



## **Guidance notes for the administration of users and user rights**

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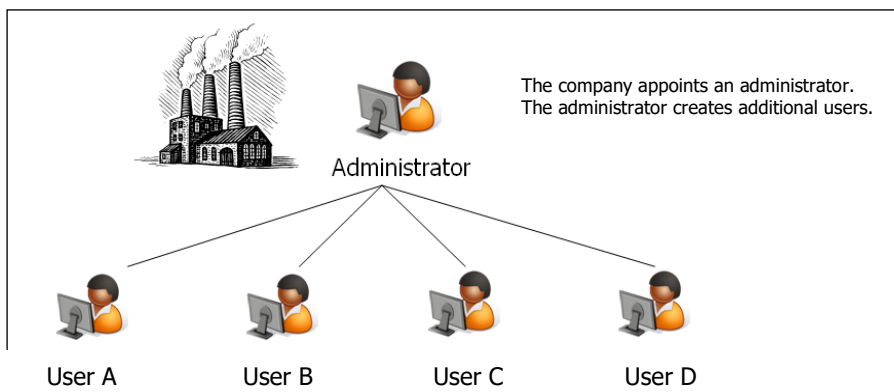


## 1. Introduction

The AGES Medicines and Medical Devices Agency (*AGES Medizinmarktaufsicht*) allows you to appoint one administrator per organisation. The appointed administrator can create and maintain additional employees of the organisation. Especially, the administrator can:

- Create and change access rights
- Inactivate access rights
- Assign and withdraw function rights

Please note that administrators can only transfer rights which the administrator has been assigned by the AGES Medicines and Medical Devices Agency.



The AGES Medicines and Medical Devices Agency provides a special application called „Benutzeradministration“, in order that the administrator can carry out his tasks. The functionality of the application is described below.

## 2. Access to the „Benutzeradministration“ application

The user and rights administration application is accessible over the 'Applications' page of the BASG eServices web portal.

The screenshot shows the AGES eServices web portal interface. At the top, there are dropdown menus for 'organisation:' (Bundesamt Für Sicherheit Im Gesundheitswesen, Traisengasse, 5, LOC-100006059) and 'Department:'. Below this is the logo and name of the 'Bundesamt für Sicherheit im Gesundheitswesen AGES Medizinmarktaufsicht'. The main content area is titled 'APPLICATIONS' and features a sidebar with navigation options: 'Applications', 'Edit Favorites', 'Change Password', and 'Refresh'. The main area displays a grid of application cards, each with an icon, a title, and a 'More' link:

- Anträge Chargenfreigabe und Notifikationen
- Berechtigung beantragen
- Meldungen lt. Veterinär-Antibiotika-Mengenströme VO
- Benutzeradministration
- Inspektionen und Überwachung
- Zulassung und Lifecycle ASP

At the bottom left, a footer reads: 'PVP - Standardportal - (c) BMI & LFRZ - User Portal - 2.0.7 (Build 480)'.



### 3. Overview of the External User Administration

#### 3.1. Header

The entry page of the external user administration is divided into two sections. In the upper part of the page, the header, the following functions are available:



- Deutsch/Englisch: You can switch between German and English by clicking on one of the two words.
- Back to Portal: Use this function to return to the eService portal.
- Contact: If you have any questions you can contact us by clicking on „Contact“.
- Imprint: You will be forwarded to the the Imprint of „AGES Medizinmarktaufsicht“.
- Support: Here you can find the „Frequently Asked Questions“ (FAQs) and the Guideline for the user administration.
- Logout: Via „Logout“ you can logout of the user administration and eService portal at the same time.

#### 3.2. Workspace

In the lower part, the working area, the administrator will find an overview of the organizations to which it is authorized. Moreover all employees of these organizations and their authorizations are listed in this table.

Organisation/Login	Displayname	Administrator									
> Mustermann AG, Teststraße, 47, -											
▼ Mustermann GmbH, Mustermannstraße, 20, -											
muster@frau.at	Frau Muster	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
muster@mann.at	Mann Muster	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This table is only available in the reading mode. The values in the table can be exported via the Excel icon. With the „Full Screen“ button on the right of the Excel icon, the table can be enlarged and displayed in full screen mode.



## 4. Creating new users for your employees (incl. Assignment of rights)

With the "New" button in the overview table, new users can be created and given permissions at the same time.

### 4.1. User data

The necessary data for the creation of users should be completed as follows.

Organisation	Administrator	👤	✍️	🔒	📄	🗑️	👁️	✏️	?	🔗
Mustermann AG, Teststraße, 47, -	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mustermann GmbH, Mustermannstraße, 20, -	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following data must be entered:

- **Email/Login:** The e-Mail address is the unique identifier of the employee. As a user identifier the corresponding personal E Mail address (eg Max.Mustermann@xxx.at) has to be entered (please no functional e-mail address like office@xxx.at). Please note, that the e-Mail address can not be changed because of the unique identifier of the registered user.
- **Firstname:** Please enter the first name of the employee.
- **Lastname:** Please enter the last name of the employee.

Additionally, you can also specify the gender and the telephone number of the employee. The function „Access locked” will be explained in more detail in another chapter.

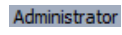
### 4.2. Assignment of rights and organizations


The assignment of these rights can be carried out by ticking the check boxes for the organization. The different and multiple rights for the new employee can be added in one step for the different organisations.





It should be noted that only those rights can be assigned to the users, which uses the administrator himself


The following rights are currently available:


 Right group "Administrator": Users with this right receive the same rights as the existing administrator.


 Right group „User administration“: Users with this right receive reading access to the application „Benutzeradministration“.


 Right group „Lifecycle“: Users with this right receive reading access to the application „Zulassung & Lifecycle ASP“

 Right group: „AWE“: With this right, the employee receives access to the application „Arzneiwareneinfuhr und –verbringung“ and has the right to deliver notification and applications.

 Right group „Antibiotika Mengenströme Veterinär“: With this right, the employee receives access to the application „Veterinary antibiotic amount streams“ and can deliver annual notifications.

 Right group "eService Inspection": Users with this right receive access to the application "eService Inspection".

 Right group "eService BGV": Users with this right receive access to the application "eService BGV".

 Right group "Application for batch release and notifications": Users with this right receive access to the application "Application for batch release and notifications".

 Right group "Online-Processing Packages (PZN)": Exclusive service for PZN users.

 Right group "Ethics Commission": Exclusive service for the ethics commission.

**Note:** Rights apply to all procedures of an organisation. It is not possible to provide procedure-specific rights for individual employees.

By clicking „Save“ the entries are accepted and you will be forwarded to the overview page with the updated data.



Email/Login

Access locked

\* Firstname

\* Lastname

Gender

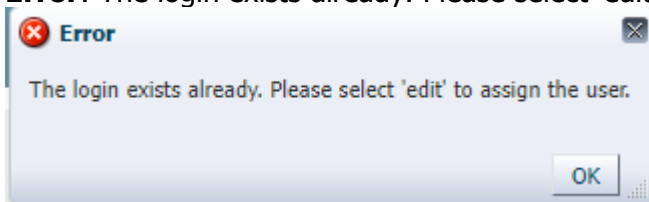
Phonenumber

View

Organisation	Administrator									
Mustermann AG, Teststraße, 47, -	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mustermann GmbH, Mustermannstraße, 20, -	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Click on "Save" to save the entries and return to the overview page with the updated data.

**Error:** The login exists already. Please select 'edit' to assign the user.



If you see this error message, just send an email to **basg-eservices@basg.gv.at**. Include the email address and the organization you were trying to set up the e-services user for. The eServices team will take care of creating it for you, and then you'll be able to manage the permissions.



## 5. Changing data or rights of employees

If you want to change the data or rights of employees, select an employee in the overview list and click on the button „Edit“.

Organisation/Login	Displayname	Administrator									
▼ Mustermann AG, Teststraße, 47, - muster@mann.at	Mann Muster	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
> Mustermann GmbH, Mustermannstraße, 20, -											

Email/Login

Access locked

\* Firstname

\* Lastname

Gender

Phonenumber

Organisation	Administrator									
Mustermann AG, Teststraße, 47, -	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mustermann GmbH, Mustermannstraße, 20, -	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

You can change the user data of the employee as well as the assigned rights by ticking on or ticking off of the checkboxes.

Solely the email address field can not be changed later on because the e-mail address is the unique identifier of a user.

If you have a false or a changed email address, please delete the user and create a new one.

### 5.1. Deleting users

Users can be deleted, by removing all the assigned rights . After clicking „Save“ a security check pops up. With the confirmation of the safety question the user for this organisation is deleted and is no longer available in the user management of this organisation.



## 5.2. Unlock access

„Disabled access“ will be set automatically by the system when the employee

- has not logged in on the eServices portal more than 360 days
- has entered the wrong password ten times

The administrator has the possibility to unlock the access again.

## 6. Organization view

In addition to the user view there is also available an organisation view in the user management tool.

In the organization view the administrator can edit all users and their assigned rights at the same time.

To do this, select an organization in the overview table and click „Edit“.

Organisation: Mustermann AG, Teststraße, 47, -  
Organisation Id: 103676602  
E-mail addresses for notifications

View: Add

Topic: E-mail addresses (multiple addresses append with ';')  
No data to display.

Login	Displayname	Administrator										
▽ assigned to ORG												
muster@mann.at	Mann Muster	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
▽ not assigned to ORG												
muster@frau.at	Frau Muster	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
test@test-ages.at	Mustermann Test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Save Cancel

The rights can now be edited or removed for several or all members of the organization at the same time.

### 6.1. Enter or change e-mail addresses for notifications

E-mail addresses for notifications can be saved for each topic area. To do this, the desired addressees can be entered in the "E-mail addresses" column, separated by semicolons.





Organisation Mustermann AG, Teststraße, 47, -  
Organisation Id 103676602  
E-mail addresses for notifications

View ▾ Add

Topic	E-mail addresses (multiple addresses append with ';')	
PHV ▾	person@test.at	
Tissuevigilance ▾	person@test.at	
Haemovigilance ▾	test.person@test.com	
lifecycle MP ▾	test@test.com;test1@test.de	

If a grouping is no longer required, an entire row can be deleted using the trash can icon.

## 6.2. E-mail addresses for notifications about current or completed applications in eService „Authorisation & Lifecycle MP“

In the field „E-mail addresses for notifications“, topic area Lifecycle one or more e-mail addresses (separated by ;) can be listed. In the following events notifications will be sent automatically to the listed e-mail addresse(s):

- A new procedure is displayed in „current applications“ on the eService portal „Authorisation & Lifecycle“
- A new additional claim was uploaded to the eService portal „Authorisation & Lifecycle“
- A procedure was completed and is no longer available in „current applications“ but is visible in „completed applications“.

Note: Those emails are automatically generated and sent by the system, please do not answer!

There is also the possibility to specify an e-mailadresse for the different procedures. For this purpose, please open

### „L Z34 User Manual Marketing Authorisation and Lifecycle Management of Medicines.pdf“

Chapter 4. „Current applications“, **Email- addresses for notifications (procedure-related).**

[www.basg.gv.at/en/eservices/guidance-notes-for-eservices/](http://www.basg.gv.at/en/eservices/guidance-notes-for-eservices/)

## 7. Adding employees to other organisations (additional administrator)

An administrator of another company can create the same user with its email address for its organization in the user management as well.

After login on the eService Portal of the AGES Medizinmarktaufsicht, the user can chose between all assigned organisations regardless of which administrator has created the user in the user management.



organisation: <input type="text" value="Mustermann GmbH, Mustermannstraße, 20, -"/>	Department: <input type="text"/>	
	<b>AGES eServices</b>	
organisation: <input type="text" value="Mustermann GmbH, Mustermannstraße, 20, -"/>	Department: <input type="text"/>	
	<input type="text" value="Mustermann GmbH, Mustermannstraße, 20, -"/> ces <input type="text" value="Mustermann AG, Teststraße, 47, -"/>	

### Notice to Consultants:

Consultants will be created as user of the representing organization. Please note, that rights apply to all procedures of the assigned permission of an organisation unit. A limitation to procedure-specific or product-specific rights for individual consultant staff, is not possible via the user administration.

However, if consultants themselves have portal access and are registered in the procedure as the organization's introducer or authorized representative during the process, they can only view this specific procedure.