'Select File' and select the respective documents. Alternatively, an upload via drag&drop into the file field is feasible.

It is possible to add more than one document of the same type (e.g. national translation of the PIL).

You are free to submit comments to the assessor with your document. If you click “Append document” your files will be shown in the table below.

In this table ("Document list") you are able to change the document type, the objects and your comment, if necessary.

Now you are able to add more types and documents as described above.
When you click the button „Continue“ you will be forwarded to the Confirmation page. The button "Send" on this page will upload all your documents into the agency’s system Pharos. A summary of your submission can be downloaded as pdf. This summary is sent to your email address as well.
2.3 Finished communications

All finished communications of a procedure are shown in the table „finished procedures“. This does not depend on the type of response (response or voluntary response, e.g. national translation of the product information, see section 2.4 below).

For your overview you all communications can be marked with the drop-down menu in the column “Ext. Communication State”. This mark cannot be seen by the assessor! The value “Closed” removes the envelope symbol.

2.4 'Voluntary Response' = submission of documents without having received a deficiency letter of the BASG/AGES MEA

If you want to upload procedure-specific documents, without having received a deficiency letter of the BASG/AGES MEA, use the menu item 'Voluntary Response' in the communications field of the respective procedure.

Then proceed as above ("Reply to a communication").

See also FAQ 4 and FAQ 5
2.5 Control of the envelope symbol in the view "Current Applications"

Since 01.04.2020 the envelope symbol is controlled only by the eService users.

For an easier overview, the date and time of the last document uploaded from BASG to eService is now displayed. The column is sortable.

The envelope is displayed until all lines in the procedure detail page have the value "closed" in the "Ext. Communication State" field. The remaining statuses (empty/edit/open) do not remove the icon.

To remove the envelope symbol, the process must be opened by clicking on the process number and the ""Ext. Communication State " field in both tables must be set to the value "closed" in all lines.

The Back button saves the entries.

Finally, refresh the view by clicking on "Current Applications".

- Select Closed in both tables to remove the envelope
- Click the procedure number to open the detail
- Click on the Back button to save the procedure
- Click on Current Application to refresh
3. **Completed applications**

Click the menu „Completed Applications“ to view this procedures. The completion date is limited to the last three month by default, but can be extended up to July 1st 2013. Earlier completion dates cannot be shown.

The approved SmPC (national translation), PIL (national translation), SmPC accessible (national translation), PIL accessible (national translation), labelling (national translation), Mock-ups of the labelling and if applicable the approval letter, the administrative decision, the PAR (Public Assessment Report), the final statement on the national PSUR and the final statement on the national PSUR cycle changes are shown in the detail of the respective procedure.

See also [FAQ 3](#)
4. Overview Medicinal Products

All your currently authorised or registered Medicinal Products can be found here.

You may announce the marketing status for every Medicinal Product when you select one row and click the menu bar “Edit”.

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5. **New Application**

In this section the following pre-submission applications can be submitted online:

- Presubmission DCP
- Presubmission MRP
- Presubmission RMS transfer
- Presubmission RUP
- Presubmission Splitting

If you have any questions, please send them to rms@basg.gv.at