Austrian
Federal Office for
Safety in Health Care
BASG

# GUIDANCE NOTES for the notification of medicine shortages

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Since February 1, 2018, marketing authorisation holders and their authorised representatives have to submit medicine shortages electronically by using the application eServices "Authorisation and Lifecycle of Medicinal Products". Medicine shortages are published on the "Medicine shortages catalogue" on the actual date of beginning of the shortage. Marketing authorisation holders and their authorised representatives have to submit medicine shortages because of the Regulation on ensuring the Provision of Medicinal Products that entered into force as from April 1, 2020, and because of the "Austrian Ordinance on Good Manufacturing Practices". They are now obliged to report any restriction in supply of prescription-only human medicinal products using the eServices "Zulassung und Lifecycle ASP". The notification of a shortage affecting over-the-counter medicinal products is voluntary, unless it is subject to notification in accordance with the "Austrian Ordinance on Good Manufacturing Practices 2009". The notification of a shortage affecting veterinary medicinal products is voluntary.

## 1. General

The Austrian Federal Office for Safety in Health Care ("Bundesamt für Sicherheit im Gesundheitswesen", hereafter: BASG) publishes medicine shortages that are reported either by marketing authorisation holders or their authorised representatives or by the BASG itself on the basis of the Regulation on ensuring the Provision of Medicinal Products and the "Austrian Ordinance on Good Manufacturing Practices". Notifications pursuant to section 21 (2) of the "Austrian Medicines Act", referring to a temporary or permanent marketing cessation are not included.

The following authorities are responsible for enforcing the provisions of the ordinance of the Federal Minister of Social Affairs, Health, Care and Consumer Protection on ensuring the provision of medicinal products ("Verordnung über die Sicherstellung der Arzneimittelversorgung, hereafter: Regulation on ensuring the Provision of Medicinal Products) and the "Austrian Ordinance on Good Manufacturing Practices" ("Arzneimittelbetriebsordnung 2009" – AMBO 2009):

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

The operational handling of the Regulation on ensuring the Provision of Medicinal Products and the "Austrian Ordinance on Good Manufacturing Practices" is the responsibility of the:

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

Contact for reporting of medicine shortages:
mailto://medicineshortage@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 applied on the BASG website in the section "Registration online services".
Access data will be sent to the applicant after registration.

After receipt of these access data, medicine shortages can be notified in the eServices "Authorisation and Lifecycle of Medicinal Products".

Further details on registration are 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 medicine shortages notifications

~~are required~~ For the submission of notifications in the eServices "Authorisation and Lifecycle of Medicinal Products", authorisations are required, which are assigned on request.

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)
- "**Notifier medicine shortage**" for the medicinal product to be notified:
  The following authorised representatives of the marketing authorisation holder are intended for the role of "notifier medicine shortage":
  - Local representatives of the marketing authorisation holders or distributors, which are listed and clearly assigned in the package leaflet
  - Person(s) or companies authorised by the marketing authorisation holder

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

  If the organisation is not yet registered, proceed according to chapter 2.

  To obtain the role "notifier medicine shortage", send an e-mail to medicineshortage@basg.gv.at after registration and clearly state that you are the local representative of the marketing authorisation holder or the distributor or submit a power of attorney issued by the marketing authorisation holder to the entrusted company to perform this function for dedicated medicinal products.

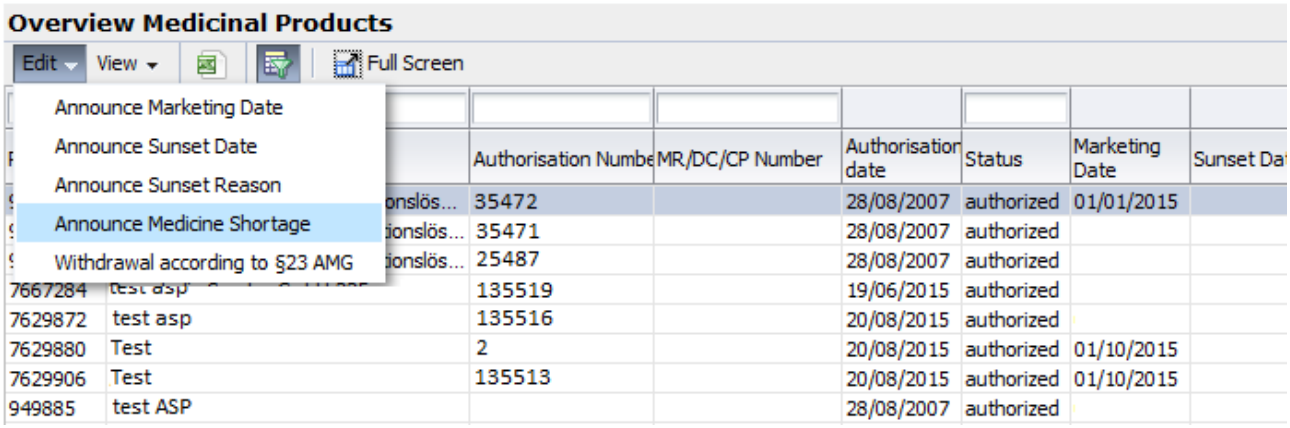
  In case of any change in the role of "notifier medicine shortage", the BASG must be informed immediately by e-mail notification to medicineshortage@basg.gv.at.

## 4. Notification of a medicine shortage

After logging in to the eService, click on "Authorisation and Lifecycle of Medicinal Products".

On the left side you will find the navigation area and continue with "Overview Medicinal Products".

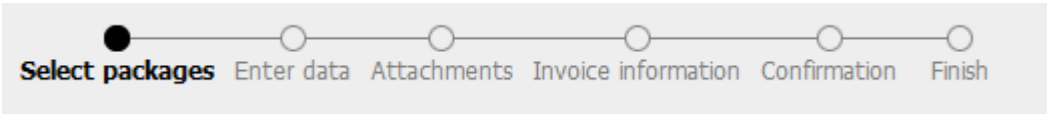
Mark the medicinal product, which is in shortage.
Click on the function "Edit", "Announce Medicine Shortage" to access the notification form.




The notification of a medicine shortage is divided into six sections:

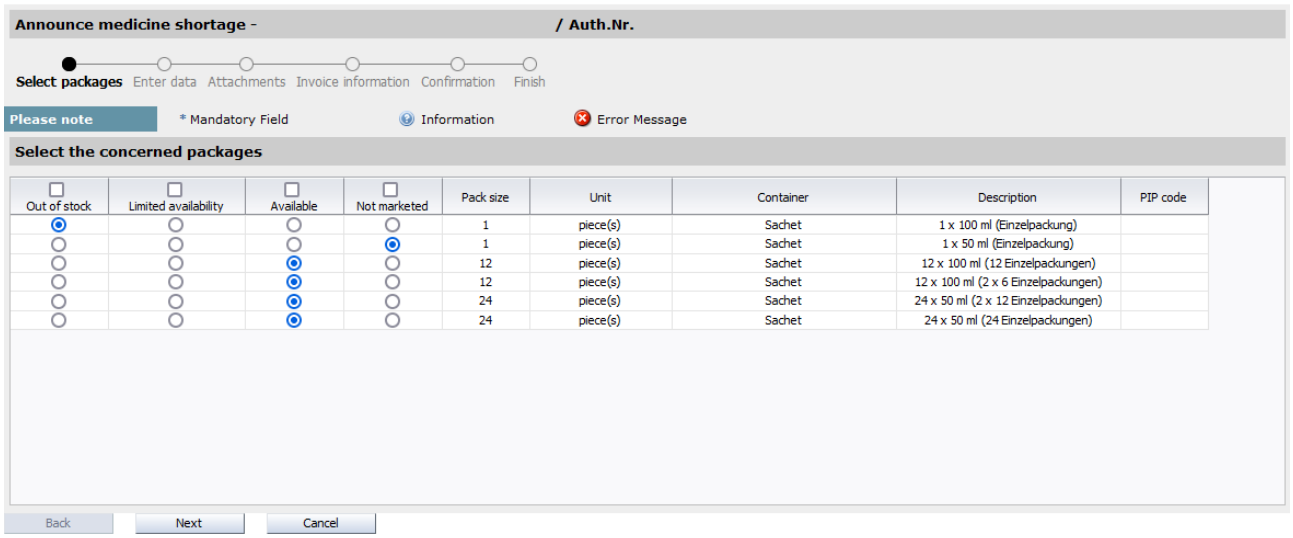
- Select packages
- Enter data
- Attachments
- Invoice information
- Confirmation
- Finish

At the top of each page, these sections are listed as a "train". The section you are currently accessing is highlighted in bold.



### 4.1. Select packages

In the first view, select the status of all approved pack sizes. You can make an individual adjustment of the delivery status of each pack size with "Out of stock", "Limited availability", "Available" and "Not marketed".



### 4.2. Enter Data

In the first section of the notification form, you have to select a suitable value of the provided catalogue for "Reason for the medicine shortage". If these specifications do not correspond to your reason, it is possible to enter another reason ("Other"). In this case, you have to type a description of the reason.

The catalogue values are as follows:

- Change of the pharmaceutical form
- Change in pack size
- Non compliance with legal requirements *
- Distribution stop due to a quality defect *
- Cybercrime: delays during release and distribution of the finished product
- Increased demand
- GMP inspection procedure of the manufacturer not yet completed *
- Manufacturer not GMP compliant *
- Capacity constraints at the manufacturing site
- Insolvency proceedings of the manufacturer or marketing authorisation holder
- Transfer of manucacturing to an alternative site
- Quality issues during manufacturing *
- Quality issues of the bulk *
- Quality issues of the finished product *
- Quality issues of the active substance *
- Regulatory changes
- Batch recall *
- Investigations at the manufacturer related to GMP issues *
- Shortage of the active substance
- Insufficient quota for Austria
- Delay in manufacturing
- Delay in the distribution due to implementation of the Falsified Medicines Directive *
- Delivery delay
- Delays during the release of the finished product
- Delays during the release of the active substance
- Constraints affecting packaging material availability
- Change of the marketing authorisation holder
- Temporary marketing cessation
- Other

For reasons marked with an asterisk (*), an investigation report (see point 4.7. ) must be submitted at the end of the procedure.
The catalogue value for the reason is displayed in the public registers *"Medicine Shortages Catalogue"* and *"Catalogue according to the Regulation on ensuring the Provision of Medicinal Products pursuant to Section 57a (2) of the Medicinal Products Act"* respectively.
You can write comments to the BASG via the comment field (for example, the possibility of importing medicinal products). Comments represent a communication between the applicant and the BASG and are not displayed in the public registers.

In the next part, you must enter the current stock level at the marketing authorisation holder (number of packs in stock at the time of initial notification), the beginning of the medicine shortage/limited availability and, optionally, the expected supply. The start date and the current stock level cannot be changed after the initial notificaton.

Furthermore, the following items are mandatory on the level of the medicinal product (please provide the information per authorised medicinal product and not on the package, active substance or indication level)

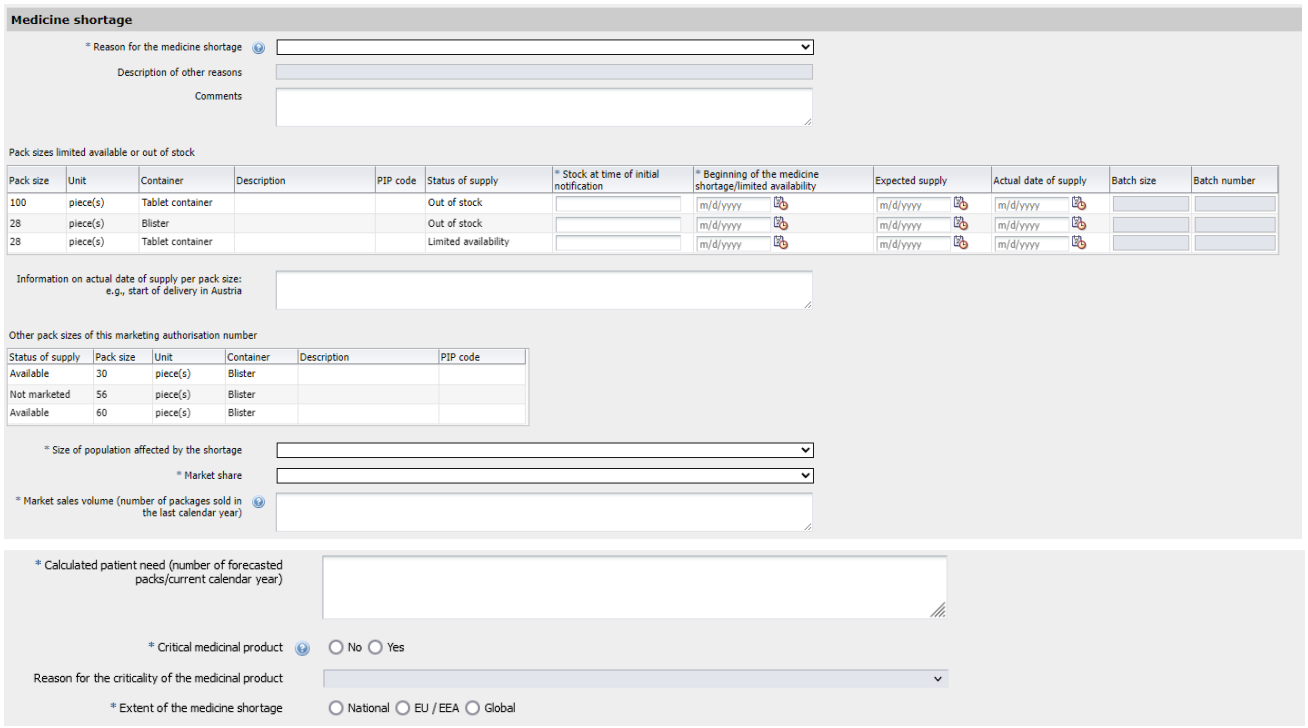
- Size of population affected by the shortage
- Market share
- Market sales volume (number of packages sold in the last calendar year)
- Calculated patient need (number of forecasted packs/current calendar year)

This information is confidential and the BASG uses it exclusively internally for assessing the notification. This data is not displayed in the public registers.

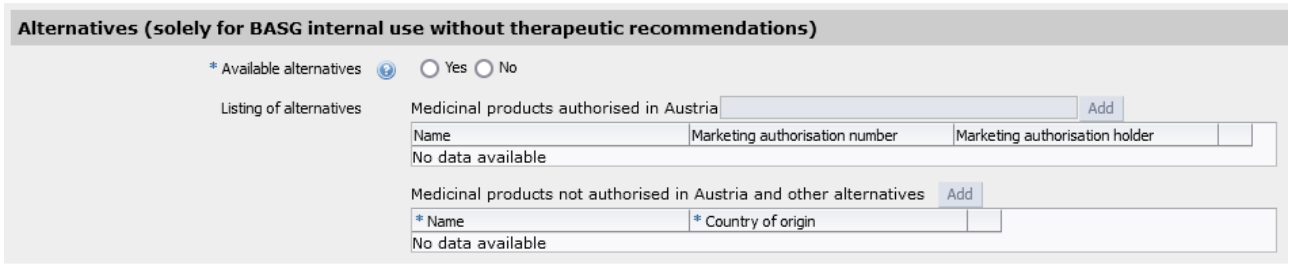
The following section concerns the criticality, whether the medicinal product is essential for the Austrian market with a yes / no selection. If yes, please classify regarding the *"Criteria for classification of critical medicinal products"* of the European Medicines Agency (EMA).
Therefore, the following catalogue values are available for "Reason for the criticality of the medicinal product":

- Therapeutic use (the medicinal product is an integral part of the treatment of a disease, which is life-threatening or irreversibly progressive, or without which the patient could be severely harmed).
- No alternative manufacturing site for the same product (caveat: manufacturing capacity)
- No alternative authorised medicinal (caveat: availability and volume)
- No different strengths/formulations of the same product
- No alternative dosing
- No alternative active substances to reach success of a therapy

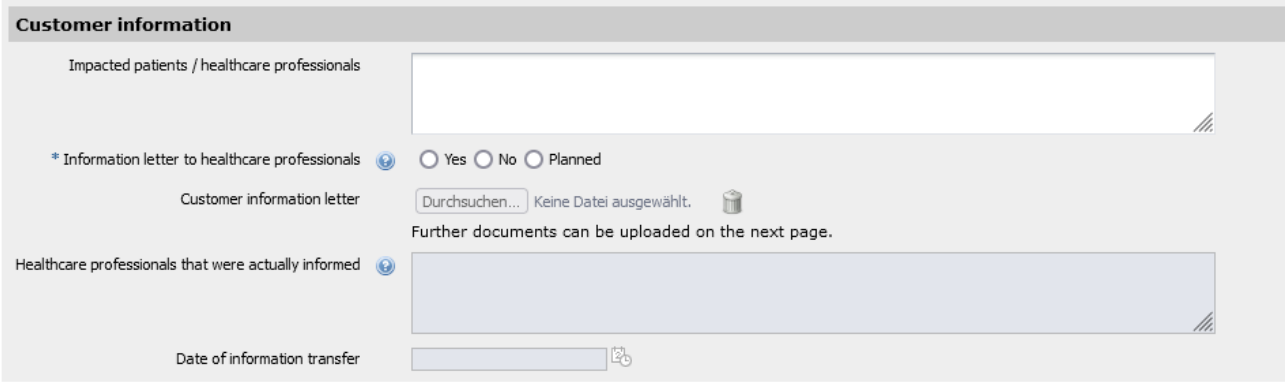
Furthermore, the extent of the medicine shortage is requested (national, EU/EEA or global). This information represents a communication between the applicant and the BASG and is not displayed in the public registers.




The second section concerns – solely for BASG internal use - necessary information on possible alternatives that are either available on the market or can be made available from abroad according to the "Austrian Act on the Import of Medicinal Products". If alternatives are available on the Austrian market, you can select and add medicinal products authorised in Austria through an autosuggest-function. For medicinal products not authorised in Austria or other alternatives, type in the name of the medicinal product and the country of origin manually.

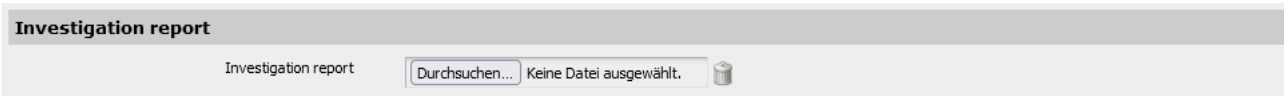


The third section refers to customer information and asks for information material on the existing shortage. In the first field, indicate the impacted patient group or healthcare professionals. In the field "Information letter to healthcare professionals", the selection option yes / no / planned indicates whether information has been provided or is planned to healthcare professionals, affected customers and other authorities. The value selected (yes / no / planned) is displayed in the public catalogues. In the next field, upload the customer information letter. Furthermore, fill in the actually informed customers (e.g. certain physicians, wholesalers) as well as the date of the information transfer. With the exception of the selected value in the field "Information letter to healthcare professionals", no information is displayed in the public catalogues.



The fourth section - measures and additional information - is primarily intended for those notifications that are related to a quality defect or a notification according to Section 34 "Austrian Ordinance on Good Manufacturing Practices". The manufacturer must investigate the quality defect, the root cause and has to address appropriate corrective and preventive measures. Please note that in the case of a quality defect according to Section 75q Austrian Medicines Act, you must notify am-qualitaetsmangel@basg.gv.at using the respective form. Further information is on the BASG website for "Quality defects".


The fifth section is for uploading the investigation report if the reason for the shortage relates to a quality defect. For all other reasons, no investigation report is needed. Upload the investigation report at the least when the actual date of supply comes into force in order to close the procedure. You will receive a reminder by e-mail if the investigation report has not been submitted within 14 days after the actual date of supply.



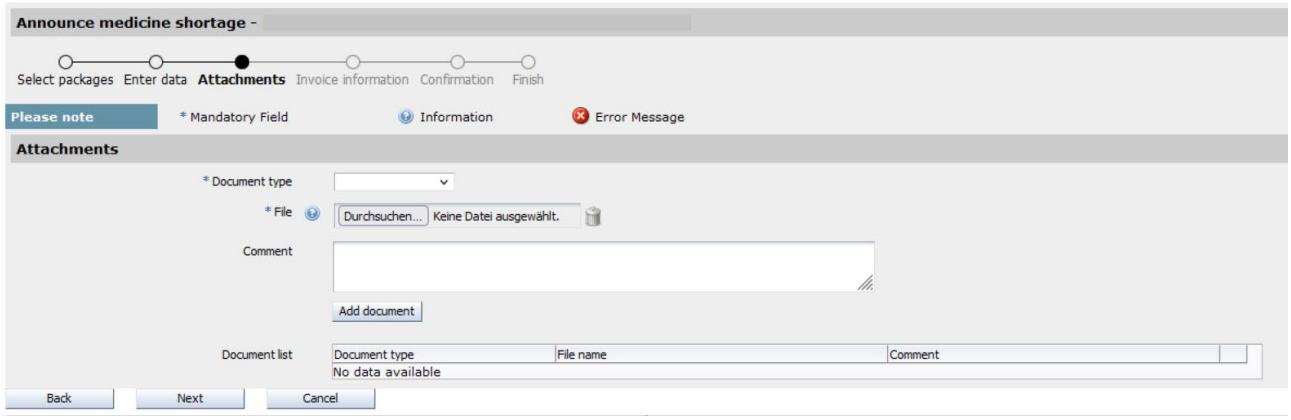

The sixth section is for entering a telephone number that will be published in the public catalogues in order to ensure that patients and healthcare professionals are able to address any queries.

If all mandatory fields (marked with *) have been filled in, you are forwarded to the control page by clicking "Next".

If mandatory fields (*) are not filled in, you will be reminded by a corresponding mark and information.

The "Back" button takes you to the previous page; the "Cancel" button allows you to discard the notification.

On the next page, there is the possibility to add further (Other) documents such as a cover letter. If a customer information letter and/or an investigation report was uploaded in the section "Enter data", there is also the selection "Attachment to the customer information letter" and/or "Attachment to the investigation report" in the drop-down menu. The uploaded documents are for solely for the BASG and are not displayed in the public registers.



### 4.3. 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"
- "Select a different invoice recipient using OMS data"
- "Enter different invoice recipient"

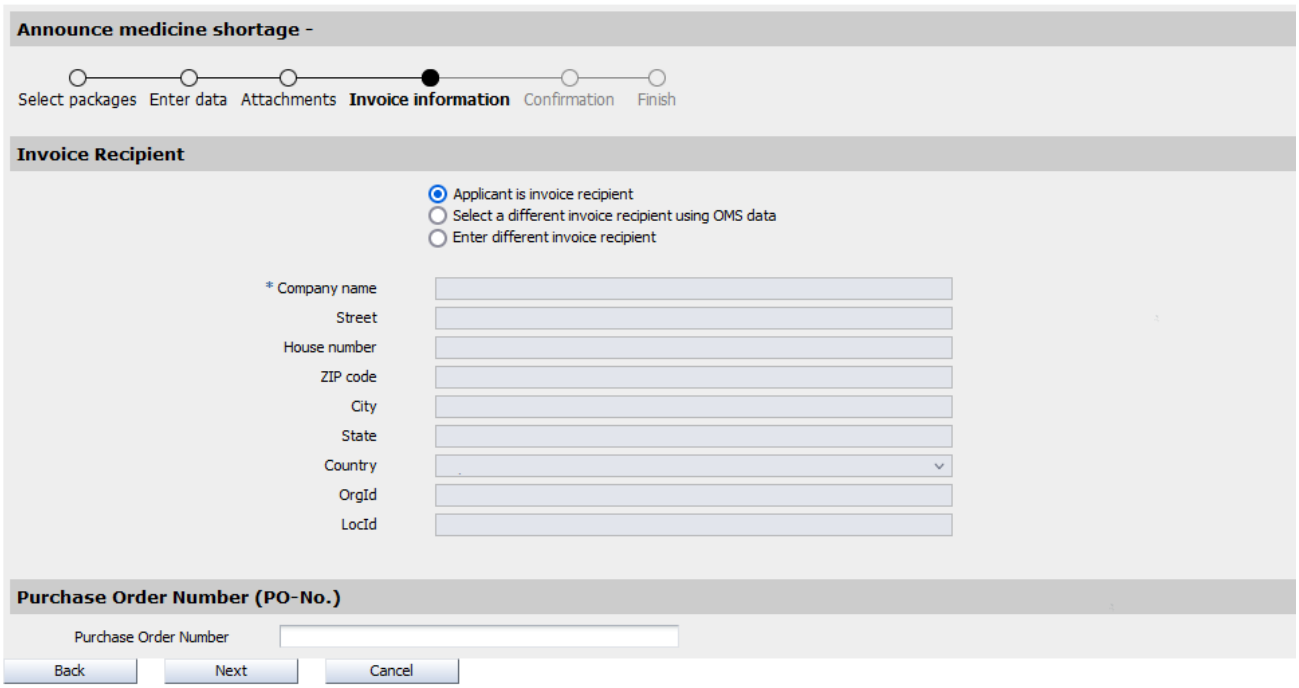
If you select "Applicant is invoice recipient", the information of the logged-in organisation is used to create the invoice.

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

If you have selected "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.

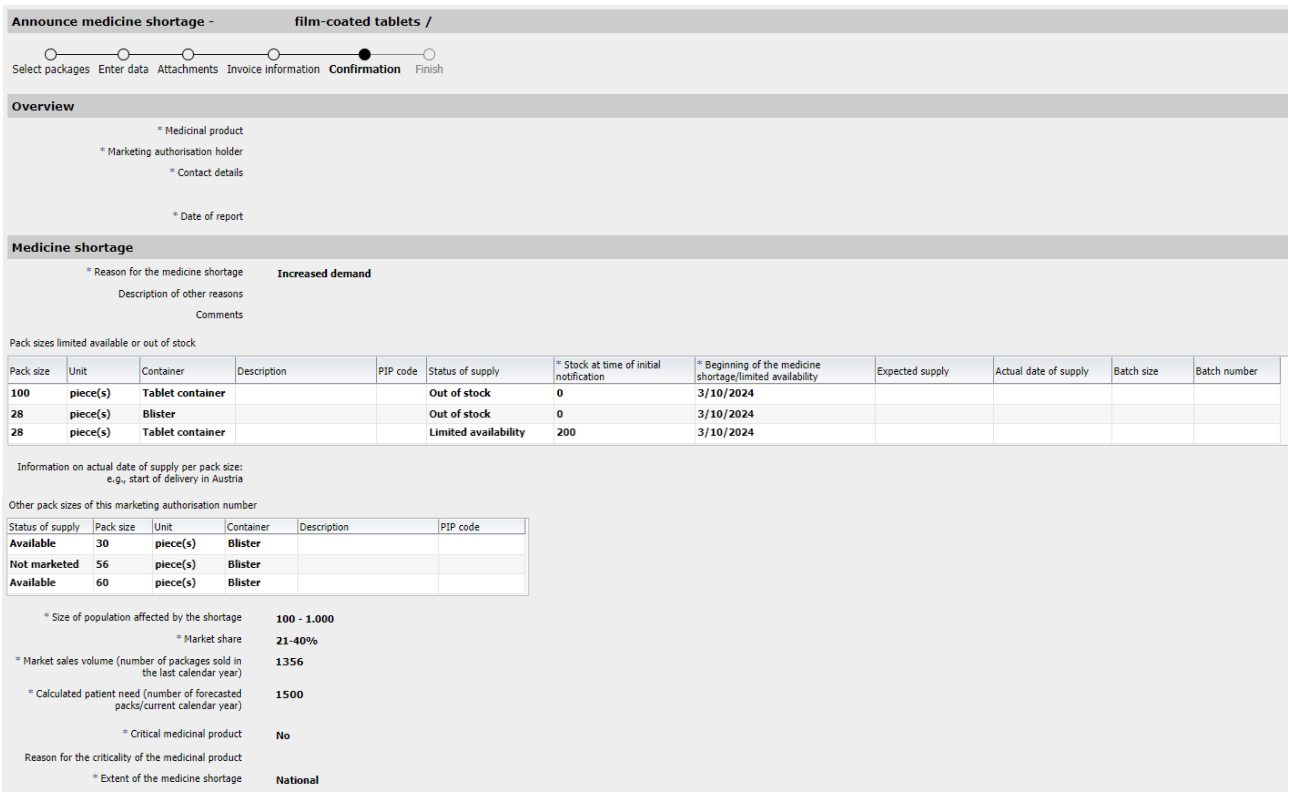
With "Enter different invoice recipient", enter the data for an alternative invoice recipient manually in the fields below.

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.




### 4.4. Confirmation page

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



**Announce medicine shortage - film-coated tablets /**

Select packages – Enter data – Attachments – Invoice information – **Confirmation** – Finish

**Overview**

* Medicinal product
* Marketing authorisation holder
* Contact details
* Date of report

**Medicine shortage**

* Reason for the medicine shortage: **Increased demand**
Description of other reasons
Comments

Pack sizes limited available or out of stock

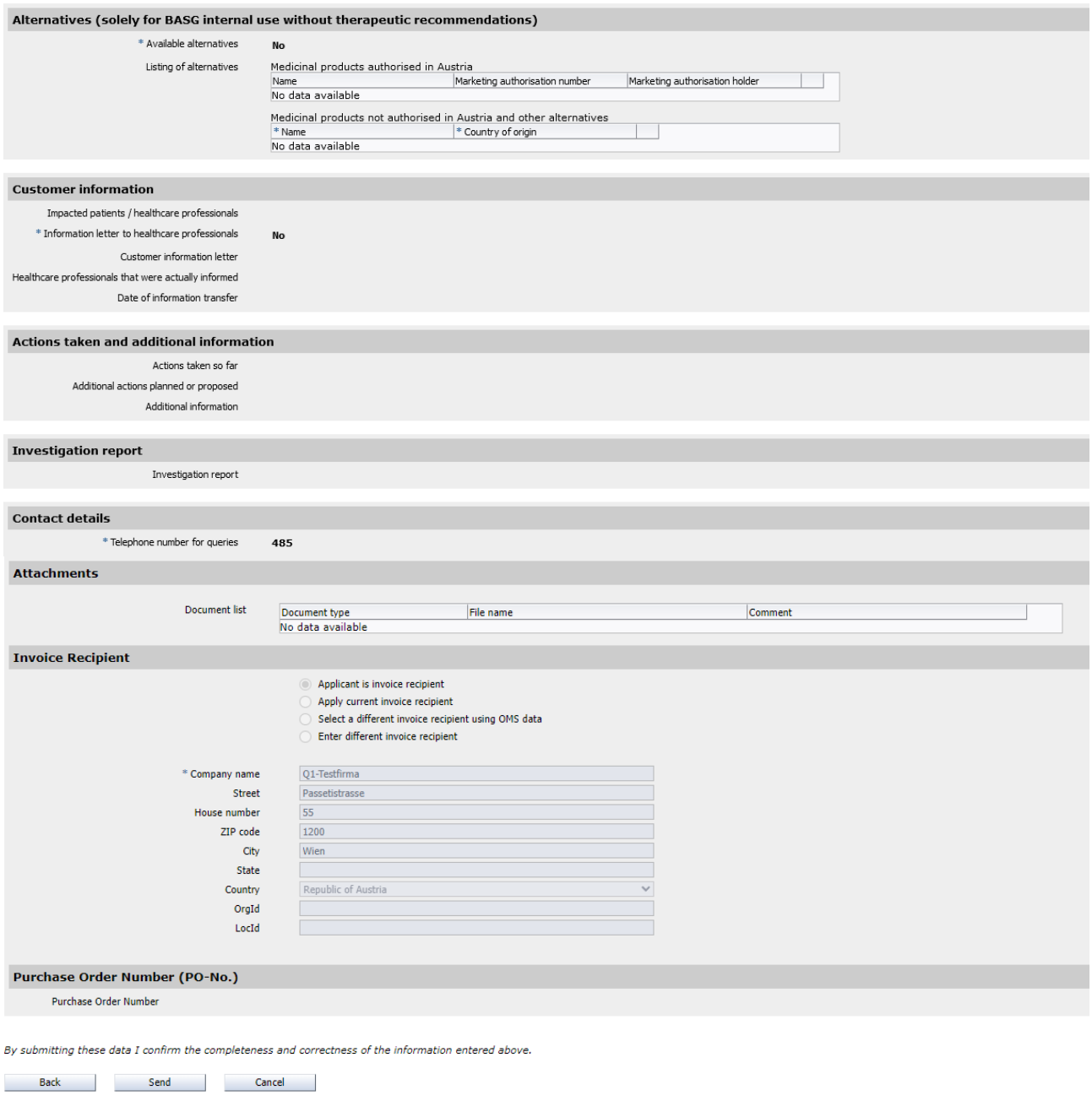
| Pack size | Unit | Container | Description | PIP code | Status of supply | * Stock at time of initial notification | * Beginning of the medicine shortage/limited availability | Expected supply | Actual date of supply | Batch size | Batch number |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 100 | piece(s) | Tablet container | | | Out of stock | 0 | 3/10/2024 | | | | |
| 28 | piece(s) | Blister | | | Out of stock | 0 | 3/10/2024 | | | | |
| 28 | piece(s) | Tablet container | | | Limited availability | 200 | 3/10/2024 | | | | |

Information on actual date of supply per pack size: e.g., start of delivery in Austria

Other pack sizes of this marketing authorisation number

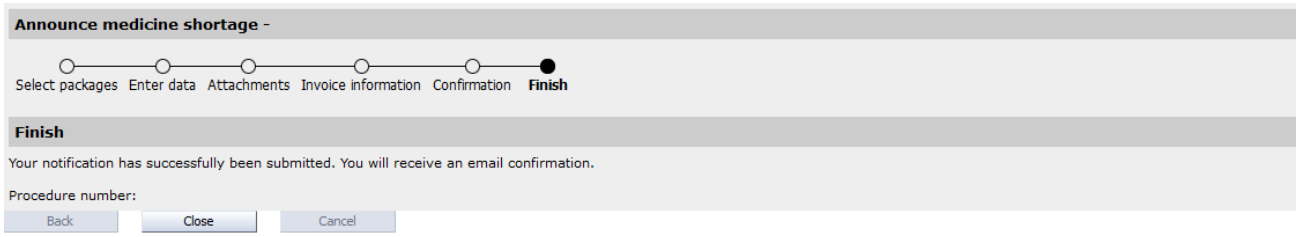
| Status of supply | Pack size | Unit | Container | Description | PIP code |
|---|---|---|---|---|---|
| Available | 30 | piece(s) | Blister | | |
| Not marketed | 56 | piece(s) | Blister | | |
| Available | 60 | piece(s) | Blister | | |

* Size of population affected by the shortage: **100 - 1.000**
* Market share: **21-40%**
* Market sales volume (number of packages sold in the last calendar year): **1356**
* Calculated patient need (number of forecasted packs/current calendar year): **1500**
* Critical medicinal product: **No**
Reason for the criticality of the medicinal product
* Extent of the medicine shortage: **National**




## 4.5. Finish page

On the "Finish" page you will receive a confirmation that the notification was successfully submitted. You will also receive a written confirmation of the form to the e-mail address of your eServices account. 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.




The following information from your notification will be published in the public catalogues after assessing the notification:

- On the overview page:
  - Name of the medicinal product
  - In the "Medicine shortages catalogue": Status (out of stock, partially available, available according to §4 (1)*, available)
  - In the "Catalogue according to the Regulation on ensuring the Provision of Medicinal Products": Parallel export ban: yes
  - Applicant
  - PIP code of not available packs
  - PIP code of limited available packs
  - PIP code of packs, that are available again
  - Marketing authorisation number (hidden by default)
  - Procedure number (hidden by default)
  - Date of report
  - Last modification date

* *According to the Regulation on ensuring the Provision of Medicinal Products.*

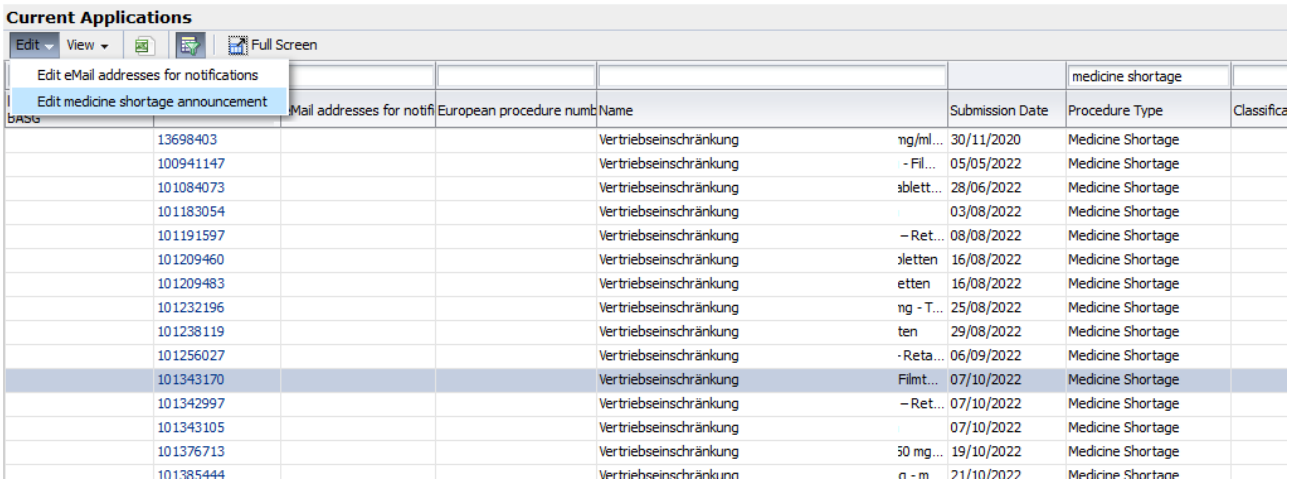
- On the detailed page:
  - Name of the medicinal product
  - Marketing authorisation number
  - Strength
  - Dosage form
  - Marketing authorisation holder
  - Telephone number of marketing authorisation holder
  - Date of report
  - Reason for the medicine shortage
  - Active substances
  - Information letter to healthcare professionals: yes / no
  - Legal basis of the notification
  - Important BASG-information
  - PIP code of not available / partially available packs
  - Pack size
  - Unit
  - Container
  - Description
  - Status of supply: out of stock, partially available, available according to §4 (1) or available
  - Beginning of the medicine shortage / limited availability
  - Date of the expected supply
  - Actual date of supply
  - PIP code of available packs of the medicinal product, if applicable
  - If applicable, pack size of available packs
  - If applicable, unit of available packs
  - If applicable, container of available packs
  - If applicable, description of available packs

### 4.6. Modification of the ongoing procedure

In order to be able to edit or close an ongoing medicine shortage, you will find the navigation area with "Current Applications" on the left side.

In the overview, you can search for your report with either the procedure number or the procedure type "Medicine Shortage".

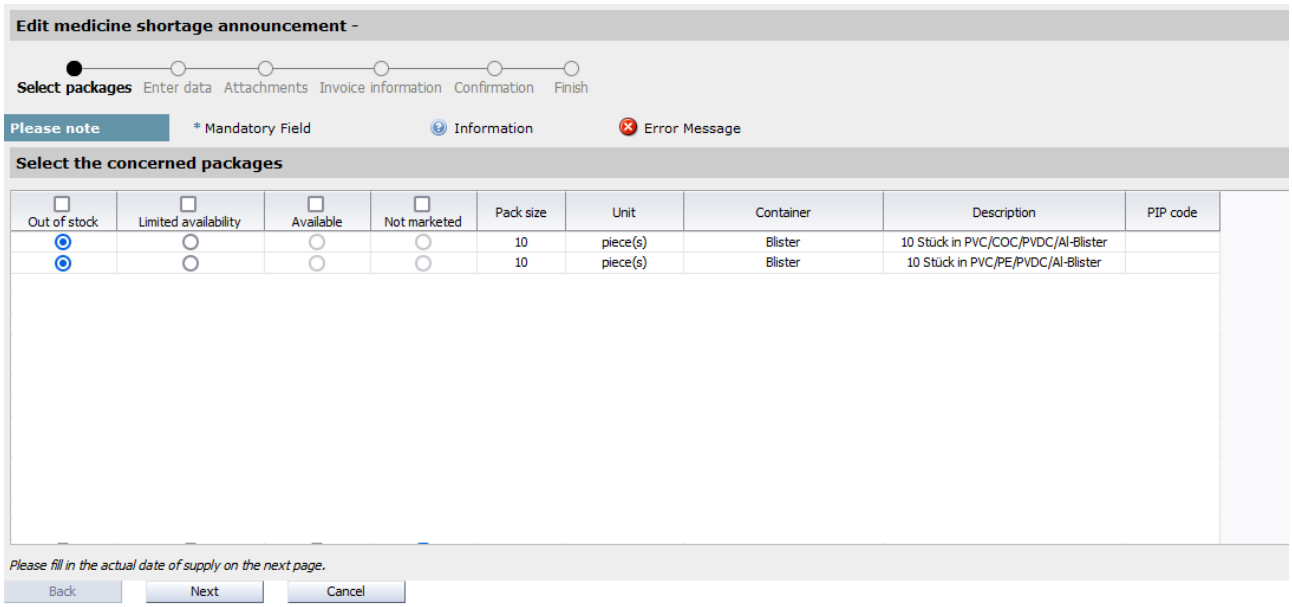
Mark the row of the medicinal product in the list and click on "Edit", "Edit medicine shortage announcement" to return to the notification form.



On the first page of the announcement form, the pack sizes are listed again.

On this page, the supply status of the pack size can only be changed from "Out of stock" to "Limited availability" or *vice versa*. If the delivery status is "Available" or "Not marketed", reset the status as desired.

Note: A pack size that has been reported as "limited available" or "out of stock" cannot be changed to "available" in the "Select packages" tab. For this purpose, you have to enter an actual date of supply in the next tab "Enter data". See also chapter 4.7. "Completion of the current procedure". The start date of the medicine shortage/limited availability and the stock level at the time of the initial notification cannot be changed after the initial notification..




After entering the updated data in the "Enter data" area, please confirm the changes on the control page. You will then receive a confirmation by e-mail. The procedure number will not change.

### 4.7. Completion of the current procedure

Proceed as described in Chapter 4.6 and enter the actual date of supply in "Enter data".

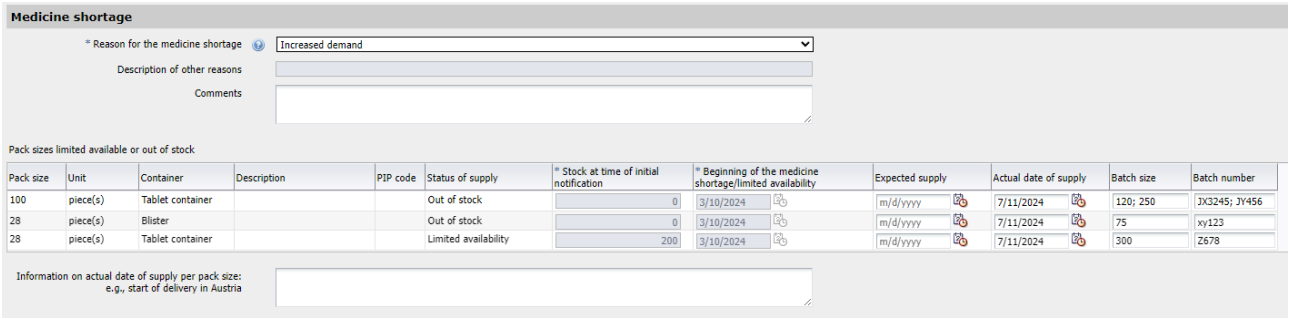
If an actual date of supply has been entered for all pack sizes referring to an out of stock or limited availability,two further text fields ("Batch size" and "Batch number") are activated. . These mandatory fields must be filled in with the relevant information for each pack size.

In the field "Information on actual date of supply per pack size", the start date of actual delivery in Austria can be specified if this differs from the actual resupply date, and further voluntary information can be added.

This information is only used internally by the BASG for verification purposes to be able to complete the procedure.

If the medicine shortage has occurred due to a quality issue or a batch recall, an investigation report is mandatory for the successful completion of the procedure.

If the investigation report is not uploaded within 14 days after the latest actual supply date, you will automatically receive a reminder by e-mail. Medicinal products that are completely available again are visible in the "Medicine shortages catalogue" with the status "Available". For traceability purposes, this status is displayed for three weeks; afterwards the entry is automatically removed from the register.



## 5. Form confirmation

After submitting the electronic announcement, you will receive a PDF file by e-mail from "medicineshortage@basg.gv.at". The PDF attachment contains a confirmation from the BASG on the first page, followed by the notificaton data entered in the eServices "Authorisation and Lifecycle of Medicinal Products".

## 6. Medicine shortages catalogue

The two public registers are:

- „Shortages catalogue" (common catalogue)
- „Catalogue according to the Regulation on ensuring the Provision of Medicinal Products"

The "Shortages catalogue" represents all reported procedures. BASG assesses all prescription-only human medicinal products before publication. Voluntary announcements of e.g. over-the-counter medicinal products not subject to notification in accordance with the "Austrian Ordinance on Good Manufacturing Practices" are automatically published. The publication in the "Shortages catalogue" starts at the actual start of the shortage.

Further information on the medicine shortage can be gathered in the column "Details" by clicking on "display". On the detailed page, information from the BASG is present if necessary (e.g. the possibility of importing medicinal products).

## 7. Catalogue according to the Regulation on ensuring the Provision of Medicinal Products

The "Catalogue according to the Regulation on ensuring the Provision of Medicinal Products" is based on the same data as the "Shortages catalogue", but is restricted to those medicinal products having an export ban after assessment by the BASG.

The BASG assesses an export ban according to the criteria of the dedicated decision tree (see FAQ Notification medicine shortages).

The announcements are made available on the BASG website in the "Catalogue according to the Regulation on ensuring the Provision of Medicinal Products" at the actual start of the export ban.

Further information on the medicine shortage can be gathered in the column "Details" by clicking on "display". On the detailed page, information from the BASG is present if necessary (e.g. the possibility of importing medicinal products).

## 8. Fees

Since July 1, 2020, procedures according to the Regulation on ensuring the Provision of Medicinal Products are charged in accordance with the applicable fee schedule ("Gebührentarif").