



Guidance notes for the notification of national stockpiling

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According to the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024), all marketing authorisation holders must have sufficient stock from 21 April 2025 in Austria if they place medicinal products for human use listed in the annex to the ordinance on the market. The four-months demand throughout Austria must be transferred to stock and is calculated from the total number of packs dispensed per PIP code in the entire previous calendar year.

All marketing authorisation holders affected by the ordinance will be notified by the Austrian Federal Office for Safety in Health Care (BASG) via the e-mail address(es) registered in the lifecycle management (LCM) subject area from the electronic user administration of the eServices that a stockpiling demand notification must be submitted for the medicinal products listed in the annex. This must be done annually by 31 March of each calendar year at the latest, using the application eServices "Authorisation and Lifecycle of Medicinal Products". For the year 2025, in which the Ordinance on Stockpiling of Medicinal Products for Human Use comes into force, marketing authorisation holders can submit their stockpiling demand notification by 21 April 2025. After positive feedback from the BASG, the required quantity must be stockpiled as soon as possible.

A temporary reduction of stock must be reported to the BASG immediately via the eServices portal for the following reasons:

- an increased demand of at least 25% compared to the calculated demand pursuant to Section 2 (2) of the Ordinance,
- force majeure or other unforeseeable events or
- to fulfil the European solidarity mechanism

The amount of the temporary reduction of stock, the expected duration and all documents to enable the BASG to assess the issue need to be attached to the notification. Temporary reduction of stock resulting from the usual circumstances of a rolling warehouse system are not subject to reporting.

A notification of the temporary reduction of stock is only possible after the stockpiling demand notification has been concluded by the BASG.



Austrian
Federal Office for
Safety in Health Care
BASG

1 General information

The following authority is responsible for enforcing the provisions of the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024)

Austrian Federal Office for Safety in Health Care (BASG)
Traisengasse 5, 1200 Vienna

The operational handling of the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024) is the responsibility of the:

Austrian Federal Office for Safety in Health Care (BASG)
Institute Surveillance
Traisengasse 5, 1200 Vienna

Contact details for stockpiling issues: bevorratung@basg.gv.at



2 Registration for the eServices "Authorisation and Lifecycle of Medicinal Products"

Existing registrations can continue to be used. The notification was integrated into the existing eServices "Authorisation and Lifecycle of Medicinal Products".

New registrations to receive access data can be requested on the BASG website in the section "[Registration online services](#)".

Access data will be sent to the applicant after successfully completing the registration process.

After receiving the access data, the stockpiling demand notification can be performed in the eServices "Authorisation and Lifecycle of Medicinal Products".

Further details for the registration are published on the BASG website in the section "[Guidance notes](#)" or in the guidance notes "[For the registration of companies/organisations \(L M49\)](#)".

3 Authorisations required for the submission of stockpiling demand notifications

To submit notifications, authorisations are required in the eServices portal "Authorisation and Lifecycle of Medicinal Products" which are issued on request (see "[FAQ online services - BASG](#)").

The following organisations are authorised to submit notifications:

- "**Holder**" of the concerned medicinal product (marketing authorisation holder)
- "**Authorised representative according to the marketing authorisation procedure**" of the medicinal product concerned (according to the marketing authorisation)

If the organisation is already registered, no further registration is required.

If the organisation is not yet registered, proceed according to chapter 2 "Registration for the eServices Authorisation and Lifecycle of Medicinal Products".



4 How to submit the stockpiling demand notification in the eServices Portal

All marketing authorisation holders affected by the ordinance will be notified by the BASG by e-mail using the e-mail address registered in the LCM subject area from the electronic user administration of the eServices that a stockpiling demand notification must be submitted for the medicinal products listed in the annex. This must be done annually by 31 March of each calendar year at the latest, using the application eServices "Authorisation and Lifecycle of Medicinal Products". Please note that for the year 2025, in which the Ordinance on Stockpiling of Medicinal Products for Human Use comes into force, you can submit your stockpiling demand notification by 21 April 2025.

The screenshot shows an email interface. The subject line is "Bevorratung Bedarfsmeldung Meldeverfahren 100340523 - Neues Verfahren im eService/Stockpiling demand notification reference number 100340523 - New procedure in eServices". The email content is in German and English. The German text says: "Sehr geehrte Damen und Herren, im Betreff genanntes Verfahren zur Bedarfsmeldung gemäß der Verordnung betreffend die Bevorratung von Humanarzneispezialitäten (BGBl II Nr. 161/2024) wurde am 05.11.2024 im eService vom BASG gestartet. Bitte geben Sie die Bedarfsmeldung über das eService des BASG ab. Betrifft: Test ASP 2024-08-12 06:50:52 23 mg. Bitte geben Sie bei jeglicher Kommunikation die Verfahrensnummer an. Mit freundlichen Grüßen Bundesamt für Sicherheit im Gesundheitswesen Traisengasse 5 A-1200 Wien". The English text says: "Dear Ladies and Gentlemen, The procedure mentioned in the subject line for the stockpiling demand notification in accordance with the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024) was started on 05.11.2024 in the eService by BASG. Please submit the stockpiling notification via the eService of BASG. Subject: Test ASP 2024-08-12 06:50:52 23 mg. Please quote the procedure number in all communications."

After logging in to eServices, click "Approval and Lifecycle ASP".

On the left-hand side you will find the navigation area and continue with „Current Applications“.

The screenshot shows a vertical navigation menu. The top section is titled "eServices 'Authorisation and Lifecycle of Medicinal Products'" and contains four items: "New Application", "Current Applications" (highlighted with a red box), "Completed Applications", and "Overview Medicinal Products". The bottom section is titled "eServices 'Notification of pet products'" and contains three items: "New Application", "Current Applications", and "Completed Applications".



The procedure can be searched for using the procedure number specified in the e-mail. All stockpiling procedures can also be filtered via the procedure type ("Stockpiling demand notification").

Select the row of the medicinal product to be stockpiled. Use the "Edit" function and "Edit demand for stockpiling" to access the notification form.

Current Applications

Edit View Full Screen

Communications (All/Pending/Closed)	latest message from BASG	Procedure Number	eMail addresses for n	European procedure	Name	Submission Date	Procedure Type
		100338791				10/25/2024	Stockpiling deman...
		100338803			Test ASP Lisa_Bevorratung	10/25/2024	Stockpiling deman...
		100338815			Test ASP 2024-07-08 09:47:54 23 mg	10/25/2024	Stockpiling deman...
		100338821				10/25/2024	Stockpiling deman...

Current Applications

Edit View Full Screen

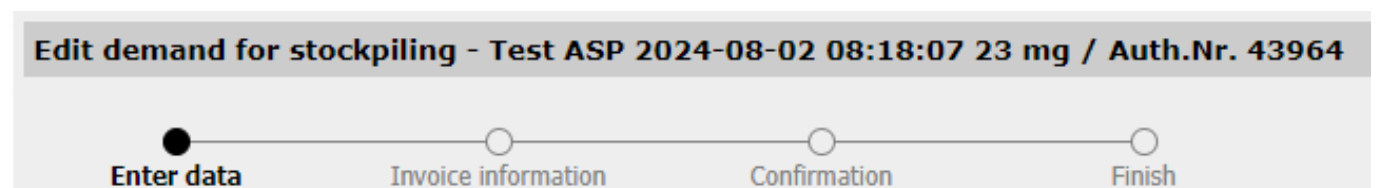
Communications (All/Pending/Closed)	latest message from BASG	Procedure Number	eMail addresses for n	European procedure	Name	Submission Date	Procedure Type
		100338890			Test ASP 2024-08-02 08:18:07 23 mg		

Edit eMail addresses for notifications
 Edit medicine shortage announcement
 Edit demand for stockpiling

The stockpiling demand notification process is divided into four sections:

- Enter data
- Invoice information
- Confirmation
- Finish

At the top of each page, these sections are listed as "Train", with the section currently accessed being highlighted in bold.



4.1 Entry of data

The respective demand must be entered for all packs in the "demand" field that are marked as "yes".

Edit demand for stockpiling - Test ASP 2024-08-02 08:18:07 23 mg / Auth.Nr. 43964

Enter data Invoice information Confirmation Finish

Please note * Mandatory Field Error Message

Pack size	Unit	Container	Description	PIP code	Stockpiling	* Demand
1	ml	Box	Antibiotika-Packung	0866665	yes	



If a pack size is not affected by the Ordinance on Stockpiling of Medicinal Products for Human Use, "No" is entered in the "stockpiling" field and no demand can be specified.

Stockpiling	* Demand
yes	
yes	
no	
no	

The four-months average of the quantity sold throughout Austria in the last calendar year according to the Annex to the Ordinance on Stockpiling of Medicinal Products for Human Use must be stored, i.e.


$$x = (\text{total sales in Austria in the previous calendar year}/12)*4.$$


As an aid, information on the calculation will also be displayed when you click in the "Demand" field.

			* Demand
4-month average quantity delivered in Austria in the last calendar year according to annex of the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024)			
0866660	yes		100
8666670	yes		
8666672	no		
8666671	no		

Once you have entered your demand data, click "next" to go to the next page.

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

05/11/2024 | 06:55 AM Procedure not listed? 

logged in as pharos.test@ages.at, AGES Medizinmarktaufsicht

eServices "Authorisation and Lifecycle of Medicinal Products"

New Application

Current Applications

Completed Applications

Overview Medicinal Products

eServices "Notification of pet products"

New Application


Current Applications

Completed Applications

Edit demand for stockpiling - Test ASP 2024-08-12 06:50:52 23 mg / Auth.Nr. 43970

● Enter data ○ Invoice information ○ Confirmation ○ Finish

Please note * Mandatory Field ❌ Error Message

View 

Pack size	Unit	Container	Description	PIP code	Stockpiling	* Demand
1	ml	Box	Antibiotika-Packung	0866660	yes	100
1	ml	Box	Antibiotika-Packung	8666670	yes	50
1	% (V/V)	Strip	Antibiotika-Packung	8666672	no	
1	A	Bottle	Antibiotika-Packung	8666671	no	



4.2 Invoice information

Under the item "Invoice information" the data for billing can be entered.

There are four options:

- **"Applicant is invoice recipient"**
- **"Use stored invoice recipient"** (this option will only be displayed, if an invoice recipient has been reported by the holder beforehand)
- **"Select a different invoice recipient using OMS data"**
- **"Enter different invoice recipient"**

If you select **"Applicant is invoice recipient"**, the information of the logged-in organisation is used to create the invoice.

In case you select **"Use stored invoice recipient"**, the invoice recipient reported by the market authorisation holder is used. This option will only be displayed, if an invoice recipient has been reported by the holder.

If you choose **"Select a different invoice recipient using OMS data"**, you can search for and select your organisation using the organisation name, your organisation ID (ORG ID) or location ID (LOC ID). All active organisations that are available in the Organisation Management Service (SPOR OMS) of the European Medicines Agency (EMA) are available for selection.

By choosing **"Enter different invoice recipient"**, enter the data for an alternative invoice recipient manually in the fields below.

If necessary, an additional order number (PO-No. - Purchase Order Number) can be assigned; this must be entered in the "Purchase Order Number" field in order to be taken into account for the creation of the invoice. Please note that the applicant is solely responsible for the correctness of the data entered.

Edit demand for stockpiling - Test ASP 2024-08-12 06:50:52 23 mg / Auth.Nr. 43970

○ Enter data ● **Invoice information** ○ Confirmation ○ Finish

Invoice Recipient

Applicant is invoice recipient
 Select a different invoice recipient using OMS data
 Enter different invoice recipient

* Company name	<input type="text" value="AGES Medizinmarktaufsicht"/>
Street	<input type="text" value="Traisengasse"/>
House number	<input type="text" value="5"/>
ZIP code	<input type="text" value="1200"/>
City	<input type="text" value="Wien"/>
State	<input type="text"/>
Country	<input type="text" value="Republic of Austria"/>
OrgId	<input type="text" value="LOC-10000004"/>
LocId	<input type="text" value="LOC-10000004"/>

Purchase Order Number (PO-No.)

Purchase Order Number



4.3 Confirmation page

The confirmation page provides you with an overview of the information you have entered. By submitting this control page, you confirm that the data is complete and correct.

Edit demand for stockpiling - Test ASP 2024-08-12 06:50:52 23 mg / Auth.Nr. 43970

Enter data Invoice information **Confirmation** Finish

Overview

* Medicinal product **Test ASP 2024-08-12 06:50:52 23 mg**

* Marketing authorisation holder **AGES Medizinmarktaufsicht**

* Contact details **Traisengasse 5
1200 Wien
Österreich**

* Date of report **05/11/2024**

View

Pack size	Unit	Container	Description	PIP code	Stockpiling	* Demand
1	ml	Box	Antibiotika-Packung	0866660	yes	100
1	ml	Box	Antibiotika-Packung	8666670	yes	50
1	% (V/V)	Strip	Antibiotika-Packung	8666672	no	
1	A	Bottle	Antibiotika-Packung	8666671	no	

Invoice Recipient

Applicant is invoice recipient
 Select a different invoice recipient using OMS data
 Enter different invoice recipient

* Company name AGES Medizinmarktaufsicht

Street Traisengasse

House number 5

ZIP code 1200

City Wien

State

Country Republic of Austria

OrgId LOC-10000004

LocId LOC-10000004

Purchase Order Number (PO-No.)

Purchase Order Number

By submitting these data I confirm the completeness and correctness of the information entered above.

Back **Submit** Cancel



4.4 Finish page

On the "Finish" page you will receive confirmation that the notification was successfully submitted. You will also receive a confirmation form at the e-mail address registered in the eServices portal. Furthermore, an individual procedure number is generated by the system. This number allows you to subsequently identify the procedure and, if necessary, further process or complete it.

Edit demand for stockpiling - Test ASP 2024-08-12 06:50:52 23 mg / Auth.Nr. 43970

○ ————— ○ ————— ○ ————— ●

Enter data Invoice information Confirmation **Finish**

Finish

Your notification has successfully been submitted. You will receive an email confirmation.

Procedure number: 100338932

If you have successfully submitted the stockpiling demand notification, the procedure will not be visible to you in the eServices portal until the BASG has completed its review.



5 Review of the stockpiling demand notification by the BASG

The plausibility of the demand data entered by the marketing authorisation holders is checked by the BASG.

5.1 Positive outcome of the review

If the plausibility test is positive, the marketing authorisation holders are going to be informed via the eServices portal and via the e-mail address(es) registered in the eServices portal and are requested to store the four-months demand. The letter confirming the completion of the stockpiling demand notification ("Approval Letter") will be made available in the "Completed Applications" section of the BASG eServices portal.

Procedure Number	European procedure	Name	Submission Date	Completion Date	Procedure Type	Classification	RMS status	Subject	all documents
100340523		Test ASP 2024-08-12 06:50:52 23 mg	11/5/2024	11/5/2024	Stockpiling deman...				Approval Letter SmPC (national translation) SmPC accessible (national translation) Package Leaflet (national translation) Package Leaflet accessible (national translation)

5.2 Negative outcome of the review

If the plausibility test is negative, a notification will also be sent via the eServices portal and by e-mail to the e-mail address(es) registered in the eServices portal, in which the marketing authorisation holders are requested to explain their calculated four-months demand, upload any documents for re-examination and, if necessary, correct the demand.

The procedure can still be found and edited under "Current Applications". The document "Subsequent request after negative plausibility test" is available in the documents section.

#	Portal Submission Date	Has to be done by	Ext. Communication State	Variationtype	Name of Objekt
3	11/5/2024				Test ASP 2024-08-01 06:31:54 23 mg

DocID	Document Type	Title	Comment	Objects of Concern	Create Date
15350952		Nachforderung nach negativer Plausibilitä...		Test ASP 2024-08-01 06:31:54 23 mg	11/5/2024

To edit the procedure, select the desired medicinal product. Click "Edit" and "Edit demand for stockpiling" to return to the editing page.

Procedure Number	eMail addresses for n	European procedure	Name
100338890			Test ASP 2024-08-02 08:18:07 23 mg



On the "Enter data" page, you can edit the demand and must provide a justification for your calculation of the demand data.

Edit demand for stockpiling - Test ASP 2024-08-09 06:35:12 23 mg / Auth.Nr. 43969

Enter data Invoice information Attachments Confirmation Finish

Please note * Mandatory Field Error Message

Pack size	Unit	Container	Description	PIP code	Stockpiling	* Demand	Justification	Status of plausibility test
1	ml	Box	Antibiotika-Packung	0866661	yes	134		positive
1	AgU/ml	Pre-filled pen	Packung	0866671	yes	167		positive
1	ml	Box	Antibiotika-Packung	0866670	yes	267		positive
1	AgU	Pre-filled pen	Packung	0866672	yes	70		negative

In the next step, the invoice information can be edited, see detailed explanation under "4.2 Invoice information".

In the third section, documents can be uploaded to enable the BASG to assess your demand calculation.

Edit demand for stockpiling - Test ASP 2024-08-09 06:35:12 23 mg / Auth.Nr. 43969

Enter data Invoice information Attachments Confirmation Finish

Attachments

* Document type

* File Keine Datei ausgewählt

Comment

Document list

Document type	File name	Comment
No data available		

In the next step, you are on the confirmation page and furthermore on the finish page of the initial stockpiling demand notification. For detailed explanations, please refer to „4.3 Confirmation page“ and „4.4 Finish page“.

You will also receive a confirmation form to the email address registered in the eServices portal.

Edit demand for stockpiling - Test ASP 2024-08-09 06:35:12 23 mg / Auth.Nr. 43969

Enter data Invoice information Attachments Confirmation Finish

Finish

Your notification has successfully been submitted. You will receive an email confirmation.

Procedure number: 100338920



5.3 Re-examination of the demand quantities after negative outcome of the review

After you have updated your data following a negative outcome of the plausibility test, the BASG reviews your stockpiling demand notification again. If the plausibility test can be completed positively, the marketing authorisation holder will be requested to store the four-months demand.

The 'Approval Letter' confirming the completion of the notification will be made available in the 'Completed applications' section of the BASG eServices and sent by e-mail to the e-mail address(es) registered in the eServices portal.

Completed Applications									
View - [Full Screen] Completion Date 6/5/2024 To 11/5/2024 Search									
Procedure Number	European procedure	Name	Submission Date	Completion Date	stockpiling	Classification	RMS status	Subject	all documents
100340523		Test ASP 2024-08-12 06:50:52 23 mg	11/5/2024	11/5/2024	Stockpiling deman...				download zip
Current Applications									
		Name	SmPC (national translation)	Approval Letter	SmPC accessible (national translation)	Package Leaflet (national translation)	Package Leaflet accessible (national translation)		
		Test ASP 2024-08-12 06:50:52 23 mg							
Completed Applications									
Overview Medicinal Products									

Any further review required after a negative plausibility test will be processed in accordance with points 5.2 and 5.3.

6 Fees

Procedures in accordance with the Ordinance on Stockpiling of Medicinal Products for Human Use (Federal Law Gazette II No. 161/2024) are charged in accordance with the applicable fee schedule ("[Gebührentarif](#)") after the procedure of the stockpiling demand notification has been completed.

7 Notification of the temporary reduction of stock

Detailed information on the notification of the temporary reduction of stock in the eServices portal will be added as soon as the complete IT infrastructure is available.