

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.

攀	Bundesamt für Sicherheit im Gesundheitswesen AGES Medizinmarktaufsicht	AGES eServices		
				ANMELDUNG
			Benutzername	INSbasgq2-pharos.test@ages.at
			Passwort	••••••••
			Passwort vergessen?	
				Anmelden

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

	棣	Bundesamt für Sicherheit im Gesundhe AGES Medizinmarktaufsicht	itswesen	AGES eServices	2 0
*					
	Ģ	Applikationen	APPL	IKATIONEN	
	*	Favoriten verwalten		Applikation	Beschreibung
	٩	Passwort ändern	<u>00</u>	Benutzeradministration	User administration
	ť	Aktualisieren	ට්	Berechtigung beantragen	User access management
			Ē	Inspektionen und Überwachung	Inspections and surveillance
			ð	Meldungen It. Veterinär-Antibiotika-Mengenströme VO	Reporting antibiotics consumption in veterinary medicines
			P	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 or Certificate for a Pharmaceutical Product (CPP) 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	Back t	to Portal Contact Imprint FAQ Support Logout
Austrian Federal Office for Safety in Health Care Austrian Medicines and Medical Devices Agency Traisengase 5 1200 Vienna	攀	Austrian Federal Office for Safety in Health Care Austrian Medicines and Medical Devices Agency
28(04/2022 10:32 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

eServices "Authorisation and Lifecycle of Medicinal Broducte"		d Current Applications									
		Edit eMail ad	ldresses for notifica	tions	20		104374583				
New Application		C Edit medicine	e shortage announci I for stockpiling	ement	sage from BAS	SG	Procedure Number	eMail addresses for	n European procedure	Name	
Current Applications		Edit temporary reduction of stock		:k	5 13:13:30		104374583	pharosq2.test@ag.		Test 25 mg Kap	
Completed Applications											
Overview Medicinal Products											
eServices "Authorisation and	Current	t Applications									
Lifecycle of Medicinal Products"	Edit 🗸 🕚	View 🗸 😰 🔯	Full Screen		104374583						
New Application	Communica Closed)	ations (All/Pending/	latest message from B			_	<u> </u>				
Current Applications	(2/2/0)		25/06/2025 13:13:30	Mail addres	ses for notification	s for procedure	104374583			t	
Completed Applications				pharosq2.te	est@ages.at						
Overview Medicinal Products											
eServices "Notification of pet products"											
New Application										1.	
Current Applications				OK Canc	el						

If an email address is to be automatically populated, please follow the instructions in section 6.2 of the <u>Guidance notes: administration of users and user rights (L_M59)</u>





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@a	iges.at, Q2-Testf	irma-R-6-16-0
eServices "Authorisation and Lifecycle of Medicinal	Current Applications	Full Screen										
Products"		m/d/yyyy 🔯	104374583									
New Application	Communications (All/Pending/ Closed)	latest message from BASG	Procedure Number	eMail addresses for n	European procedure	Name	Submission Date	Procedure Type	Classification	Scope Variation	Subject	Agreed submission date (slot)
	Sig(2/2/0)	25/06/2025 13:13:30	104374583	pharosq2.test@ag		Test 25 mg Kapseln	6/25/2025	variation national	B.II.b.2.c.1 Finish			1
Current Applications												
Completed Applications												
Cervices "Authorisation an Lifecycle of Medicinal Products" New Application Current Applications Completed Applications Overview Medicnal Products												

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.

							logged in as	pharosq2.test@ages.al	, Q2-Testfirma-R-6-16-0				
eServices "Authorisation and Lifecycle of Medicinal Products"	Open communica Edit + View + Line	Open communications by BASG: 1043745883: Test 25 mg Kapseln Edit + Verv + Line break											
New Application	#	Portal Submission Date	Has to be done by	Ext. Communication State	Variationtype	Name of Objekt							
Current Applications	DocID	Document Typ	e	Title	/ Typ IB	Comment	Objects of Concern	Create Date	Create User				
Completed Applications	20531035	Request for s	upplementary information	Nachforden	ng_List of questions.pdf	Sehr geehrte Damen und Herren, dieses Nachforderungsschreiben wird ausschließlich via eService übermittelt. Dear applicant, the list of questions is submitted via eServices	Test 25 mg Kapseln h	6/25/2025	Königshofer Sonja				
Overview Medicinal Products						orny.							
eServices "Notification of pet products"													
New Application	Finished commu	nications by E	ASG: 104374583: Tes	t 25 mg Kapseln									
	View + Line break	Full Screen											
Current Applications	#	Portal Submission Date	Has to be done by	Ext. Communication State	Variationtype	Name of Objekt							
Completed Applications	≥ 4 I	6/25/2025			, Typ IB	Test 25 mg Kapseln							

Gültig ab: 02.07.2025

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_09





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'.

eServices "Authorisation and Lifecycle of Medicinal Products"	Open communication	ons by BAS	G: 104374583: Test 25 Gareen	i mg Kap	seln				
New Application	Requested response Voluntary Response	al Submission	Has to be done by	Ext. Commu	nication State	Variationtype	Nar	ne of Objekt t 25 ma Kanseln	
Current Applications	DocID	Document Typ)e	11	Title	110 10		Comment	Objects of Concern
Completed Applications	20531035	Request for s	upplementary information		Nachforderung_Li	st of questions.pdf		Sehr geehrte Damen und Herren, dieses Nachforderungsschreiben wird ausschließlich via eService übermittelt. Dear applicant, the list of questions is submitted via eServices only.	Test 25 mg Kapseln
Overview Medicinal Products								Se a y.	

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, and if necessary, click the symbol next to "Objects of Concern" to confirm that the product information text in PDF-UA format is identical in content to the final WORD version.

Now you are able to add more types and documents as described above.

		Response	с	O		Closing F	² age
Please note * Man	datory Field	Information	🔇 Error Message				
Response: Add document	t						
to Procedure	104371088						
* to Object(s) of Consideration	Test 2 mg Pulver für ein Kon	Ze					
* Document type			v		1		
* File 😡	Select type first, please!					Click here to add	the
Comment			11.			confirmation text	
	Append Document						
	Please check your selection	on in the list belo	w before submitting the form:				
Document list	Document type		File	Objects of Concern	Comme	nt	
	Package Leaflet accessible (national translation	GI_PIL_qrd-product-information-ter	mpla Test 2 mg Pu 💌	It is co inform	nfirmed that the product ation text in PDF-UA format is alin content to the final WORF	1
Return to Ovenview Continue	1				Confirm	ation accessible docur	ment
Continue	1						





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.

				logged in as pharosq1.test@ages.at, Q1-Testfirma
eServices "Authorisation and Lifecycle of Medicinal Products"		O Response	Confirmation Page	O Closing Page
New Application	Confirmation Page			
Current Applications	Response Type	Requested response		
Completed Applications	to Procedure	11443871		
Overview Medicinal Products	to Object of Consideration Document Type	ABC 5mg film-coated tablet 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_G1.00C (70143 bytes)		
	Comment	ABC Smg film-coated tablet		
	to Object or Consideration	Labelling (national translation)		
	File	QRD_Version 3.0_2013-04-11_KE.doc (53247 bytes)		
	Comment	test 3		
	Back Send Return to Over	view		

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	l@ages.at, Q1	Testfirma
eServices "Authorisation and	Open co	ommunica	ations of proce	dure: 11443871					
Lifecycle of Medicinal Products"	Edit - V	View -	ine break 📗 🖂 Eu	II Screen					
	Luit		Portal Submission	il Doleen					
New Application	#		Date	Has to be done by	Ext. Communication State				
ien rippiezen	⊳ 2		15/03/2019					~	
urrent Applications									
Completed Applications									
Overview Medicinal Products									
verview medicinal Products									
	Finishou	d commu	nications of pro	coduro, 11442971					
	rinsited	a commu	incations of pro	Cedure: 11443871					
	View -	Line brea	k 🛃 Full Screen	1					
	#		Portal Submission Date	Has to be done by	Ext. Communication State				
	⊽ 1		15/03/2019		Open			~	
		View → Line break Image: Constraint of the second							Croate
	DocID		Document Type		Title	Comment	Objects of Concern	Create Date	User
	Finished comm View - Line br V Line br Line br Line br View - Line br Line br Line br back Line br	ŧ .	SmPC (national tra	anslation)	QRD_Version 3.0_2013-04-11_FI.doc	test	ABC 5mg film-coated tablet	02/04/2019	pharos
	14942405	i	Package Leaflet (n	ational translation)	QRD_Version 3.0_2013-04-11_GI.doc	test 2	ABC 5mg film-coated tablet	02/04/2019	pharos
	14942406	5	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	1	Request for supple	mentary 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								

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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 <u>FAQ 4</u> and <u>FAQ 5</u>

eServices "Authorisation and Lifecycle of Medicinal Products"	Open communic	e break	G: 104374583: Test 2:	ō mg Kapseln		
New Application	Requested respons	e al Submission	Has to be done by	Ext. Communication State	Variationtype	Name of Objekt
	Yoluntary Response	5/2025		~	Тур ІВ	Test 25 mg Kapseln
Current Applications						
Completed Applications	Finished commu	inications by E	3ASG: 104374583: Tes	t 25 mg Kapseln		
	View 👻 Line break	Full Screen				
Overview Medicinal Products	#	Portal Submission Date	Has to be done by	Ext. Communication State	Variationtype	Name of Objekt
	▶ 4	6/25/2025		~	Тур ІВ	Test 25 mg Kapseln

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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".

	logged in as pharosq2.test@agec.at, Q2-Testfirma	
eServices "Authorisation and Lifecycle of Heddinal Products" New Application Completed Applications	Cerrent Applications Bit: View i i i i i i i i i i i i i i i i i i	
	logged in as planosq2.testBages.at, Q2Testfirma	
clericita Tuthkototion and Hindexts" Rea Aplatoti Camet Aplatotio Camet Aplatotion Camet Aplatotion Oranies Medical Podacs	Open communications by BASC 1291080 Ells * Terr / Inchedi 2415 State P = 4 P = 5 dams P = 4 P = 6 dams	
	Fielderf consensitivations by BASG: 12913003 Ver Extra Million g A Profit	Select Closed in both tables to remove the envelope Click on the Back button to save the procedure
	logged in as pharong2.textBages.ut, Q2-TextFirma	
eServices "Authorisation and Lifecycle of Medicinal Products" New Application Carnet Applications Completed Applications Convices Medicinal Brok-res	Contrast Applications Eff: Ven<*	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, composition document 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. The second table shows the communications conducted in the procedure via eService, which can be downloaded by selecting "Export communication for procedure" when clicking on the Excel symbol. To do this, you must have opened the detailed table for the procedure and there must be at least one line in table 2.



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4. Overview Medicinal Products

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

GERMAN ENGLISH											Ba	ck to Portal Contact Imprint FAQ Support Logout
Austrian Federal Office for Sa Austrian Medicines and Medic Traisengasse 5 1200 Vienna	fety in Health Care al Devices Agency										攀	Austrian Federal Office for Safety in Health Care Austrian Medicines and Medical Devices Agency
25/06/2025 02:09 PM												
											logged in	as pharosq2.test@ages.at, Q2-Testfirma-R-6-16-0
eServices "Authorisation and Lifecycle of Medicinal Products"	Overview Medicinal Products Edit + View + B + B Full Scre	en				-			-	1		
New Application	Reference Name of Medicinal Product	Authorisation Numbe	MR/DC/CP Number	Authorisation	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base	Risk dass		
Current Applications	104371 Test 15 mg Kapseln 104371 Test 2 mg Pulver für ein Konzentrat zur 104371 Test 25 mg Kapseln	142803 142802 142804		6/18/2025 6/18/2025 6/18/2025	authorized authorized authorized				Known active subs Generic application Known active subs			
Completed Applications	104371 Test 1 mg Pulver für ein Konzentrat zur	142801		6/18/2025	authorized				Generic application			
Overview Medicinal Products												

4.1 Marketing data according to Art. 21 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.

oComplete "Authorization and	Overview Medicinal Products									
Lifecycle of Medicinal	Edit 🗸 View 🗸 📓 🖌 📷 Full	Scre	en							
Products	Announce Marketing Date									
New Application	Announce Medicine Shortage		Authorisation Numbe	MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base
	withdrawal according to 325 AMG		142803		6/18/2025	authorized				Known active subs
Current Applications	Announce temporary reduction of stock	ur	142802		6/18/2025	authorized				Generic application
	104371 Test 25 mg Kapseln		142804		6/18/2025	authorized				Known active subs
	104371 Test 1 mg Pulver für ein Konzentrat :	zur	142801		6/18/2025	authorized				Generic application
Completed Applications										
Overview Medicinal Products										

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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 specialty are empty in the overview Medicinal specialty, 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 🕶	1								
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 o	lata Exce)	ation Page Closing Page									
Marketing da If not all pac	i ta for ABC kages are	10 mg - Filmta listed below, p	bletten Ilease contact your contact point ac	cording to allocatio	n scheme (https://	/www.basg.gv.at/en/hc	ow-to-contact-us)					
Package V	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	2		
30	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456780	Marketed	~	01/12/2023	2		
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	20
<												>
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.

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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





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.

<u>Never delete rows that describe a historical marketing period when you start a new period.</u> 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.

Announce Marketin	g Date			
Marketing data Exception	Confirmation Page Ck			
Marketing data for ABC 10	mg - Filmtabletten			
	Add row			
	Marketing Date	Sunset Date	Actions	
	01/12/2023	dd/mm/yyyy 🍪	<u>i</u>	
Sunset Reason	please select		~	
	Back Next Return to O	Iverview		

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





Change/addition of data reported since 06.12.2023 4.1.2

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 M	arketing Date												
• Marketing data	Marketing data Exception Confirmation Page												
Marketing data f	for ABC 10 mg - Film	itabletten											
If not all packag	es are listed below,	, please contact your c	ontact point according to allocation sch	neme (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	~					
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, ٠
- •
- 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 (

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.

on scheme (https:/	/www.basg.gv.at/en/ho	ow-to-contact-us)				
Device	PIP code	* Marketing status		Marketing start	Marketing end	
		Never marketed	~			
	2345670	Not marketed	~	01/12/2023	05/12/2023	20
	3456780	Not marketed	~	01/12/2023	07/12/2023	20
		Never marketed	~			
	1234560	Not marketed		01/10/2022		
		2345670 3456780 1234560	Never marketed 2345670 Not marketed 3456780 Not marketed Never marketed 12345670 Not marketed Never marketed Never marketed	Never marketed 2345670 Not marketed 3456780 Not marketed Never marketed	Never marketed 01/12/2023 2345670 Not marketed 01/12/2023 3456780 Not marketed 01/12/2023 Never marketed 01/12/2023	Never marketed 01/12/2023 05/12/2023 2345670 Not marketed 01/12/2023 05/12/2023 3456780 Not marketed 01/12/2023 07/12/2023 Never 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.

<u>Never delete rows that describe a historical marketing period when you start a new period.</u> 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.

Announce Marketin	ig Date			
Marketing data Exception	Confirmation Page Clo			
Marketing data for ABC 10) mg - Filmtabletten			
	Add row			
	Marketing Date	Sunset Date	Actions	
	01/12/2023	07/12/2023	1	
Sunset Reason	plaza calact			
Suilset Redson	piedse select		v	
	Back Next Return to O	verview		

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

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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

Overvie	w Medicinal Products							
Edit 👻 👌	View 👻 國 🔯 🖬 Full Screen							
	АВС	143692						
Reference	Name of Medicinal Product $ riangleq$	Authorisation Numb	MR/DC/CP Number	Authorisatio 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

View -	11-14	Contribut	Description	Chathan	Davies	010	a staductiva atabia	Manda a start	Madaable and
ackage size	Diece(s)	Bister	10 Stück in Alu/PVC-Bister	valid	Device	PIP Code	· Marketing status	Marketing start	Markeung end
0	piece(s)	Bister	50 Stück in Alu/PVC-Blister	valid			~		
	piece(s)	Blister	14 Stück in Alu/PVC-Blister	valid			~		
)	piece(s)	Blister	30 Stück in Alu/PVC-Blister	valid		3456789	~		
	piece(s)	Bister	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.

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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 dat	a Exception Conf	firmation Page Closing	g Page						
Marketing data	for ABC 5 mg - Film ges are listed belo [.]	n tabletten w, please contact yo	our contact point according to all	ocation scheme (h	tps://www.basg.gv.at/	en/how-to-contact-us)			
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 V		, manual y and
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.

<u>Never delete rows that describe a historical marketing period when you start a new period.</u> 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.

Announce Marketin	ig Date			
Marketing data Exception	n Confirmation Page C			
Marketing data for ABC 5	mg - Filmtabletten			
	Add row			
	Marketing Date	Sunset Date	Actions	
	01/08/2021 🍪	07/12/2023	i i	
Sunset Reason	please select		~	
Suiser Neuson	product delett			
	Back Next Return to (Overview		



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4.2 Drug shortage/ National Stockpiling

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 <u>Guidance notes: Medicine Shortages</u> (L I242) or <u>Guidance notes: National Stockpiling (L I285)</u>.

eServices "Authorisation and Lifecycle of Medicinal Products"	Overview Medicinal Products Edt View + Image: Second Sec										
	Announce Marketing Date										
New Application	Announce Medicine Shortage	Authorisation Number	MR/DC/CP Number	Authorisation	Status	Marketing	Sunset Date	Sunset Reason	Legal Base		
	Withdrawal according to §23 AMG	142902		6/19/2025	authorized	Date			Known active subs		
Current Applications	Announce temporary reduction of stock gr	142802		6/18/2025	authorized				Generic application		
	104371 Test 25 mg Kapseln	142804		6/18/2025	authorized				Known active subs		
	104371 Test 1 mg Pulver für ein Konzentrat zur	142801		6/18/2025	authorized				Generic application		
Completed Applications											
Overview Medicinal Products											

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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.

eServices "Authorisation and Lifecycle of Medicinal Products"	Overview Medicinal Products									
New Application	Announce Marketing Date Announce Medicine Shortage Withdrawal according to 523 AMG	norisation Number	MR/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base	Risk class
Current Applications	Announce temporary reduction of stock 1428 104371 Test 25 mg Kapseln 1428	803 802 804		6/18/2025 6/18/2025 6/18/2025	authorized authorized authorized				Known active subs Generic application Known active subs	
Completed Applications	104371 Test 1 mg Pulver für ein Konzentrat zur 1428	301		6/18/2025	authorized				Generic application	
Overview Medicinal Products										
eServices "Authorisation ar Lifecycle of Medicinal Products"	d Withdrawal according to §23 Al	MG - Test 1	L5 mg Kapse	n - Auth	.Nr. 142	803				
New Application								Enter data	Confirmation Fi) nish
Current Applications	Please note * Mandatory	Field	😢 Err	or Message	8					
Completed Applications	* The withdrawal of the marketing authorisation is effective	n/reg- e from	m/d/yyyy	20						
Overview Medicinal Products	* The withdrawal is based on any of the foll re	lowing	please select	۷						
	* Are there any marketing authorisations with i cal active substance and indication in Austria	identi- avail- able?	🔿 No 🔿 Yes							
eServices "Notification of p products"	et * Any inpact perceived on further marketing au sation of the same	uthori- MAH?	🔿 No 🔿 Yes							
New Application	* Information update for users about this withd is inter 	drawal ended?	🔿 No 🔿 Yes							
Current Applications		nments								li.
Completed Applications	Back Next	Cancel								

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.





4.4 Export packages of a medicinal product

As of July 2025, the BASG/AGES MEA will provide an excel export of the packs available in our database per medicinal product for **human** use. The function lists the pack data in real time, so it may take a few seconds before the download is available. The file name contains the authorisation number followed by the time of the call.

											logged in as pharosq2.test@ages.at, Q2-Testfirma-R-6-16-0	
eServices "Authorisation and Lifecycle of Medicinal	Overview Me Edit • View •	Iverview Medicinal Products Edt + Vew + Image: Mail Screen										
Products	test	Export all medicinal products										
New Application	Reference Name o	Export package information of	of a medicinal product	/DC/CP Number	Authorisation date	Status	Marketing Date	Sunset Date	Sunset Reason	Legal Base	Risk class	
	104371 Test 15	mg Kapseln	142803		6/18/2025	authorized				Known active subs		
Current Applications	104371 Test 2 n	ng Pulver für ein Konzentrat zur	142802		6/18/2025	authorized				Generic application		
	104371 Test 25	mg Kapseln	142804		6/18/2025	authorized				Known active subs		
Completed Applications	104371 Test 1 n	ng Pulver für ein Konzentrat zur	142801		6/18/2025	authorized				Generic application		
Overview Medicinal Products												

The excel contains the following columns and is available in German and English. If catalogue values are used in our database, the TermID from SPOR RMS is also specified. If columns are empty, the BASG/AGES MEA has no information in this regard (e.g: Description: no English translation of the free text description is saved).

	Column name
А	Name der Arzneispezialität / Name of Medicinal Product
В	Zulassungsnummer / Authorisation Number
С	Packungsgsgröße / Package size
D	Einheit
E	Unit
F	TermID Einheit / Unit
G	Packungsnummer / Package number
Н	Beschreibung
Ι	Description
J	Pharmazentralnummer / PIP code
К	Container Anzahl / Container amount
L	Container DE
М	Container EN
Ν	TermID Container
0	Packungsgröße IDMP Anzahl / Packsize IDMP numeric value
Р	Packungsgröße Einheit IDMP unit of presentation
Q	Packsize Unit IDMP unit of presentation
R	TermID Packungsgröße Einheit / Packsize Unit IDMP unit of presentation
S	Darreichungsform Manufactured Item
Т	Pharmaceutical dose form Manufactured Item
U	TermID Darreichungsform MI / Pharmaceutical dose form Manufactured Item
V	Applikationshilfe
W	Administration Device

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Х	TermID Applikationshilfe / Administration Device					
Y	Packungsstatus					
Z	Package status					
AA	TermID Packungsstatus / Package status					
AB	Packungsstatus seit / Package status since					
AC	Vermarktungsstatus					
AD	Marketing status					
AE	Term ID Vermarktungsstatus / Marketing status					
AF	Vermarktungsstart / Marketing start					
AG	Vermarktungsende / Marketing end					

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 <u>rms@basg.gv.at</u>.

You can also apply for Certificate for a Pharmaceutical Product (CPP) in this area. Information on this can be found on the <u>BASG website</u> and in the <u>User Manual: Application for</u> <u>confirmation of office (L M76)</u>.

GERMAN ENGLISH				Ba	ck to Portal Contact Imprint FAQ Support Log
Austrian Federal Office for Sa Austrian Medicines and Medic Traisengasse 5 1200 Vienna	afety in Health Care al Devices Agency			曫	Austrian Federal Office for Safety in Health Car Austrian Medicines and Medical Devices Agency
25/06/2025 02:24 PM					
				logged in	as pharosq2.test@ages.at, Q2-Testfirma-R-6-16-
eServices "Authorisation and	New Application				
Products"	* Procedure	×			
New Application		Application for a partificate of marketing suthering transition			
Current Applications		Application for a certificate of marketing autonsation/registration Application for a certificate of the manufacture			
Completed Applications		Presubmission DCP Presubmission MRP			
Overview Medicinal Products		Presubmission RMS-Transfer			
		Presubmission RUP			
		Presubmission Splitting			

