

Information sheet eIAM Portal Administrator

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1 Requirements for using the eIAM portal

To use the eIAM portal as a user administrator, it is necessary to sign up to the Swissmedic website:

eGov Portal and MESA: <https://www.swissmedic.ch/swissmedic/en/home/services/egov-services/portal/egov-portal-registration.html>

CT (clinical trials): <https://www.swissmedic.ch/swissmedic/en/home/services/egov-services/portal/egov-portal-registration-klv.html>.

2 Setting up and changing user administrators for companies

Once a user license agreement with Swissmedic has been signed, Swissmedic sends an invitation email to the user administrators stated in the contract. These users can register themselves on the eIAM portal and set up new user accounts for their company. After the user administrator account is set up, the administrator receives an e-mail from eamnoreply-prod@bit.admin.ch with an onboarding code plus an e-mail from it@swissmedic.ch with registration information..

Any changes to the details of the user administrators can be reported to the Swissmedic IT Service Centre (ISCS) by phone or in writing.

3 Systems

3.1 CH-LOGIN

A CH-LOGIN (Federal Administration account) is required in order to access the eGov portal. Each user (including user administrators) must create a CH-LOGIN account to access the eGOV portal. A two-factor token, e.g. MTA sent by SMS or authenticator app, and some security questions must be entered for two-factor authentication and to reset the personal password. The latter are required for account recovery and to reset the password.

Note: Each user can change the login details (phone number, email, password) of their own CH-LOGIN account.

For more information about the CH-LOGIN account, visit:

<https://www.bit.admin.ch/bit/de/home/dokumentation/ch-login.html>

3.2 User administration (eIAM portal)

The eIAM (eGovernment Identity and Access Management) portal is used for "delegated administration" <https://www.myaccount.eiam.admin.ch>.

Documentation for onboarding newly registered users is available on this page: portal.swissmedic.ch.

3.3 Logging into the eGov portal



To access the eGov applications which your company is authorised to use, please follow this instruction.

Requirements:

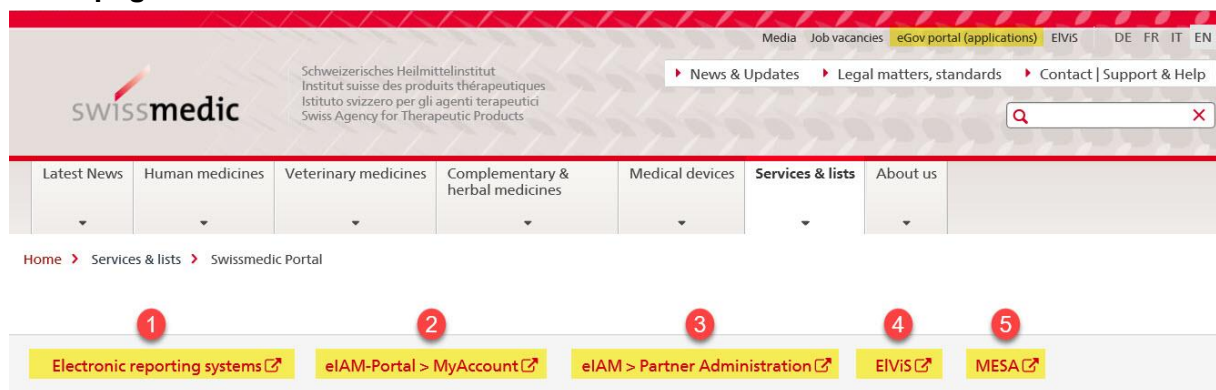
PC: Internet Explorer/Microsoft Edge and Mozilla Firefox are tried and tested browsers

Mac: Mozilla Firefox (the "Safari" browser is not suitable)

1. Call up the URL www.swissmedic.ch in your browser's address bar
2. Click the "eGov Portal (applications)" link in the top right corner,

or, alternatively,  type portal.swissmedic.ch into your browser and press "ENTER/OK"  on your keyboard.

Menu page for the various eGov services:



1. **Reporting portals:** CPP, eMessage, eSubmission, GMP-GDP, CT, Licences – major changes, OCABR, Safety communication
2. **MyAccount:** CH-LOGIN Personal Federal Administration account (*here anyone can adjust their access data, such mobile no. or password, themselves*)
3. **Partner Administration:** User management for use within your own company (for user administrators only)
4. **EIVIS:** (Electronic Vigilance Reporting Portal)
5. **MESA:** (Narcotics)

4 Setting up and changing users

4.1 Logging into the eIAM portal

User administrators log into <https://www.portal.eiam.admin.ch> with their CH-LOGIN account



Selection of login procedures

Please select with which login procedure you would like to access the application of your choice.
You can find out more about the individual procedures in the help.



4.2 Setting up a new user

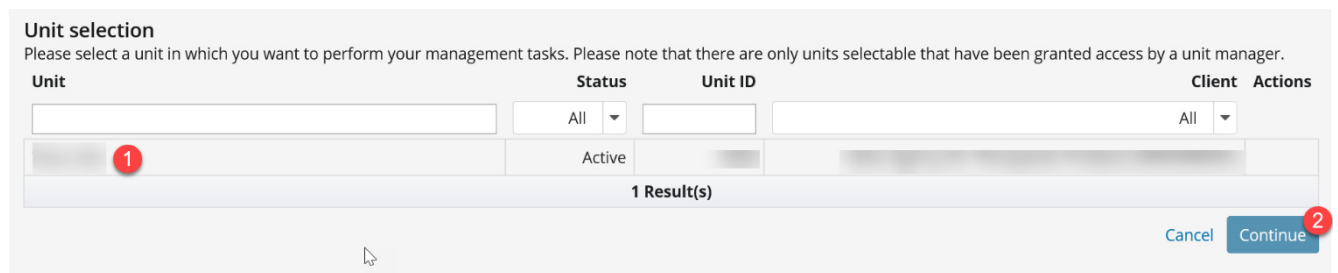
Note:

The user administrator can also authorise the employees of a third-party company.

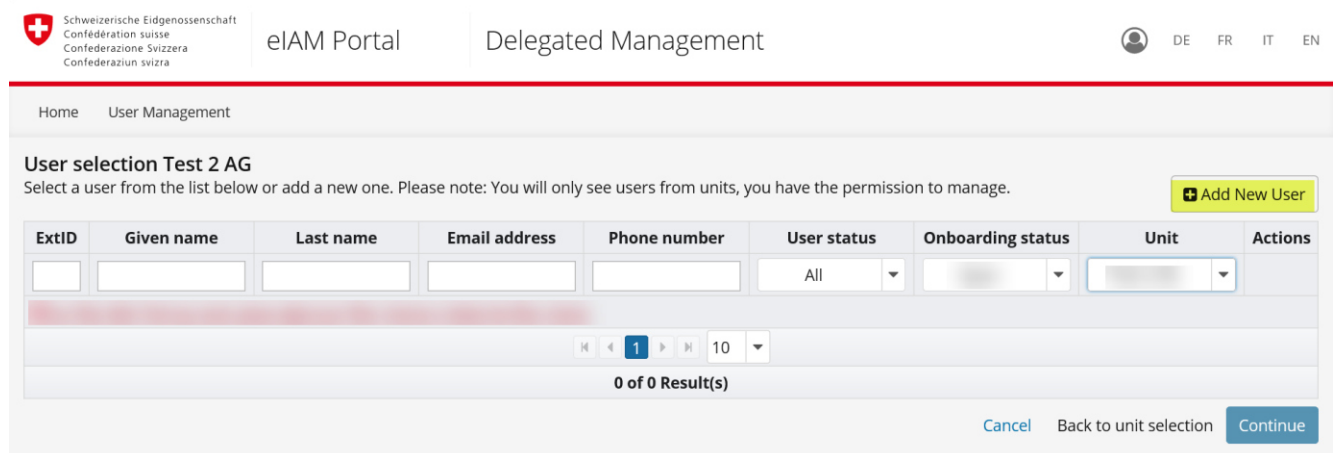
To create a new user, select (1) *User Management* and (2) "*Delegated Management*".



Select the unit (company) from the *Unit selection* menu and then confirm your selection by pressing "**Continue**".



Click the "Add New User" button.




Enter the user details in the window that appears now.

The **Given name** and **Last name** and **Email address** are mandatory. The other fields are optional and not relevant for access to the eGov portal.

Note:

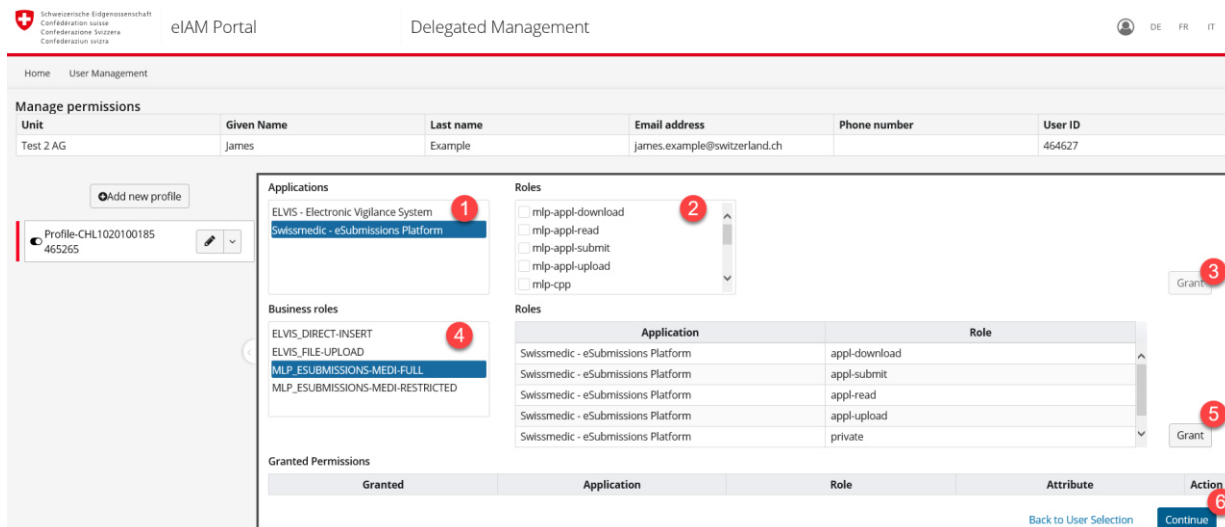
The "Mobile / Landline number" field required for the two-factor authentication (mTAN) is stored with the user's CH-LOGIN account.

Add New User

| User Data | Address | Access Data |
|--|--|---|
| Salutation <div>Mr. Ms.</div> | Address line 1 <input type="text"/> | Email address <input type="text" value="james.example@switzerland.ch"/> |
| Given name <input type="text" value="James"/> | Address line 2 (optional) <input type="text"/> | Mobile / Landline number <input type="text"/> |
| Last name <input type="text" value="Example"/> | Country <div>Please select country ▼</div> | |
| Date of birth <input type="text"/>  | City <input type="text"/> | Zip code <input type="text"/> |
| Correspondence language <div>DE FR IT EN</div> | Unit <div>Test 2 AG</div> | |
| Change Notes <input type="text"/> | | |

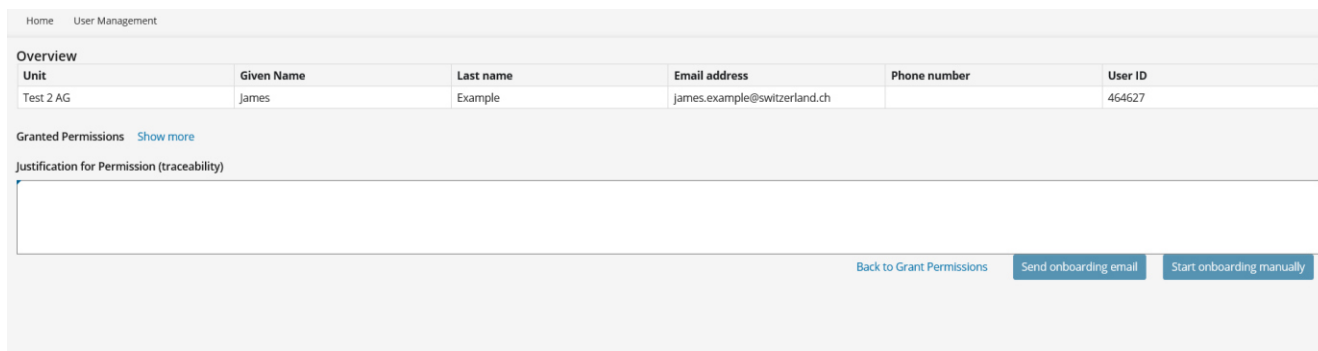
Once you have entered the user details, press “Save and continue”. You will now be taken to the “Manage permissions” page.

User administrators can assign the following roles/permissions to the users. Only the roles that correspond to the scope of use are available for selection.



The screenshot shows the 'Delegated Management' interface in the eIAM Portal. The user 'Test 2 AG' (James Example, james.example@switzerland.ch, 464627) is selected. The 'Manage permissions' section shows the user's profile and a list of applications and business roles. The 'Applications' list includes 'ELVIS - Electronic Vigilance System' and 'Swissmedic - eSubmissions Platform'. The 'Business roles' list includes 'ELVIS_DIRECT-INSERT', 'ELVIS_FILE-UPLOAD', 'MLP_ESUBMISSIONS-MEDI-FULL', and 'MLP_ESUBMISSIONS-MEDI-RESTRICTED'. The 'Roles' section shows a list of roles for the selected application, including 'mlp-appl-download', 'mlp-appl-read', 'mlp-appl-submit', 'mlp-appl-upload', and 'mlp-cpp'. The 'Granted Permissions' table shows the roles assigned to the user. The 'Continue' button is highlighted with a red circle.

Once you have selected the application roles and/or business roles (see [Authorisation roles](#)) press the “Continue” button. This takes you to an overview of the user you have just entered. First check the authorisation roles granted for the user (Granted permissions → “Continue”). Enter your justification in the mandatory field “Justification for permission (traceability)”. You can complete the process by pressing the “Send onboarding email” button:



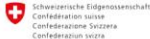
The screenshot shows the 'Overview' page for the user 'Test 2 AG' (James Example, james.example@switzerland.ch, 464627). The 'Granted Permissions' section shows the roles assigned to the user. The 'Justification for Permission (traceability)' field is highlighted with a red circle. The 'Send onboarding email' button is highlighted with a red circle.

The user will then receive an onboarding email with the relevant link and the onboarding code. The newly registered user carries out the onboarding process themselves.

The onboarding instructions are available on our portal home page under portal.swissmedic.ch.

4.3 Onboarding status overview

Use the Delegated Management option under User Selection to check if the users you authorised have followed the link to the CH-LOGIN account.



eIAM Portal
Delegated Management

DE
FR
IT
EN

Home
User Management

User selection Test 2 AG
Select a user from the list below or add a new one. Please note: You will only see users from units, you have the permission to manage.

Add New User

| ExtID | Given name | Last name | Email address | Phone number | User status | Onboarding status | Unit | Actions |
|-------|------------|-----------|---------------|--------------|-------------|-------------------|------|---------|
| | | | | | All | All | All | |
| | | | | | | None | | |
| | | | | | | Ongoing | | |
| | | | | | | Ongoing | | |
| | | | | | | Ongoing | | |
| | | | | | | Ongoing | | |
| | | | | | | Ongoing | | |
| | | | | | | Completed | | |
| | | | | | | Ongoing | | |
| | | | | | | Completed | | |
| | | | | | | Ready | | |

10 of 14 Result(s)

Cancel
Back to unit selection
Continue

| Onboarding Status | Description |
|--------------------|--|
| In process / ready | User has been entered, onboarding email is being sent. |
| Ongoing | The user has not yet used the onboarding code. |
| Overdue | The onboarding code is still valid but will expire soon. > Notify user |
| Expired | The onboarding code has expired (is only valid for a limited amount of time) > user administrator must send a new onboarding code. You can send a new onboarding link to the user by selecting the user's name under the company and then selecting Action. |
| Completed | Onboarding process completed, user has successfully linked their personal CH-LOGIN account. |

4.4 Authorisation roles:

Allocating individual application roles:

User administrators can only see the application roles that have been approved for their company.

eSubmissions (electronic application submission for medicinal products)

| Roles | Description |
|-------------------|---|
| mlp-appl-read | If this role is assigned, the user has read access to the whole dashboard (see also the roles " <i>medi-full</i> " and " <i>medi-restricted</i> "). |
| mlp-appl-upload | If this role is assigned, the user additionally has the right to upload or modify documents relating to an application. |
| mlp-appl-download | If this role is assigned, the user additionally has the right to download and view documents. |
| mlp-appl-submit | If this role is assigned, the user additionally has the right to submit an application. |
| mlp-private | Required role for access to application |

| Roles | Description |
|--|---|
| Assign products (only enter one of the two following roles) | |
| mlp-medi-full | If this role is assigned, the user has access to all the company's preparations. |
| mlp-medi-restricted | If this role is assigned, the user only has access to the explicitly specified preparations. |

CPP (Certificate of a Pharmaceutical Product):

| Role s | Description |
|-------------|---|
| mp-cpp | If this role is assigned, the user can submit CPP orders via the eSubmissions platform. |
| mlp-private | Required role for access to application |

| Roles | Description |
|-------------|--|
| mlp-ocabr | With this role, the user can submit documentation on OCABR services. |
| mlp-private | Required role for access to application |

CT (clinical trials):

| Roles | Description |
|-------------------|---|
| klv-appl-read | If this role is assigned, the user has read access to the whole dashboard (see also the roles " <i>medi-full</i> " and " <i>medi-restricted</i> "). |
| klv-appl-upload | If this role is assigned, the user additionally has the right to upload or modify documents relating to an application. |
| klv-appl-download | If this role is assigned, the user additionally has the right to download and view documents. |
| klv-appl-submit | If this role is |

MESA:

| Roles | Description |
|--------------|--|
| mesa-sender | This authorisation allows the user to write MESA reports |
| mesa-private | Required role for access to application |

4.5 Business roles

The business role is a package of application roles. This makes it easier to assign authorisations as only one business role needs to be assigned. The following business roles are currently available:

| Business role | Description | Roles of business role |
|---------------------|--|------------------------|
| ELVIS_DIRECT-INSERT | Includes all the roles required to capture an adverse reaction report in ELVIS | |

4.7 Changing a user

The user administrator can change a user with the following actions:

- Delete/archive user (e.g. departure from the company)
- Deactivate user (if the user is to be temporarily denied access to the portal)
- Activate user (if the user was previously deactivated)
- Give the user access to certain preparations (medi-restricted role)
- Click the icon below the no. 1 (Actions column).

