

## User Manual for Marketing Authorisation and Lifecycle Management of Medicines

### Contents:

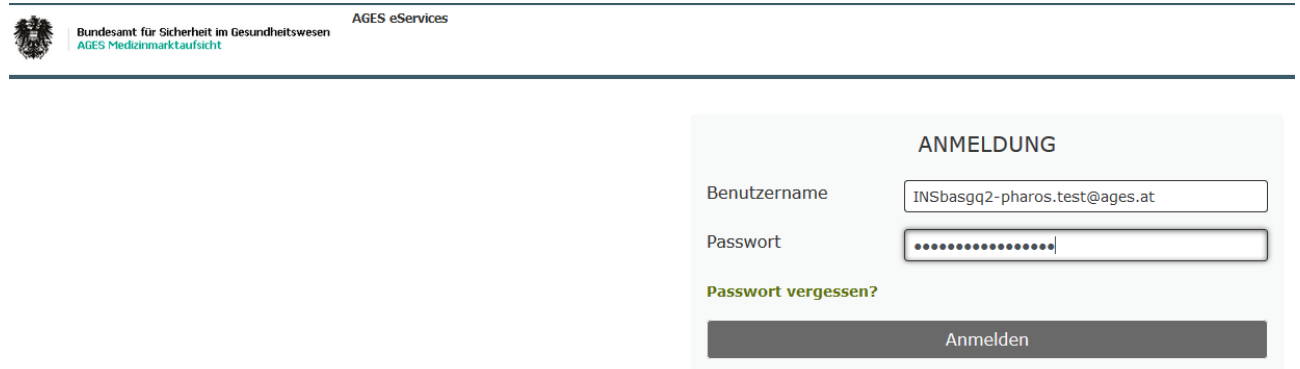
User Manual for Marketing Authorisation and Lifecycle Management of Medicines .....	1
1. General information .....	2
1.1 Login .....	2
1.2 Home .....	3
2. Current applications.....	4
2.1 New communication (procedure-specific).....	6
2.2 Reply to a communication.....	7
2.3 Finished communications.....	8
2.4 'Voluntary Response' =submission of documents without having received a deficiency letter of the BASG/AGES MEA .....	9
2.5 Control of the envelope symbol in the view "Current Applications" .....	9
3. Completed applications .....	10
4. Overview Medicinal Products .....	11
4.1 Marketing data according to Art. 22 AMG (Austrian Medicinal Act) .....	11
4.1.1 First-time notification for a medicinal product.....	12
4.1.2 Change/addition of data reported since 06.12.2023.....	14
4.1.3 Amendment/addition of data already reported before 06.12.2023 .....	16
4.2 Drug shortage .....	18
4.3 Withdrawal of marketing authorisation according to Art 23 AMG (Austrian Medicines Act) .....	19
5. New Application.....	20

# 1. General information

## 1.1 Login

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

To access enter your user name and your password.



Click 'Zulassung und Lifecycle ASP' ('Authorisation and lifecycle MP').

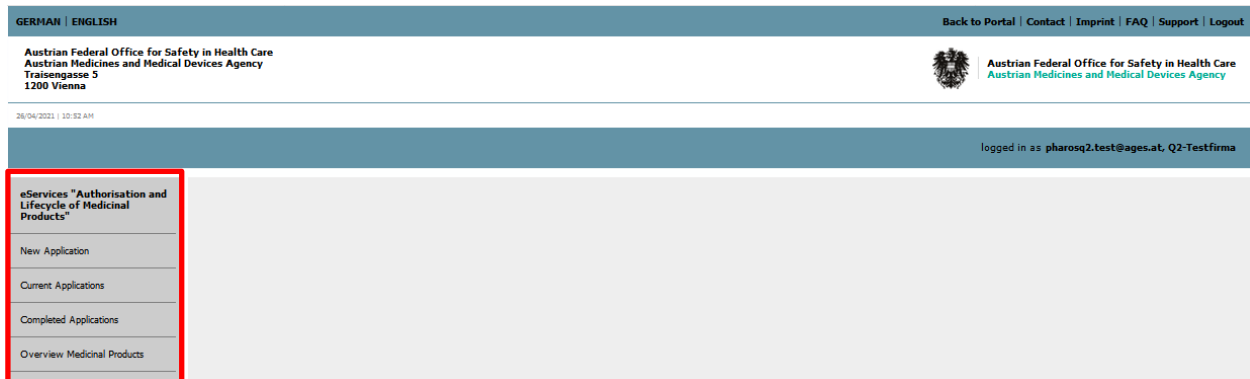


Applikation	Beschreibung
Benutzeradministration	User administration
Berechtigung beantragen	User access management
Inspektionen und Überwachung	Inspections and surveillance
Meldungen lt. Veterinär-Antibiotika-Mengenströme VO	Reporting antibiotics consumption in veterinary medicines
Zulassung und Lifecycle ASP	Authorisation and lifecycle MP

PVP - Standardportal - (c) BM.I & LFRZ - Stammportal - 2.0.4 (Build 353)

## 1.2 Home

You can find the navigation area on the left side.



Presubmission requests can be submitted online in the "New Application" section (see also section 5 in this document).

"Current Applications" shows all open applications and allows you to submit documents related to the application or to receive and respond to additional requests (see also section 2 in this document).

"Completed Applications" shows you all completed submissions including approved documents, if applicable (see also section 3 in this document).

"Overview Medicinal Products" lists all Medicinal Products assigned to your eService access. Here you can report marketing data and drug shortage as well as apply for withdrawal of marketing authorisation according to Art 23 AMG (see also section 4 in this document).

## 2. Current applications

GERMAN | ENGLISH

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency  
Traisengasse 5  
1200 Vienna

Back to Portal | Contact | Imprint | FAQ | Support | Logout

26/04/2021 | 10:52 AM

logged in as pharosq2.test@ages.at, Q2-Testfirma

eServices "Authorisation and Lifecycle of Medicinal Products"

- New Application
- Current Applications**
- Completed Applications
- Overview Medicinal Products

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) and if applicable, in a pdf-UA format for the barrier free PIL as working documents to the dossier.

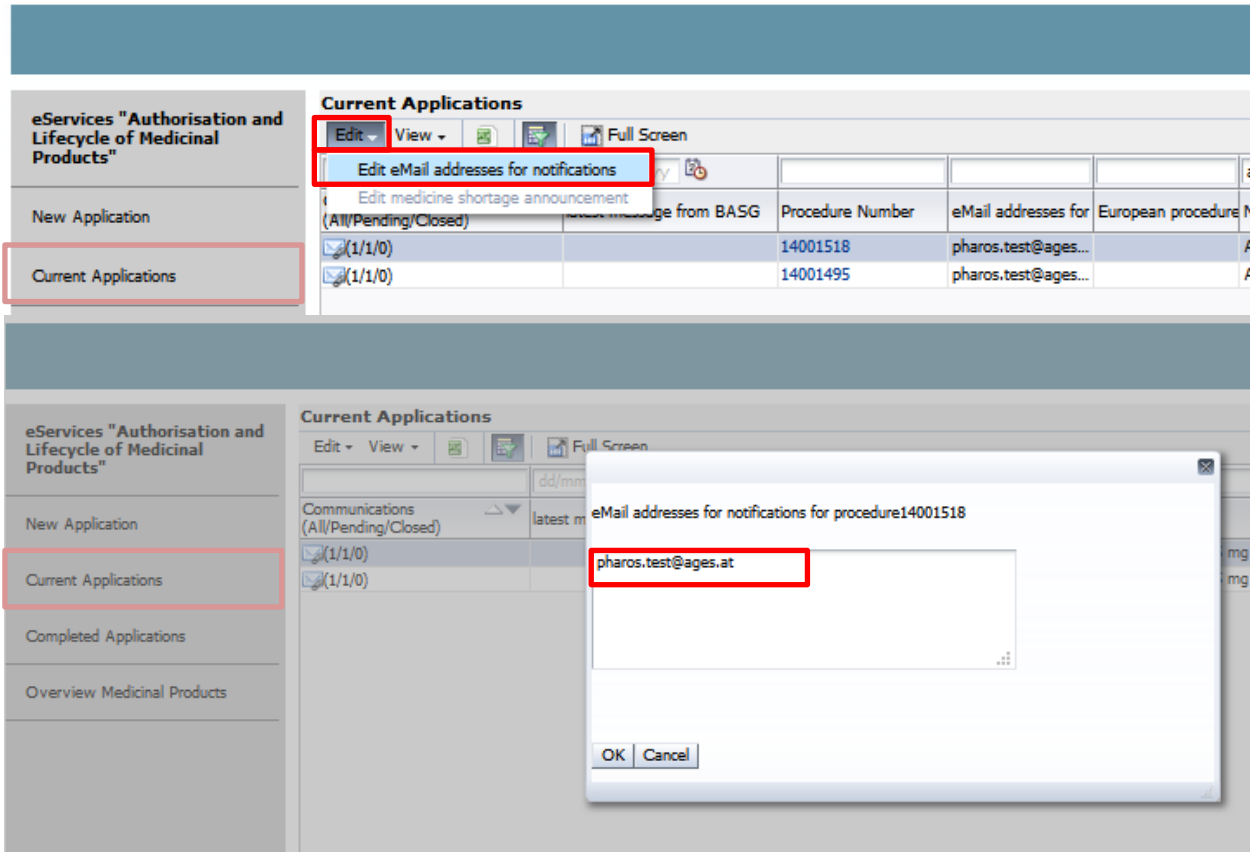
## Email addresses for notifications

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.

Separate multiple email addresses either with semicolon ; or with Enter in the input field.

See also [FAQ 7](#)



The screenshot shows the AGES application interface. The left sidebar contains navigation options: "New Application", "Current Applications" (highlighted), "Completed Applications", and "Overview Medicinal Products". The main area displays a table of "Current Applications".

Procedure Number	eMail addresses for	European procedure
14001518	pharos.test@ages...	
14001495	pharos.test@ages...	

A dialog box titled "eMail addresses for notifications for procedure14001518" is open, showing an input field with the email address "pharos.test@ages.at" entered. The dialog has "OK" and "Cancel" buttons.

If an email address is to be automatically populated, please follow the instructions in section 6.2 of the [Guidance notes: administration of users and user rights \(L\\_M59\)](#)

## 2.1 New communication (procedure-specific)

Click the blue coloured number 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.

logged in as pharosq2.test@ages.at, Q2-Testfirma

Current Applications									
Edit View Full Screen									
Communications (All/Pending /Closed)	latest message from BASG	Procedure Number	eMail addresses for	European procedure	Name	Submission Date	Procedure Type	Classification	Scope Variation
(2/2/0)	04/05/2020 14:05:24	12913063	pharosq2.test@ages	ABC	ABC 10 mg film-coated tablets   ABC	04/05/2020	variation national -   A,7	Deletion of mar	

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.

GERMAN | ENGLISH Back to Portal | Contact | Imprint | FAQ | Support | Logout

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency  
Traisengasse 5  
1200 Vienna

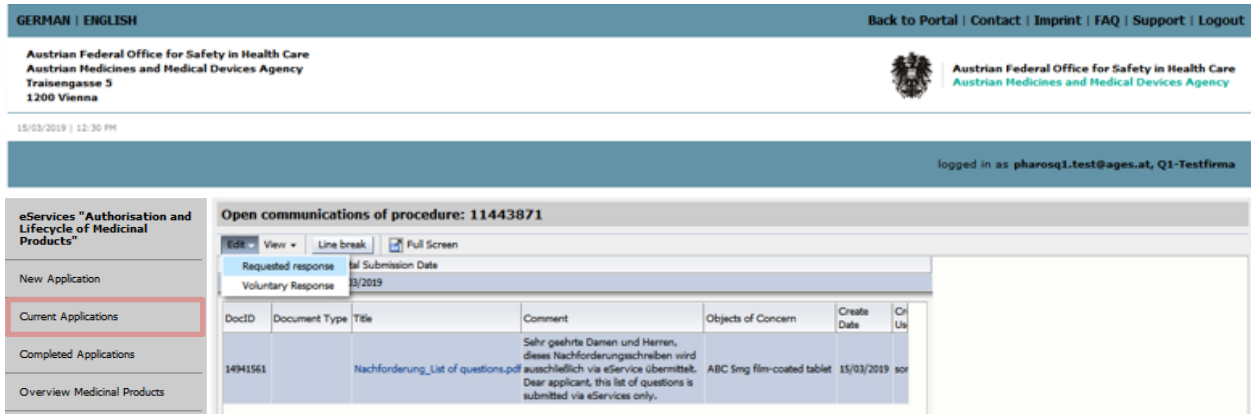
02/04/2019 | 02:20 PM

logged in as pharosq1.test@ages.at, Q1-Testfirma

Open communications of procedure: 11443871						
#	Portal Submission Date	Has to be done by	Ext. Communication State			
1	15/03/2019		Open			
DocID	Document Type	Title	Comment	Objects of Concern	Create Date	Cre/ User
14941561	Request for supplementary information	Nachforderung_List of question	Sehr geehrte Damen und Herren, dieses Nachforderungsschreiben wird ausschließlich via eService übermittelt. Dear applicant, this list of questions is submitted via eServices only.	ABC 10mg film-coated tablet,ABC 2	15/03/2019	sonj
2	15/03/2019					
Finished communications of procedure: 11443871						
#	Portal Submission Date	Has to be done by	Ext. Communication State			
No data to display.						

## 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'.



The screenshot shows the AGES portal interface. At the top, there are navigation links: 'GERMAN | ENGLISH', 'Back to Portal | Contact | Imprint | FAQ | Support | Logout', and the agency name 'Austrian Federal Office for Safety in Health Care Austrian Medicines and Medical Devices Agency'. The user is logged in as 'pharosq1.test@ages.at, Q1-Testfirma'. The main content area displays 'Open communications of procedure: 11443871' with a table of communications. The table has columns: DocID, Document Type, Title, Comment, Objects of Concern, Create Date, and Cr Us. One entry is visible with DocID 14941561, Document Type 'Nachforderung\_List of questions.pdf', and a comment in German and English.

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.

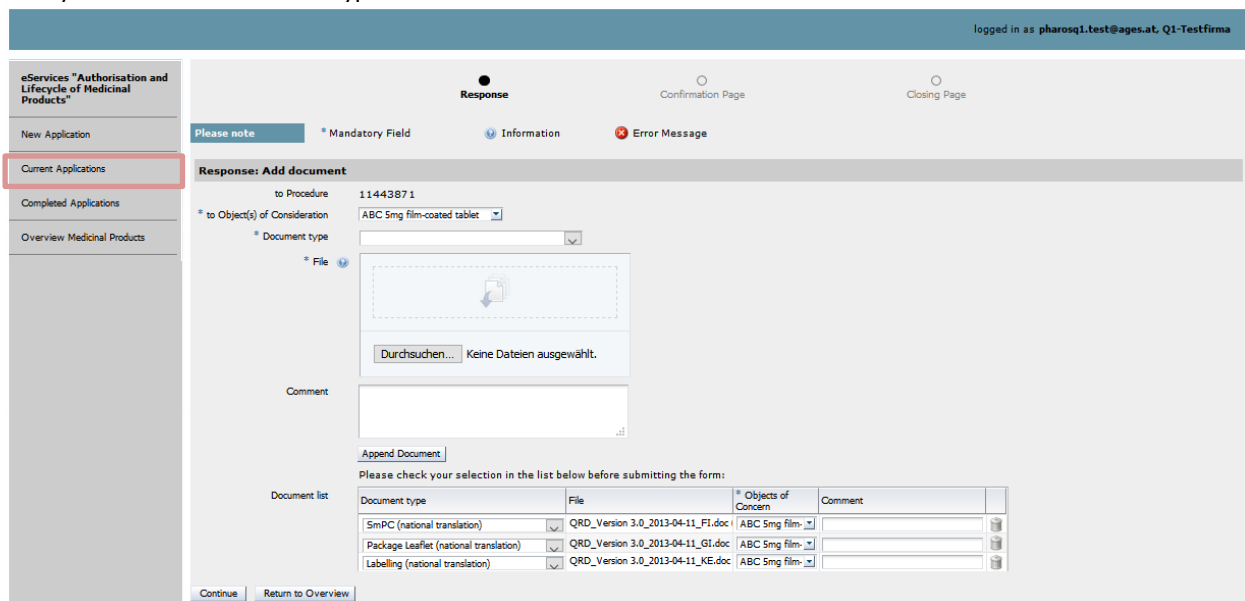
It is possible to add more than one document of the same type (e.g. national translation of the PIL).

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.



The screenshot shows the 'Response: Add document' form in the AGES portal. The form includes a 'Please note' section with mandatory field indicators, information, and error message icons. The main form area has fields for 'to Procedure' (11443871), '\* to Object(s) of Consideration' (ABC 5mg film-coated tablet), and '\* Document type'. There is a file upload area with a 'File' field and a 'Durchsuchen...' button. Below the file upload area is a 'Comment' field. At the bottom, there is a 'Document list' table with columns: Document type, File, \* Objects of Concern, and Comment. The table contains three rows of document entries with their respective file names and object types.

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.

**Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH**

Spargelfeldstraße 191 | 1220 Wien | Österreich | www.basg.gv.at | www.ages.at

DVR: 2112611 | Registergericht: Handelsgericht Wien | Firmenbuch: FN 223056z

BAWAG P.S.K. AG | IBAN: AT59 6000 0000 9605 1496 | BIC: OPSKATWW | UID: ATU 54088605

L\_LCM\_VIE\_00QM\_Z34\_07

Gültig ab: 07.12.2023



logged in as pharosq1.test@ages.at, Q1-Testfirma

Response      **Confirmation Page**      Closing Page

**Confirmation Page**

**Response**

Type	Requested response
to Procedure	11443871
to Object of Consideration	ABC 5mg film-coated tablet
Document Type	SmPC (national translation)
File	QRD_Version 3.0_2013-04-11_FI.doc (72703 bytes)
Comment	test
to Object of Consideration	ABC 5mg film-coated tablet
Document Type	Package Leaflet (national translation)
File	QRD_Version 3.0_2013-04-11_GL.doc (70143 bytes)
Comment	test 2
to Object of Consideration	ABC 5mg film-coated tablet
Document Type	Labelling (national translation)
File	QRD_Version 3.0_2013-04-11_KE.doc (53247 bytes)
Comment	test 3

Back   Send   Return to Overview

### 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.

logged in as pharosq1.test@ages.at, Q1-Testfirma

**Open communications of procedure: 11443871**

#	Portal Submission Date	Has to be done by	Ext. Communication State
2	15/03/2019		

**Finished communications of procedure: 11443871**

#	Portal Submission Date	Has to be done by	Ext. Communication State
1	15/03/2019		Open

DocID	Document Type	Title	Comment	Objects of Concern	Create Date	Create User
14942404	SmPC (national translation)	QRD_Version 3.0_2013-04-11_FI.doc	test	ABC 5mg film-coated tablet	02/04/2019	pharos
14942405	Package Leaflet (national translation)	QRD_Version 3.0_2013-04-11_GL.doc	test 2	ABC 5mg film-coated tablet	02/04/2019	pharos
14942406	Labelling (national translation)	QRD_Version 3.0_2013-04-11_KE.doc	test 3	ABC 5mg film-coated tablet	02/04/2019	pharos
14942407	form confirmation	11443871_Confirmation.pdf		ABC 5mg film-coated tablet	02/04/2019	pharos
14941561	Request for supplementary information	Nachforderung_List of questions.pdf	Sehr geehrte Damen und Herren, dieses Nachforderungsschreiben wird ausschließlich via eService übermittelt. Dear applicant, this list of questions is	ABC 10mg film-coated tablet, ABC 20mg	15/03/2019	sonja6

back



## 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.

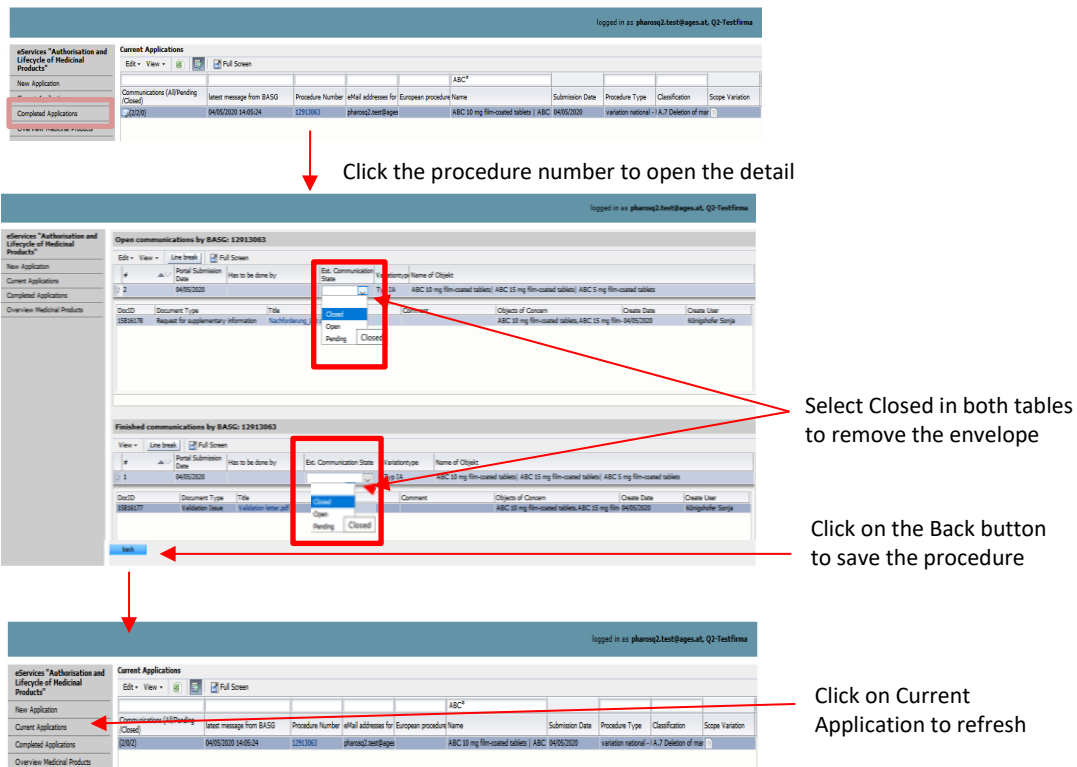
For an easier overview, the date and time of the last document uploaded from BASG to eService is now displayed. The column is sortable.

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".



The screenshot illustrates the steps to remove the envelope symbol from the 'Current Applications' view:

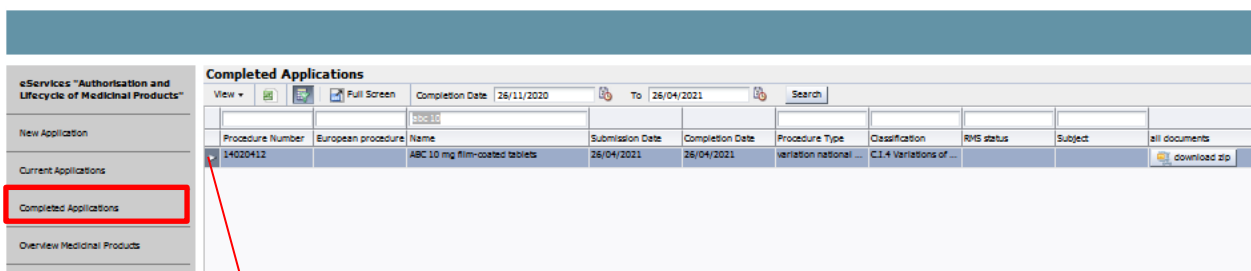
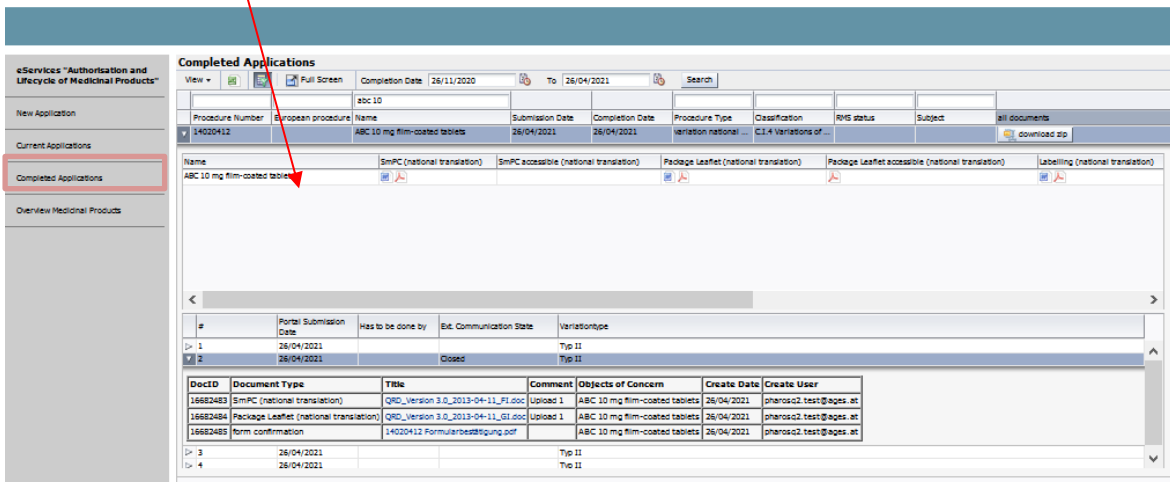
- Click the procedure number to open the detail**: The user clicks on the procedure number '12913063' in the 'Current Applications' table.
- Select Closed in both tables to remove the envelope**: In the 'Open communications by BASG: 12913063' table, the 'Ext. Communication State' dropdown is set to 'Closed'. The same is done for the 'Finished communications by BASG: 12913063' table.
- Click on the Back button to save the procedure**: The 'Back' button at the bottom of the detail view is clicked.
- Click on Current Application to refresh**: The user returns to the 'Current Applications' view and clicks on the 'Current Applications' menu item to refresh the data.

### 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. Additionally, all documents can be downloaded in a zip folder.  
See also [FAQ 3](#)

To view the documents, click on the arrow on the far left. The first table displays the approved texts. In the second table, the communications conducted in the procedure via eService are displayed.

**Table 1**

Name	SmPC (national translation)	SmPC accessible (national translation)	Package Leaflet (national translation)	Package Leaflet accessible (national translation)	Labelling (national translation)
ABC 10 mg film-coated tablets					

**Table 2**

#	Portal Submission Date	Has to be done by	Ext. Communication State	Variationtype
> 1	26/04/2021			Typ II
> 2	26/04/2021		Closed	Typ II

DocID	Document Type	Title	Comment	Objects of Concern	Create Date	Create User
16682483	SmPC (national translation)	QRD_Version 3_0_2013-04-11_F1.doc	Upload 1	ABC 10 mg film-coated tablets	26/04/2021	pharos02.test@ages.at
16682484	Package Leaflet (national translation)	QRD_Version 3_0_2013-04-11_G1.doc	Upload 1	ABC 10 mg film-coated tablets	26/04/2021	pharos02.test@ages.at
16682485	form confirmation	14020412 Formularbestätigung.pdf		ABC 10 mg film-coated tablets	26/04/2021	pharos02.test@ages.at

## 4. Overview Medicinal Products

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

GERMAN | ENGLISH Back to Portal | Contact | Imprint | FAQ | Support | Logout

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency  
Traisengasse 5  
1200 Vienna

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency

02/04/2019 | 05:08 PM

logged in as pharosq1.test@ages.at, Q1-Testfirma

**eServices "Authorisation and Lifecycle of Medicinal Products"**

**Overview Medicinal Products**

Edit View Full Screen

Reference	Name of Medicinal Product	Authorisation Number/MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base
11443872	ABC 5mg film-coated tablet		02/04/2019	authorized				Hybrid application (Article 10(3))

**Navigation:** New Application, Current Applications, Completed Applications, **Overview Medicinal Products**

### 4.1 Marketing data according to Art. 22 AMG (Austrian Medicinal Act)

You may announce the marketing status for every Medicinal Product when you select one row and click the menu bar "Edit". Select "Announce Marketing Date" to submit data to the BASG.

From 06.12.2023 on there is only one selection for announcing the marketing date, the sunset date or the sunset reason according to Art. 22 AMG.

GERMAN | ENGLISH Back to Portal | Contact | Imprint | FAQ | Support | Logout

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency  
Traisengasse 5  
1200 Vienna

Austrian Federal Office for Safety in Health Care  
Austrian Medicines and Medical Devices Agency

01/12/2023 | 05:44 PM

logged in as pharosq1.test@ages.at, Q1-Testfirma

**eServices "Authorisation and Lifecycle of Medicinal Products"**

**Overview Medicinal Products**

Edit View Full Screen

Reference	Name of Medicinal Product	Authorisation Number/MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base	Risk class
947112	ABC 10 mg - Filmtabletten	143693	01/12/2023	authorized	01/08/2021			Generic application...	

**Navigation:** New Application, Current Applications, Completed Applications, **Overview Medicinal Products**

**Edit Menu:** Announce Marketing Date, Announce Medicine Shortage, Withdrawal according to §23 AMG



#### 4.1.1 First-time notification for a medicinal product

*Note: If the columns Marketing date, Market withdrawal date and Marketing exception of the selected medicinal speciality are empty in the overview Medicinal speciality, no notification has ever been submitted to the BASG.*

Select the line of the product for which you want to make the notification in the overview of the medicinal products and select the menu item "Announce Marketing Data" in the "Edit" menu. A new "Marketing data" page opens. This shows a list of all pack sizes of the medicinal product according to the current data status in Pharos.

*Fig 1 (4.1.1): "Marketing data" page according to the current data status in Pharos when initially called up from the overview of the medicinal product.*


*As no notification has yet been made, the Marketing status\*, Marketing start and Marketing end columns are empty.*

**Announce Marketing Date**

Marketing data Exception Confirmation Page Closing Page

Marketing data for ABC 10 mg - Filmtabletten

If not all packages are listed below, please contact your contact point according to allocation scheme (<https://www.basg.gv.at/en/how-to-contact-us>)

View 

Package size	Unit	Container	Description	Status	Device	PIP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid			▼		
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid		2345670	▼		
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456780	▼		
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid			▼		
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234560	▼		

The following columns can be edited on the "**Marketing data**" page:

- Marketing status (mandatory field), please select a value from the catalog,
- Marketing start, if the value "Marketed" has been selected,
- Marketing end, if the value "Not marketed" has been selected.

The date fields cannot be edited if the value "Never marketed" has been selected or as long as no value has been selected.

You can only click on "Next" if a value for "Marketing status" has been selected for each line.


*Fig 2 (4.1.1): Marketing data page after entering your data*




*In the example, the marketing status for packs 7, 14 and 30 was first set to "Marketed" and 01.12.2023 was entered as the marketing start for each. The value of the 7 pieces was then set to "Not marketed" and the marketing end date was entered as 7.12.2023.*

**Marketing data** Exception Confirmation Page Closing Page

Marketing data for ABC 10 mg - Filmtabletten

If not all packages are listed below, please contact your contact point according to allocation scheme (<https://www.basg.gv.at/en/how-to-contact-us>)

View 

Package size	Unit	Container	Description	Status	Device	PIP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid			Never marketed		
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid		2345670	Marketed	01/12/2023 	
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456780	Marketed	01/12/2023 	
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid			Never marketed		
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234560	Not marketed	01/12/2023	07/12/2023 

Next Return to Overview

Click on "Next" to calculate the summary of the sunset data.

The "**Exception**" page shows the summary of the sunset data entered on the "Marketing data" page and refers to the medicinal product as a whole.

The oldest marketing start date is calculated from all packs for the marketing date and, if no pack has the status "Marketed", the most recent marketing end date is calculated from all packs for the market withdrawal date.

If necessary, you can edit the date values in the table. You can add another empty row using the "Add row" button. The recycle bin symbol deletes the row.

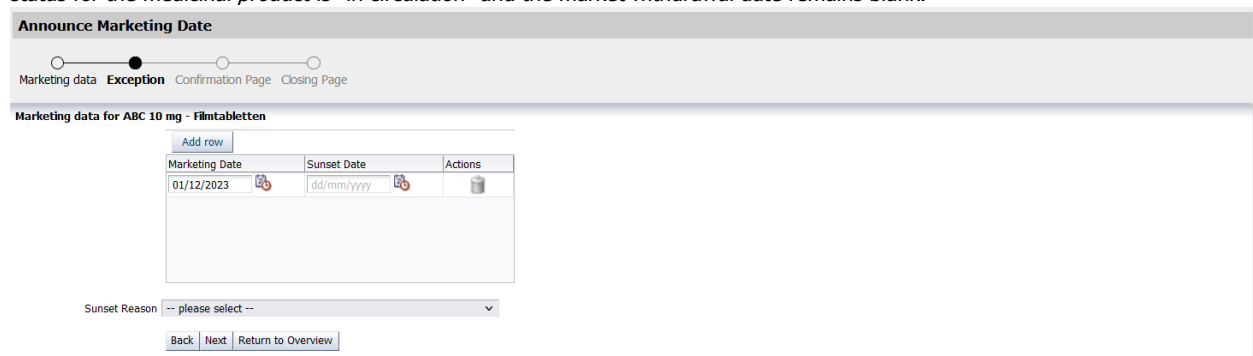
Never delete rows that describe a historical marketing period when you start a new period.

If applicable, you can also select a marketing exception.

Please note that if you switch back to the "Marketing data" page and then continue to the "Exception" page, the calculation is carried out again and manual entries on the "Exception" page are deleted.

*Fig 3 (4.1.1): Page exception with calculated marketing period*

*In the example above (Fig 2 (4.1.1)), a withdrawal was reported for the 7-piece pack, but 2 packs are still marketed, so the sunset status for the medicinal product is "in circulation" and the market withdrawal date remains blank.*



Clicking on "Next" takes you to the control and finalization page.

#### 4.1.2 Change/addition of data reported since 06.12.2023

*Note: If the columns Marketing date, Market withdrawal date and Marketing exception of the selected medicinal product are filled in the overview Medicinal product, a notification has already been sent to the BASG.*

In the overview of medicinal products, select the line of the product for which you want to make the notification and select the menu item "Announce Marketing Data" in the "Edit" menu. A new "Marketing data" page opens. This shows a list of all pack sizes of the medicinal product according to the current data status in Pharos.

*Fig 1 (4.1.2): "Marketing data" page according to the current data status in Pharos when initially called up from the overview of the medicinal product*

**Announce Marketing Date**

Marketing data   Exception   Confirmation Page   Closing Page

Marketing data for ABC 10 mg - Filmtabletten

If not all packages are listed below, please contact your contact point according to allocation scheme (<https://www.basg.gv.at/en/how-to-contact-us>)

Package size	Unit	Container	Description	Status	Device	PJP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid			Never marketed		
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234560	Marketed	01/12/2023	
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid		2345670	Marketed	01/12/2023	
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456780	Marketed	01/12/2023	
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid			Never marketed		

Next   Return to Overview

The data of the initial call from Pharos can be changed or supplemented.

The following columns can be edited on the **"Marketing data" page**:

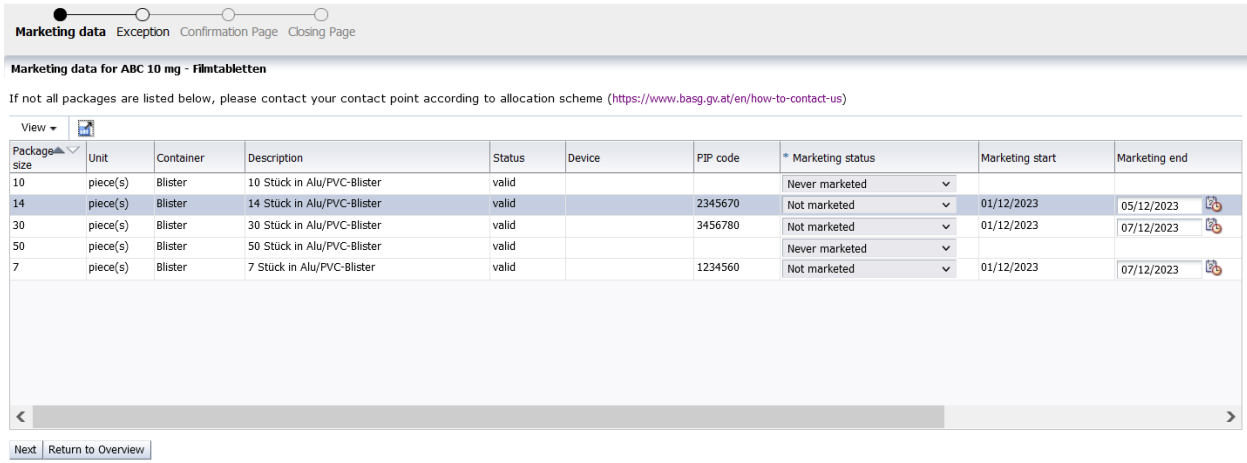
- Marketing status (mandatory field), please select a value from the catalog,
- Marketing start, if the value "Marketed" has been selected,
- Marketing end, if the value "Not marketed" has been selected.

The date fields cannot be edited if the value "Never marketed" has been selected or as long as no value has been selected.

You can only click on "Next" if a value for "Marketing status" has been selected for each line.

Fig 2 (4.1.2): Marketing data page after entering your data

In the example, the marketing status of the 14-piece and 30-piece packs has been changed to "Not marketed" and the marketing end date has been entered for both lines.



Package size	Unit	Container	Description	Status	Device	PIP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid			Never marketed		
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid		2345670	Not marketed	01/12/2023	05/12/2023
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456780	Not marketed	01/12/2023	07/12/2023
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid			Never marketed		
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234560	Not marketed	01/12/2023	07/12/2023

Click on "Next" to calculate the summary of the sunset data.

The "Exception" page shows the summary of the sunset data entered on the "Marketing data" page and refers to the medicinal product as a whole.

The oldest marketing start date is calculated from all packs for the marketing date and, if no pack has the status "Marketed", the most recent marketing end date is calculated from all packs for the market withdrawal date.

If necessary, you can edit the date values in the table. You can add another empty row using the "Add row" button. The recycle bin symbol deletes the row.

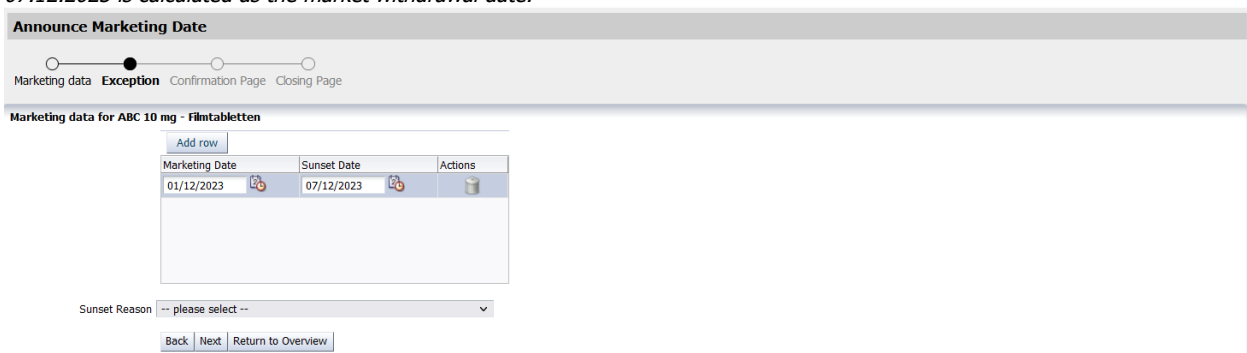
Never delete rows that describe a historical marketing period when you start a new period.

If applicable, you can also select a marketing exception.

Please note that if you switch back to the "Marketing data" page and then continue to the "Exception" page, the calculation is carried out again and manual entries on the "Exception" page are deleted.

Fig 3 (4.1.2): Exception page with calculated marketing period

In the example above (Fig. 2 (4.1.2)), the end of marketing for the 14-piece pack was reported as 05.12.2023 and for the 30-piece pack as 07.12.2023. The most recent marketing end date is therefore 07.12.2023 and no further packs have been marketed, so 07.12.2023 is calculated as the market withdrawal date.



Marketing Date	Sunset Date	Actions
01/12/2023	07/12/2023	[Recycle Bin]

Sunset Reason: -- please select --

Clicking on "Next" takes you to the control and finalization page.



#### 4.1.3 Amendment/addition of data already reported before 06.12.2023

*Note: If the columns Marketing date, Market withdrawal date and Marketing exception of the selected medicinal product are filled in the overview Medicinal product, a notification has already been sent to the BASG.*

If only the market withdrawal is reported for a medicinal product for which a marketing date before 06.12.2023 was reported, it is sufficient to enter only the marketing end date.

Fig 1 (4.1.3) Display of the marketing date reported before 06.12.2023 in the overview of the medicinal product

**Overview Medicinal Products**

Edit View   Full Screen

Reference	Name of Medicinal Product	Authorisation Numb	MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason
947113	ABC 5 mg - Filmtabletten	143692		01/06/20...	authorized	01/08/2021		

If you would also like to report the marketing start date for a complete data record, you must first select the status "Marketed", enter the date and then set the status to "Not marketed" in order to be able to enter the marketing end date.

In the overview of medicinal products, select the line of the product for which you want to make the notification and select the menu item "Announce Marketing Data" in the "Edit" menu. A new "Marketing data" page opens. This shows a list of all pack sizes of the medicinal product according to the current data status in Pharos.

Fig 2 (4.1.3): "Marketing data" page according to the current data status in Pharos when initially called up from the overview of the medicinal product.


Since the notification was made before 06.12.2023, the columns Marketing status\*, Marketing start and Marketing end are empty

**Announce Marketing Date**

Marketing data Exception Confirmation Page Closing Page

Marketing data for ABC 5 mg - Filmtabletten

If not all packages are listed below, please contact your contact point according to allocation scheme (<https://www.basg.gv.at/en/how-to-contact-us>)

View 

Package size	Unit	Container	Description	Status	Device	PIP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid					
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid					
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid					
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456789			
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234567			

The following columns can be edited on the "Marketing data" page:

- Marketing status (mandatory field), please select a value from the catalog,
- Marketing start, if the value "Marketed" has been selected,
- Marketing end, if the value "Not marketed" has been selected.

The date fields cannot be edited if the value "Never marketed" has been selected or as long as no value has been selected.

You can only click on "Next" if a value for "Marketing status" has been selected for each line.






Fig 3 (4.1.3) Marketing data after entering your data  
In the example, only the marketing end date was entered for the 7-piece pack and the 30-piece pack. The marketing start date, which was reported at an earlier date, was not added.

Marketing data Exception Confirmation Page Closing Page

Marketing data for ABC 5 mg - Filmtabletten

If not all packages are listed below, please contact your contact point according to allocation scheme (<https://www.basg.gv.at/en/how-to-contact-us>)

View 

Package size	Unit	Container	Description	Status	Device	PIP code	* Marketing status	Marketing start	Marketing end
10	piece(s)	Blister	10 Stück in Alu/PVC-Blister	valid			Never marketed		
50	piece(s)	Blister	50 Stück in Alu/PVC-Blister	valid			Never marketed		
14	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid			Never marketed		
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456789	Not marketed		07/12/2023 
7	piece(s)	Blister	7 Stück in Alu/PVC-Blister	valid		1234567	Not marketed		07/12/2023 

Next Return to Overview

Click on "Next" to calculate the summary of the sunset data.

The summary of the sunset data shows the marketing date reported in a previous procedure and the calculated market withdrawal date from the "Marketing data" page on the "Exception" page.

If necessary, you can edit the date values in the table. You can add another empty row using the "Add row" button. The recycle bin symbol deletes the row.

Never delete rows that describe a historical marketing period when you start a new period.

If applicable, you can also select a marketing exception.

Please note that if you switch back to the "Marketing data" page and then continue to the "Exception" page, the calculation is carried out again and manual entries on the "Exception" page are deleted.

Fig. 4 (4.1.3): Exception page with calculated marketing period  
The example shows the calculation of a marketing date reported before 06.12.2023. The currently reported marketing date is displayed in the Medicinal product overview.  
In the example, the medicinal product was marketed on 01.08.2021 and will be withdrawn from the market with the current notification on 07.12.2023.




Image of the page Exception

Announce Marketing Date

Marketing data Exception Confirmation Page Closing Page

Marketing data for ABC 5 mg - Filmtabletten

Add row

Marketing Date	Sunset Date	Actions
01/08/2021 	07/12/2023 	

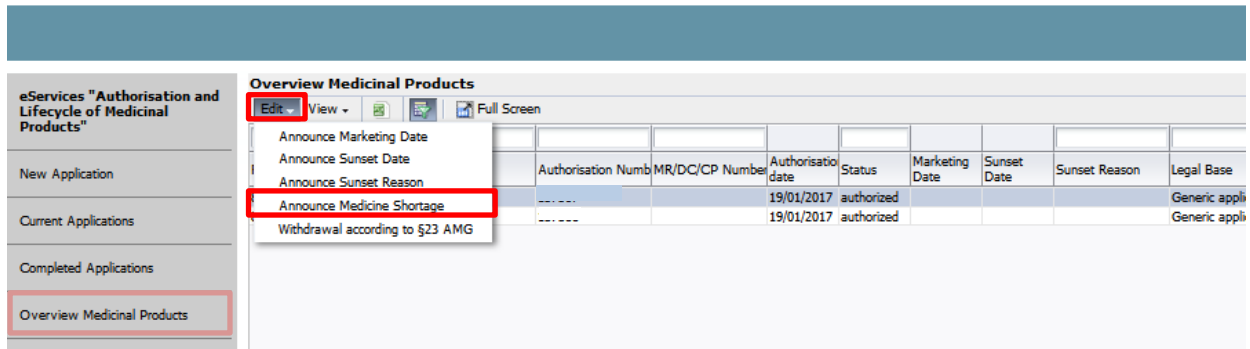
Sunset Reason: -- please select --

Back Next Return to Overview

Clicking on "Next" takes you to the control and finalization page.

## 4.2 Drug shortage

You can report the drug shortage per product by selecting the line and entering the data using the menu "Edit" --> "Announce Medicine Shortage". For more information, please refer to the guide [Meldung von Vertriebsbeschränkungen \(L\\_I21\)](#).

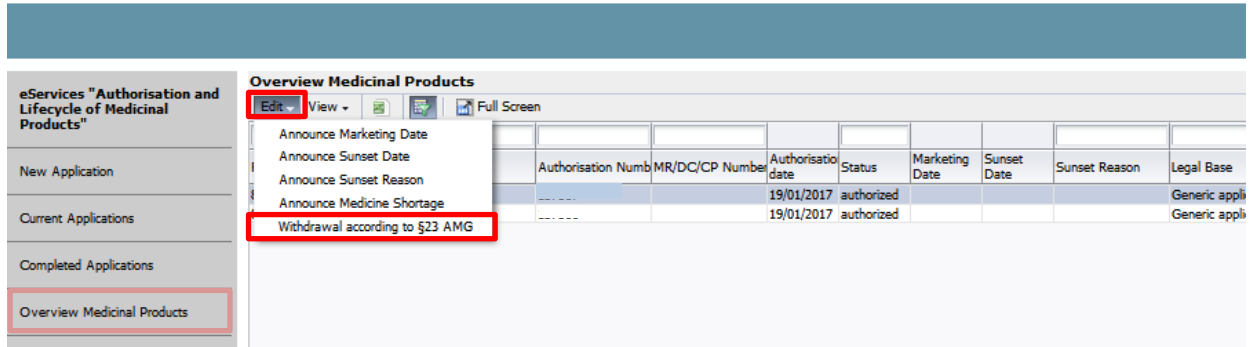


The screenshot shows the 'Overview Medicinal Products' interface. On the left, there is a navigation menu with 'Overview Medicinal Products' selected. The main area displays a table with columns: Authorisation Numb, MR/DC/CP Number, Authorisation date, Status, Marketing Date, Sunset Date, Sunset Reason, and Legal Base. A context menu is open over the first row, with 'Announce Medicine Shortage' highlighted. The table data is as follows:

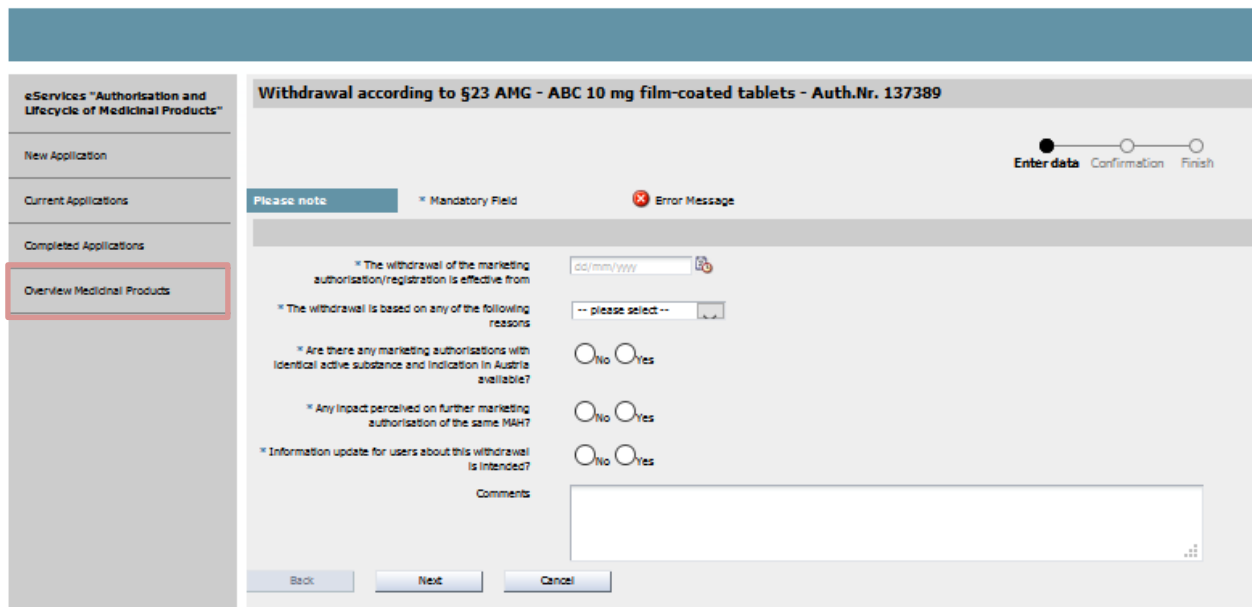
Authorisation Numb	MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base
-----		19/01/2017	authorized				Generic appli
-----		19/01/2017	authorized				Generic appli

### 4.3 Withdrawal of marketing authorisation according to Art 23 AMG (Austrian Medicines Act)

You can apply for the withdrawal of the authorisation/registration according to Art 23 AMG per product by selecting the line and entering the data using the menu "Edit" --> "Withdrawal according to §23 AMG". No separate application via CESP/via CD/DVD/email is required.



Authorisation Numb	MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base
.....	.....	19/01/2017	authorized				Generic appli
.....	.....	19/01/2017	authorized				Generic appli

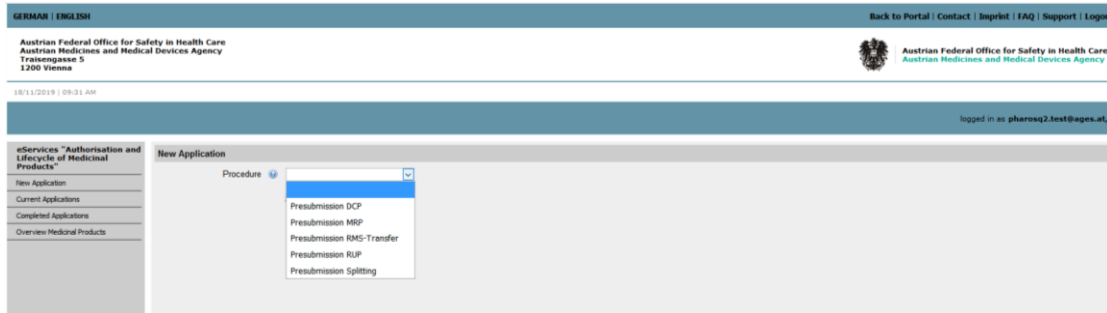


If you wish to submit additional documents, such as corrected product information texts, switch to the "Current Applications" section after submitting this application and perform a "Voluntary response" as described in Section 4.2.

## 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](mailto:rms@basg.gv.at)