Contents

1 Objective and scope

This information sheet contains the basic information on the use of the Swissmedic eGov-Portal for the eGov-Service **licences – major changes** in particular.

User administrators should refer to the *Swissmedic Portal – Administrator functions* information sheet.

2 Terms, definitions, abbreviations, glossary

Acceptance of…	Acknowledgement for a specific step
Hash algorithm, hash code	Checksum calculated for a submission or for individual files
Company reference	Reference, your reference
Dashboard	Work environment and input screen
Delivery	Submission for new or current notifications
Delivery ID	Specific identification number of uploaded file
Doc ID	Identification number of transmitted file
Delivery status	Status of a submission
eGov	eGovernment
eGov-Service	Individual service within the eGov-Portal
eSubmissions	Service for entering submissions
Inbox	Mailbox on the dashboard
mTan	Mobile transaction number via text message
Notification	Notification by e-mail
Release	Version of the Portal software
Subject no., subject number	Identification number for applications, corresponds to Delivery ID
Upload	The process for uploading files

3 Conditions for the use of the Swissmedic eGov Portal

A User Agreement with Swissmedic must be signed in order to use the Portal. For anyone wishing to use the Swissmedic eGov-Portal as a standard user, a company user administrator or account administrator must set up a new standard user account. The new user will then receive an e-mail from Swissmedic (from it@swissmedic.ch) with a link for setting up an initial password.

4 Access to the Swissmedic eGov-Portal

4.1 Requirements

- PC: Internet Explorer and Mozilla Firefox are tried and tested browsers
- iMAC: Mozilla Firefox (the "Safari" browser is not suitable)

4.2 Login

1. Type www.swissmedic.ch into 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's address bar and press *ENTER/OK* on the keyboard.
3. Menu page for the various eGov-Services: Click *Electronic reporting systems*.
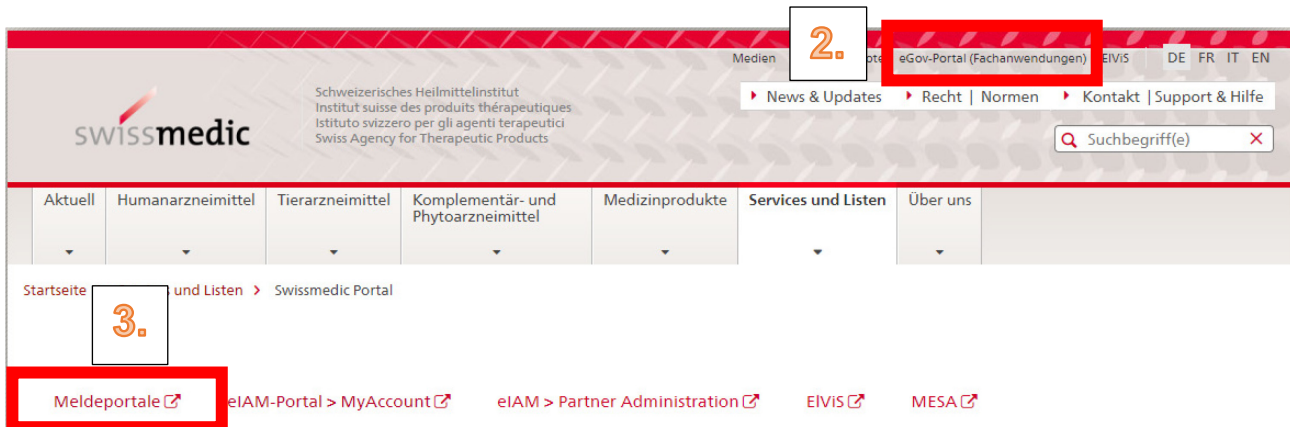
4. Click CH-LOGIN (eGovernment)

Enter your user ID and the password you previously set up. A text message containing a mobile transaction number (mTan) will then be sent to your registered mobile phone number. Enter this transaction number on the following screen in order to complete the login process. If you are logging in for the first time or if the software has been updated you must agree to the latest terms of use.

The Portal includes an option for resetting the password. Enter your registered e-mail address and the system will send a new password to that address. You should change this password immediately.

5   Using the eGov-Portal

This section explains the functions and processes of the Swissmedic eGov-Portal in more detail. The Portal is the central access point for additional government services, i.e. *eGov-Services*. The default language of the Swissmedic eGov-Portal is English. The information sheets are available in German, French and English.

5.1 eGov-licences – major changes

This service will help you upload the form for notifying major changes and other documents (see 5.2.1). A dashboard (see diagram below) is provided for users:
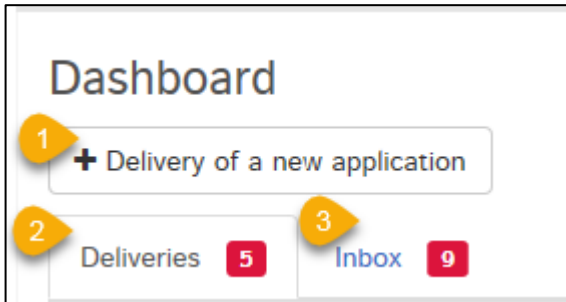
The Swissmedic eGov-Service licences – major changes offers the following options:

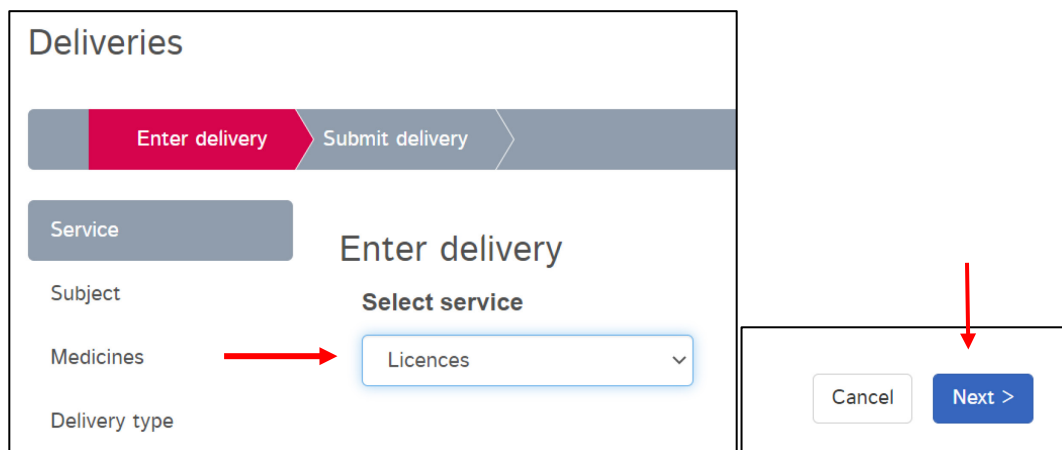|	
1	Notify a new major change
2	List of the most recent major changes notified
3	List of delivery confirmations and acceptances

5.1.1 Inbox area

The inbox contains submission documents (delivery confirmations and acceptances) which can be downloaded. With the filter function you can enter search terms to find a document and then download it. The *Retrieve status* function shows whether or not the documents have already been downloaded. Users of the licences – major changes service can only see documents relating to their own submissions.

5.2 Submitting a notification of a major change

The complete process is illustrated below by means of an example.
In the *Dashboard*, click on *Delivery of a new application* to start the process.
Next, use *Select service* to select *Licences* and then confirm by pressing *Next*.

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If you wish, you can enter an internal *Company reference* under *Features*. This reference will be displayed in the dashboard, in the inbox and on the *delivery confirmation* and acceptance documents as *Your reference*. The purpose of the *company reference* is purely to help users keep track of the change notification they have delivered. Under *Hash algorithm* we use message-digest algorithm 5, which is the default setting. Confirm with *Next*.

In the next step click *+Add file* under Files. Under *Add file* select *Request form*, then use *Choose file* to select the previously completed "Form for notifying major changes" (.pdf format) and click *Upload* to upload it.

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To upload documents containing information about the major change, click *+Add another file* under Files. Below *Add File* you will now see *Attachment*. If the documents to be uploaded are ZIP files, select *Attachment ZIP*. Use *Choose file* to select the required document (in .pdf format) and then upload it by pressing *Upload*. Repeat this process to upload further documents.

During the upload, the files are automatically checked for viruses and the correct file format. However, this is not a technical validation or structural check of the documents.

The result of the file check is displayed on the screen. A green tick indicates that the upload has been successful. Depending on the size of the delivery, this step may last several seconds.
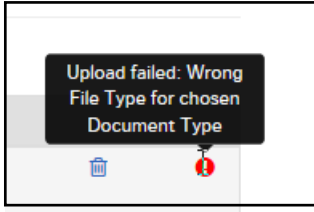
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If the file check discovers an error, a red exclamation mark is displayed. Further information about the possible problem is displayed if you move the mouse cursor over the exclamation mark.

You cannot continue the process until the error has been corrected. First delete the upload containing the error by clicking the *Recycle bin* icon. You can then re-upload the corrected file.

If everything is correct, the delivery can be completed (*Next*) and handed over to the system. A *Delivery overview* with a summary of the details is displayed.

At this point, the *checksum* generated for each upload is also displayed. This *hash code* can be used to verify that the upload was complete. For reasons of improved traceability, the checksum is also shown on the acknowledgements sent by the Portal.

Should you need to make changes, you can still correct any mistakes by clicking the *Back* button. If everything is correct, press the *Submit* button to complete the process.

A message confirming the successful submission is then displayed.

Submitted delivery

> ✅ The application was successfully submitted. You can find the corresponding delivery confirmation in your inbox.

Delivery ID
100010022146

Service
Licences

Subject
Major changes

Features

Company reference
Muster Meldung wesentliche Änderung

Files

Document type	File name	Hash
Request form	Formular_Meldung_wesentliche_Aenderungen.pdf	44ae6356099da0235f7e20b5020f994b
Attachment	WAe_Dokumentation.pdf	349e04596280919f716e9534d9d6a062

Dashboard

The delivery will remain in the *Deliveries* area while it is being processed.

The delivery confirmation has been created, and the delivery status is set to *Transmitted.* It may take several minutes to transmit the data.

Once this process is complete and the documents have been transmitted, the acceptance of delivery will be created and the delivery status on the *Dashboard* will be changed to *Accepted.*

Delivery status provides information on the processing status.

The following statuses are possible:

Status	Meaning
Paused	Delivery has been saved temporarily
Processing	Delivery is in progress
Transmitted	Delivery has been sent
Accepted	Delivery has been accepted

The magnifier icon under *Functions* can be used to obtain a detailed view of the delivery.

Dashboard

➕ Delivery of a new application   🔗 New delivery link

Ongoing applications **0**   My deliveries **3**   External deliveries **0**   Upcoming milestones **0**   Products   Inbox **6**

Delivery ID	Your Reference	Service / Subject	Delivery type	Auth./Case no.	Name of medicine	Last updated at	Last updated from	Delivery status	Functions
100010022146	Muster Meldung w…	Licences/Major changes				15.10.2020 16:34	CHL1020100274	Transmitted	🔍 📄

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All the information about the submission is summarised in the *delivery details*.
The submitted documents and the two acknowledgements (delivery confirmation and acceptance of delivery) can be downloaded as PDFs. The acknowledgements are also placed in the inbox.

In addition, an e-mail will be sent to the user's registered correspondence e-mail address.

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Dear Sir or Madam,

Swissmedic has uploaded a document to your account:

You can download this document to your computer by logging in to the Swissmedic portal.

Service: Licences
Subject: Major changes
Your reference: Muster Meldung wesentliche Änderung

This email has been automatically generated. Never reply to this sender address.

Best Regards,

Swissmedic - Swiss Agency for Therapeutic Products

Swissmedic will then start to process the major changes.

5.3 Acknowledgements and notifications

During the delivery process, the Portal automatically issues acknowledgements or notifications containing important information on status, errors or confirmations, for example.

When a change notification is submitted, the Portal automatically creates acknowledgements for each step. These acknowledgements can be downloaded on the dashboard under the specific delivery and in the inbox.

The acknowledgement types are as follows:

- Delivery confirmation → Portal has received documents
- Acceptance of delivery → Portal has accepted the delivery and forwarded it to the specialist department for assessing and processing
- Denial of acceptance → Portal cannot process documents

These acknowledgements are generated immediately, as soon as the delivery has reached a certain status. Depending on the size and general input volume, this usually occurs within a maximum of 10 hours.

The acceptance of delivery constitutes acknowledgement of receipt.

5.4 Cancellation of change notifications

Once the notification has been transmitted by clicking *Submit* in the Delivery overview, it can no longer be cancelled. A fee will be charged for the assessment if you do not send an e-mail to the following address with the subject "Withdrawal of change notification" within 24 hours: Inspectorates@swissmedic.ch.

6 Technical details

The following section addresses certain technical details.

6.1 File formats

Document type	Authorised file formats	Size
Request form	PDF	Max. 10 MB
Attachment	PDF	Max. 100 MB or max. 1 zip file containing max. 1500 MB

6.2 Doc ID

A Doc ID is created for every submission. In case of doubt or if an unexpected problem is encountered with the Portal, Swissmedic can verify on the basis of the Doc ID number if a submission has been received. The Doc ID is displayed as soon as the acceptance of delivery acknowledgement has been created.
The number can be seen in the delivery details and in the acceptance of delivery acknowledgement.

7 Support

E-mail: it@swissmedic.ch

Phone: +41 (0)58 462 06 00

www.swissmedic.ch/gate-support

Support is available on weekdays between 7.30 a.m. and 5.30 p.m.