

**Information sheet**  
**eGov-Portal CT standard functions**

<b>Identification number:</b>	OS000_00_027
<b>Version:</b>	1.1
<b>Valid from:</b>	18.08.2025

## List of contents

<b>1</b>	<b>Terms, definitions, abbreviations, glossary .....</b>	<b>3</b>
<b>2</b>	<b>Objective and scope.....</b>	<b>4</b>
<b>3</b>	<b>Conditions for use of the Swissmedic eGov Portal .....</b>	<b>4</b>
<b>4</b>	<b>Access to the Swissmedic eGov Portal .....</b>	<b>4</b>
<b>5</b>	<b>Using the eGov Portal .....</b>	<b>4</b>
5.1	Administration area.....	5
5.2	eSubmissions area .....	5
5.2.1	Delivery of an application for the approval of a clinical trial .....	5
5.2.2	Correcting an invalid delivery.....	11
5.2.3	Submission of a variation.....	11
5.2.4	Delivery of a response to an ongoing application.....	12
5.2.5	Submission of collective applications (collective deliveries).....	13
5.2.6	Submission of a change of sponsor.....	14
5.3	Ongoing applications area -> Application tracking .....	14
5.4	Upcoming milestones area → .....	15
5.5	Inbox area with Swissmedic correspondence .....	15
5.6	Time limits .....	16
5.7	Acknowledgements and notifications .....	16
5.7.1	Acknowledgements .....	17
5.7.2	Notifications.....	17
5.8	Technical details.....	17
5.8.1	Delivery status.....	17
5.8.2	File formats.....	19
5.8.3	Structure of ZIP files .....	19
5.8.4	Checksum .....	20
5.8.5	Handling of electronic / digital signatures and acknowledgements.....	21
5.8.6	Submission of a Delivery Link via eGov Portal.....	25
<b>6</b>	<b>Other eGov services.....</b>	<b>33</b>
<b>7</b>	<b>Support.....</b>	<b>33</b>

## 1 Terms, definitions, abbreviations, glossary

Acceptance of...	Acknowledgement for a specific step
Amendment	Variation application
Application no., Application number	Application ID, service order number
Application Tracking	Application tracking for ongoing applications
Authorisation	Approval of clinical trial
Case / Authorisation	Case, clinical trial
Change of Sponsor Ship	Change of sponsor
Checksum, Md5-Checksum, Hash algorithm, hash code	Checksum calculated for a delivery or for individual files
Clinical Trial Application, New application	Application for the approval of a clinical trial
Company Reference	Reference, your reference (should match the details on the form)
Concerns subsequent delivery	Subsequent delivery of documents for an ongoing application
Conditions	Conditions
Dashboard	Work environment and input screen
Delivery ID	Specific identification number per delivery
Delivery Status	Status of a delivery
Delivery type	Application type
Dossier	Dossier includes all documents required for a submission
eDok_KLV	Swissmedic submission format for CT applications
eGov	eGovernment
eGov-Service	Individual service within the eGov Portal
eMessage	Service eMessage
eSubmissions	Service for recording submissions
Extension of the time limit of an application	Extension of the time limit for an application
Inbox	Inbox for Swissmedic correspondence in the Dashboard
KLV	Clinical trials (CT)
Milestone	Breakpoints between the application phases
mTAN	Mobile transaction number via text message
New authorisation	First Authorisation, New Application
Notification	Notification by e-mail
Ongoing applications	Ongoing applications
OSS Division	Swissmedic Operational Support Services Division
Q&A	Questions and Answers
Release	Version of the Portal software
Response to Swissmedic correspondence	Response to Swissmedic correspondence
Subject	Subject

Subject no., Subject number	Identification number for applications, corresponds to Delivery ID
Transferring authorisation	Change of sponsor
Upload	The process for uploading files
Validation Report	Validation report in the event of errors during submission
ZIP file, ISO file	Packed file for upload

## 2 Objective and scope

This information sheet describes the basic principles of using the Swissmedic eGov Portal, and the eGov **eSubmissions for CT applications** service in particular. A separately managed *Questions and Answers document CT (Q&A)* covers additional questions and problems that may arise. Both documents are updated regularly and are available on the login screen of the Portal. User administrators should refer to the *Swissmedic Portal – Administrator functions* information sheet.

## 3 Conditions for use of the Swissmedic eGov Portal

The *Master CT eGov use contract* must be signed before the Portal can be used. Before a standard user can make use of the Swissmedic eGov Portal, a user administrator or account administrator at their company must set up a new standard user account for them.

The latest releases of Microsoft Edge and Mozilla Firefox are system requirements.

## 4 Access to the Swissmedic eGov Portal

The Swissmedic eGov Portal is accessed via the address <https://www.portal.eiam.admin.ch>. 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.

**Please note: Important information about scheduled maintenance is published on the login screen.**

## 5 Using the eGov Portal

This section explains the basic functions and processes of the new Swissmedic eGov Portal, and the eSubmissions eGov service in particular, in greater 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. Information sheets are available in German, French and English.

**Please note: The screenshots shown in this document do not always show the full screen.**

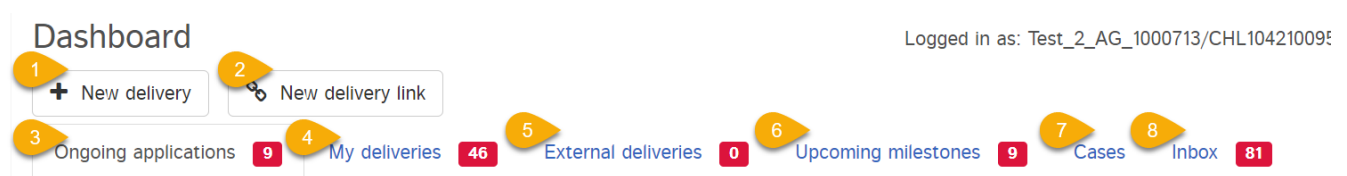
## 5.1 Administration area

Accessible to registered Portal administrators, this area is for configuring the necessary settings and, for example, creating users.

For further details please refer to the information sheet for administrators.

## 5.2 eSubmissions area

Deliveries can be created and the required files uploaded via the *Dashboard*.



1	Deliver documentation for a new application. This includes deliveries for ongoing and new clinical trials.
2	Link for third-party deliveries (confidential documents).
3	List of applications that have already been recorded and are in progress at Swissmedic. Responses to correspondence from Swissmedic that refer to a specific ongoing application can also be delivered here.
4	List of submissions to Swissmedic that have been delivered electronically by Portal users but not yet recorded by Swissmedic.
5	List of deliveries to Swissmedic by third parties (see point 2).
6	List of tasks relating to all applications with planned finish dates (milestones) that are due within the next 30 days.
7	List of clinical trials (identified by a study number)
8	Mailbox with correspondence from Swissmedic relating to a delivery (identified by a Delivery ID) or an application (identified by an Application no.)

### 5.2.1 Delivery of an application for the approval of a clinical trial

The complete process is illustrated below for a first authorisation.

- 1) *Dashboard* → *New delivery*
- 2) *Select service*, i.e. the required service → *Clinical trial*
- 3) *Select topic*, i.e. the area concerned → *Clinical trials (MP)* (assigned automatically)
- 4) *Select application case type*

Options here include deliveries relating to a *notified* or *authorised study*, *deliveries for a new study* or *deliveries for an authorisation transfer (change of sponsor)*.

5) Enter the name of the new study

**Please note: Entering the correct name in the *Name* field is absolutely essential at this point. Entries such as *notification*, *variation*, etc. are not permissible here and will mean that the dossier cannot be created correctly, which may lead to delays.**

Only the following characters may be used:

- A to Z (upper case)
- a to z (lower case)
- 0 to 9 (numbers zero to nine)
- - (hyphen)
- \_ (underscore)

No other characters, blank spaces, etc. are permitted. If an invalid *Case title* is entered, the field is outlined in red and the process cannot be continued until the error has been corrected.


Select application case type

Application for existing case/authorisation
  Application for new case/authorisation
  Application for case/authorisation transfer

Enter cases

Case title

t e s t



'Title' contains invalid characters. The following characters are permitted: 'A' to 'Z', 'a' to 'z', '0' to '9', '-', and '\_'.

The field length is limited to 20 characters. Actual study names that are longer than 20 characters must be abbreviated. However, the Swissmedic system will use the full intended name for the study (taken from the information on the Submission application form).

6) *Add case* is used to enter the study. Only then will the *Next* button be enabled.

## Enter delivery

### Select service

Clinical trial

### Select topic

Clinical trials (MP)

### Select application case type

Application for existing case/authorisation
  Application for new case/authorisation
  Application for case/authorisation transfer

### Enter cases

Case title

test

+ Add case

Case no.	Case title	eCTD Dossier	Action
0	test		

< Back

Cancel

Next >

7) Select other properties for the delivery, *Company reference* and *Hash algorithm*.

## Features

### Company reference

Test\_2023

### Hash algorithm \*

Message-Digest Algorithm 5

- *Company reference* is a free field that can be used by the user to identify the delivery. The *Company reference* on the Portal must be identical to the corresponding field on the application form.
- All fields with a red star are mandatory fields.
- The *Hash algorithm* option can be used to select the method for calculating the checksum.

8) If necessary, the delivery can be saved temporarily via *Save and exit*. The delivery can then be completed later. The Dashboard shows the status as *Paused*.

## Dashboard

Logged in as: Test\_2\_AG\_1000713/CHL1042100952

+ New delivery

New delivery link

Ongoing applications

9

My deliveries

47

External deliveries

0

Upcoming milestones




9

Cases

Inbox

81

Page 1 of 5

Delivery ID	Your reference	Service / Topic	Delivery type	Case no.	Case title	Last updated at	Last updated from	Delivery status	Functions
100010042561	Test_2023	Clinical trial/Clinical trials (MP)	Clinical trial application (CTA)		test	08.05.2023 13:06	CHL1042100952	Paused	  

To resume the delivery, click the arrow under *Functions* and *Continue delivery*.  
You can also delete an incomplete delivery by clicking the *Recycle bin* icon.

**Please note: A paused delivery will be deleted automatically after 30 days if no further work is done on it.**

- 9) In the next step, you should specify the type of document you are uploading and the format of that document (i.e. in this case *eDok\_KLV*).

**The length of the file name is limited to 90 characters. If this is exceeded, the following message appears:**

Files

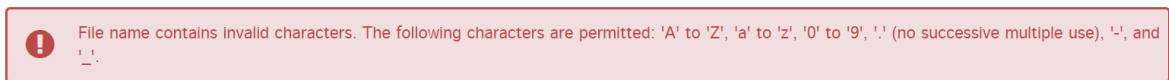
Add file



As with the study title in point 4, only certain characters are permitted.

Files

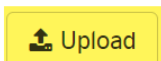
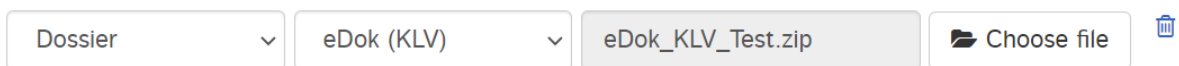
Add file



The files are transferred using the *Upload* button.

Files

Add file



**Please note: If possible, very large files should be uploaded to the Portal during off-peak times (Swissmedic core time is between 8 a.m. and 6 p.m.) as this will usually speed up processing.**

**The structure of Portal deliveries must not be modified, i.e. additional parent folders and subfolders are not permitted.**

During an *upload* an initial automatic technical check is performed (including a virus check and a correct file format check). However, this is not the same as the structural check for eDoks, which is performed separately at a later point.

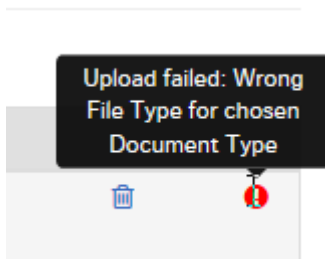
A green tick indicates that the *upload* has been successful. Depending on the size of the delivery, this step may last several minutes.

**Files**

Document type		File name		
Dossier	eDok (KLV)	eDok_KLV_Test.zip		

+ Add another file || Pause all

If the automatic check discovers an error, a red exclamation mark is displayed. Further information about the possible problem appears if you position 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.

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

Enter delivery
Submit delivery

Service

Topic

Cases

Delivery type

Features

Files

Delivery overview

### Delivery overview

Please check the entries below for correctness before submission.

**Service**  
Clinical trial

**Topic**  
Clinical trials (MP)

**Application case type**  
Application for new case/authorisation

**Cases**

Case no.	Case title
0	test

**Delivery type and materials**  
Clinical trial application (CTA)

**Features**

**Company reference**  
Test\_2023

**Files**

Document type	Structure format	eCTD dossier	File name	Hash
Dossier	eDok (KLV)		eDok_KLV_Test.zip	42545e98da2dcd071e6ad1a5aacaba

< Back
Cancel
Submit

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

- 11) Should you need to make changes, you can correct errors by clicking the *Back* button. If everything is correct, press the *Submit* button to complete the process.
- 12) A message confirming the successful delivery is then displayed by the system. In addition, a delivery confirmation will be sent to your Inbox.

### Submitted delivery

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

- 13) The delivery will remain in the *Deliveries* area while it is being processed automatically. Further checks are now made in the background preparatory to acceptance of the delivered files, including a more detailed technical validation of the eDok.




The magnifier icon shown under *Functions* can be used to obtain a detailed view of the delivery that has just been created.

14) On completion of the delivery process, a corresponding acknowledgement will be sent to your Inbox and e-mailed to the user's registered correspondence e-mail address.

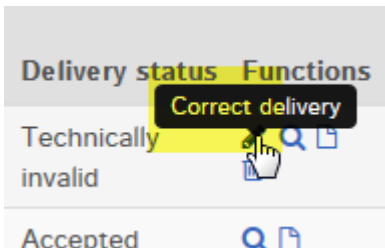
**Please note: Receipt of the *Acceptance of delivery* acknowledgement is important for Portal users. This acknowledgement is the confirmation that the delivery has been correctly transmitted to the Portal; however, it is not equivalent to the confirmation of receipt issued following a formal check by Swissmedic.**

### 5.2.2 Correcting an invalid delivery

If technical problems are noticed during the delivery, the user is informed about the error by a confirmation of rejection and a validation report delivered via the Dashboard. The system does not usually accept technically invalid deliveries.

Delivery ID	Company reference	Service / Subject	Delivery type	Authorisation/Case no.	Name of medicine	Last updated at	Last updated from	Delivery status	Functions
10000000277		Authorisation/Human medicines	Application authorisation			31.08.2016 15:08		Technically invalid	  

The user can then correct the documents and restart the *upload*. The corrected documents can be re-uploaded via the *Correct delivery* function (the small pen icon).



**Please note: If the Correct delivery function is used, all documents (corrected dossier, including any Working Documents) will also have to be uploaded again.**

### 5.2.3 Submission of a variation

The process for submitting a variation differs only marginally from that for a first authorisation.

- 1) *Application for existing case/authorisation* must be selected for a variation.
- 2) Since a variation is made to an existing case/clinical trial, the corresponding clinical trial can be selected from the drop-down list.

**Please note that a maximum of 15 cases are displayed in the drop-down list. A case that is not displayed can be located using the case number or the study title.**

- 3) The case is then added to the list via *Add case*.  
For collective applications, a further case can then be searched and added.

4) The subsequent steps follow the procedure for first authorisation.

### 5.2.4 Delivery of a response to an ongoing application

Unlike a delivery for a *First authorisation* or a *Variation*, a *Response* to an ongoing application is submitted directly under *Ongoing applications*.

- 1) You can find the application concerned by entering the *Application no.* or other information such as the *Delivery ID*.
- 2) Within the application, a small envelope icon with *Enter delivery for this application* is shown in the *Functions* area, and this starts the procedure for a delivery relating to an existing application.

+ Delivery of a new application

Ongoing applications
Deliveries
Upcoming milestones
Inbox

Filter criteria

Application no. <input style="width: 90%;" type="text" value="102554912"/>	Company reference <input style="width: 90%;" type="text"/>
Application type <input style="width: 90%;" type="text"/>	Date of letter from <input style="width: 15%;" type="text"/> to <input style="width: 15%;" type="text"/>
Authorisation/Case no. <input style="width: 90%;" type="text"/>	Name of medicine <input style="width: 90%;" type="text"/>
Application status <input style="width: 90%;" type="text" value="--"/>	Delivery ID <input style="width: 90%;" type="text"/>

Reset
Filter

Application no. ⌵	Company reference ⌵	Application type ⌵	Date of letter ⌵	Authorisation/Case no. ⌵	Name of medicine ⌵	Application status	Delivery ID	Functions
102554912	██████	NA NAS HAM	17.06.2016	66351	██████	IN PROGRESS	146502	<span style="color: #0070c0; font-size: 0.8em;">🔍</span> <span style="color: #0070c0; font-size: 0.8em;">✉</span> <span style="color: #0070c0; font-size: 0.8em;">📄</span>

3) The cases concerned are already preselected in the next screen.

## Enter delivery

### Select service

Authorisation

### Select subject

Human medicines

### Select application category

#### Enter medicines

Announced or authorised medicines  Medicines no longer authorised

Authorisation / Case no.

Name

Authorisation / Case no.	Name	eCTD Dossier	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="🗑"/>

### Select delivery type

Response to Swissmedic correspondence  
 Application [after accepted fast track/prior notification]  
 Clarification Meeting  
 Renouncement of an application  
 Extension of the time limit of an application  
 Communication

4) You can then select the files you want to upload.

### Files

#### Add file

5) The subsequent steps follow the procedure for first authorisation.

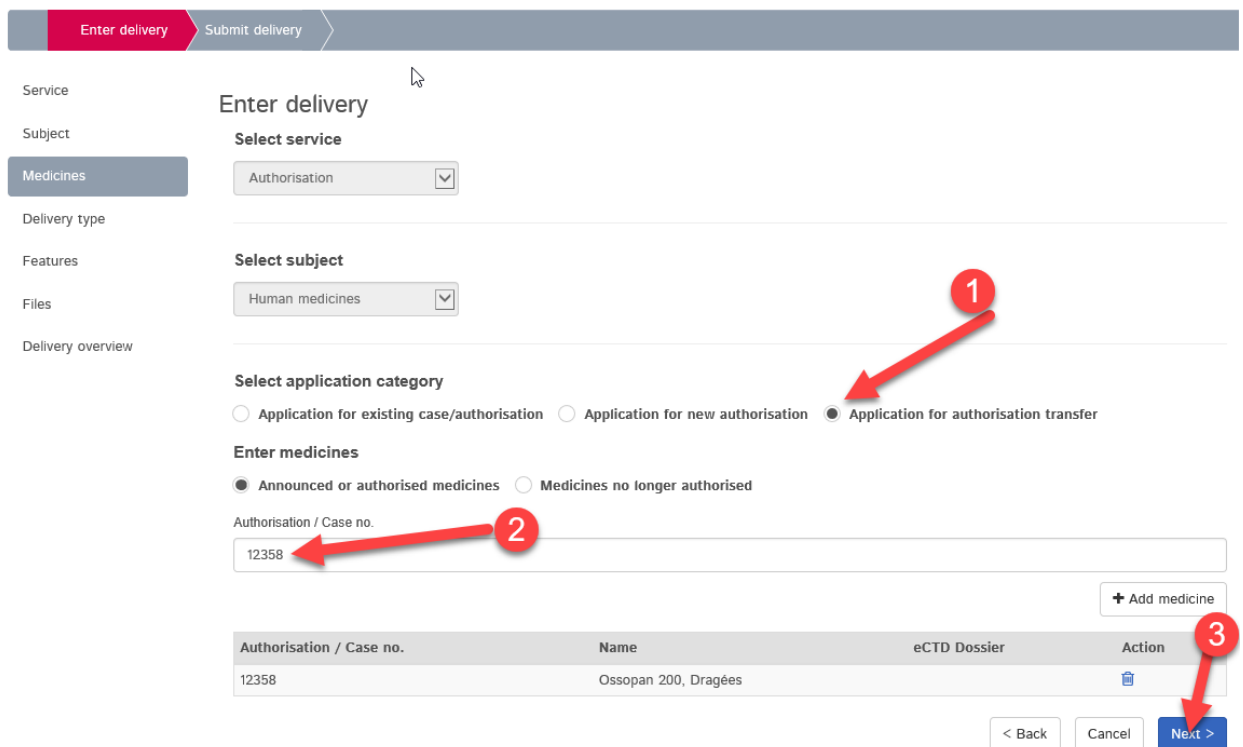
## 5.2.5 Submission of collective applications (collective deliveries)

If a delivery is created as a collective application for several cases, all the cases concerned are selected in the *Enter cases* screen and added using *Add case*.

**Please note: If no case is selected, clicking *Add case* will cause all cases registered to the user to be added to the list. This is rarely required and can lead to problems when the application is recorded by Swissmedic. To correct the situation, the delivery must be deleted and recreated.**

## 5.2.6 Submission of a change of sponsor

- 1) The Delivery type *Application for authorisation transfer* is used.
- 2) The new sponsor selects the case to be transferred using the case number and adds it to the list via *Add case*. For collective applications, several cases can be selected and added.
- 3) The eDok\_KLV is uploaded



A separate delivery should expressly not be created for each case. Swissmedic will assign the cases correctly when it records the application.

**Please note: During the 5 days prior to the submission of the change of sponsor, no other application may be submitted by the existing sponsor. Only after the re-registration is complete may the new sponsor submit new applications.**

## 5.3 Ongoing applications area -> Application tracking

In the *Ongoing applications* area of the Dashboard users can retrieve a variety of information on ongoing applications for which they possess appropriate authorisations. The *Application tracking* function is available for ongoing applications once users have registered on the eGov Portal.

Deliveries that have not been recorded by the OSS Division only appear in the *Deliveries* area; the corresponding acknowledgements can be searched in the *Inbox* using the *Delivery ID*. Once an

application has been recorded by OSS, it is assigned an Application ID. From this point onward, applications are displayed in the *Ongoing applications* area under the Application ID.

**Please note: After successful receipt, applications are recorded by Swissmedic within 5 days. A delivery may therefore not appear immediately under *Ongoing applications*. Users do not need to query this during this 5-day period.**

## 5.4 Upcoming milestones area →

Important upcoming milestones, i.e. the breakpoints between application phases, are shown in this area.

Please note the following:

- 1st When the application is opened, Swissmedic generates a schedule in accordance with the time limits stipulated in the *Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (ClinO, SR 810.305)*.
- 2nd The scheduling information is updated by Swissmedic during the course of the procedure.
  - If milestones are reached earlier or slightly later than scheduled, the time limits are adjusted when the milestone is completed.
  - If longer delays are expected (> 1 month), the procedure is rescheduled as soon as possible.
- 3rd Optional process steps (e.g. an additional round of text correction), are to some extent taken into consideration in the scheduling. If these steps are not needed, they are deleted and the schedule is adjusted accordingly.
- 4th Upcoming milestones are displayed only if they are no more than 30 days in the future.
- 5th Milestones are automatically generated schedules for time limits and are not binding. The project is not automatically adjusted if time limits are exceeded. For applications for which time limits are not relevant (non-substantial variations, reporting, etc.), in particular, the milestones represent only approximate, projected project information.

The presentation of the schedule and the milestones displayed may change if Swissmedic modifies the scheduling templates. This affects only those applications that are initiated after the templates have been modified. When an application is first entered in the Swissmedic eGov Portal, and also if the time limits for ongoing applications change, the company is informed via the correspondence e-mail address stated in the contract.

## 5.5 Inbox area with Swissmedic correspondence

Depending on the contractual agreement with Swissmedic, correspondence from Swissmedic to companies is made available in the Inbox. Other documents (such as acknowledgements) can also be downloaded from this area.

The *Retrieve status* function shows whether or not documents have already been downloaded.

Standard users only see those documents for which they possess authorisation.

In the *Subject* column it is possible to see whether the correspondence is assigned to a *Delivery*, an *Application* or a *Case* (case/clinical trial). The identification number in the *Subject no.* column is used for unambiguous identification.

The Inbox must be checked for new documents at regular intervals. If documents are not retrieved on time, Swissmedic must arrange a follow-up e-mail after the time limit has passed. The *Special Terms of Use for the eSubmissions Module* state that the official decision of Swissmedic must be sent by registered mail if the corresponding e-mail is not opened or downloaded within the time limit of 7 days from delivery.

Since this non-retrieval causes considerable extra work for Swissmedic, repeated failure to acknowledge receipt of official decisions on time may prompt Swissmedic to switch from electronic opening back to the postal opening of official decisions.

**Please note: The documents can be retrieved via the Swissmedic eGov Portal for up to 60 days from the date of the official decision or application closure, after which they will be automatically deleted. The Inbox should not therefore be treated as an archive. Users are urged to make back-ups of the documents.**

## 5.6 Time limits

The Usage Contract contains the provisions relating to time limits for Portal users.

The Terms of Use in section 4.3 of the Contract entail the following:

- Data can be submitted electronically at any time.
- The "clock" starts running on the next working day after the issue of the *Acceptance of Delivery* acknowledgement indicating successful delivery. The *Delivery confirmation* acknowledgement is not in itself sufficient.
- The *Acceptance of Delivery* counts as the acknowledgement of receipt for specific applications.
- If the submitted dossier (ZIP file) does not satisfy the requirements for eDoks, a Validation Report is issued and the delivery is deemed not to have been delivered. In this case too, an *Acceptance of delivery* acknowledgement is not yet issued.

Two examples are listed below:

- Deadline for delivery is 25 Jan. Application is submitted on 25 Jan. *Acceptance of delivery* acknowledgement is dated 25 Jan. → Deadline is met.
- Deadline for delivery is 25 Jan. Application is submitted on 25 Jan. But the company experiences technical problems and no *Acceptance of delivery* acknowledgement is issued. → Deadline is missed. A request for extension of the time limit must be submitted.

## 5.7 Acknowledgements and notifications

For certain steps during submission and subsequently, the Portal automatically issues acknowledgements or so-called notifications containing e.g. important information on status, errors, confirmations or official decisions.

### 5.7.1 Acknowledgements

Acknowledgements are automatically created by the Portal for the individual steps connected with a submission. These acknowledgements can be downloaded in the Dashboard under the specific deliveries and in the Inbox.

The following acknowledgement types exist:

- *Delivery confirmation* → Portal has received documents
- *Acceptance of delivery* → Portal has accepted documents and is starting processing
- *Denial of acceptance* → Portal cannot process documents

**Please note: The *Acceptance of delivery* is very important here, since only this acknowledgement serves as confirmation of receipt of the delivery via the Portal. If this acknowledgement is missing, Swissmedic will not start processing the delivery.**

### 5.7.2 Notifications

For applications recorded by Swissmedic and made available under *Ongoing applications*, notifications are generated by the Portal for various steps.

The following notification types exist:

- *Delivery notification* → Portal informs the user that Swissmedic documents are available
- *Download notification* → Portal confirms that registered documents have been downloaded
- *Expiration notification* → Portal confirms that registered documents have not been downloaded and initiates a paper letter

E-mails on the various milestones are sent by the system overnight. Notifications about newly available correspondence from Swissmedic are sent as soon as the documents are available in the Inbox.

## 5.8 Technical details

The following section addresses certain technical details. Please also note the separate Q&A document.

### 5.8.1 Delivery status

*Delivery status* provides information on the processing status. Information on any errors or problems that are encountered is displayed here.

The following statuses exist:

Status	Meaning
<i>Paused</i>	Delivery has been saved temporarily
<i>Processing</i>	Delivery is in progress

<i>Transmitted</i>	Delivery has been sent
<i>Technically invalid</i>	Technically invalid
<i>Accepted</i>	Delivery has been accepted

**Please note: Deliveries in the *Paused* or *Technically Invalid* status are automatically deleted after 30 days.**

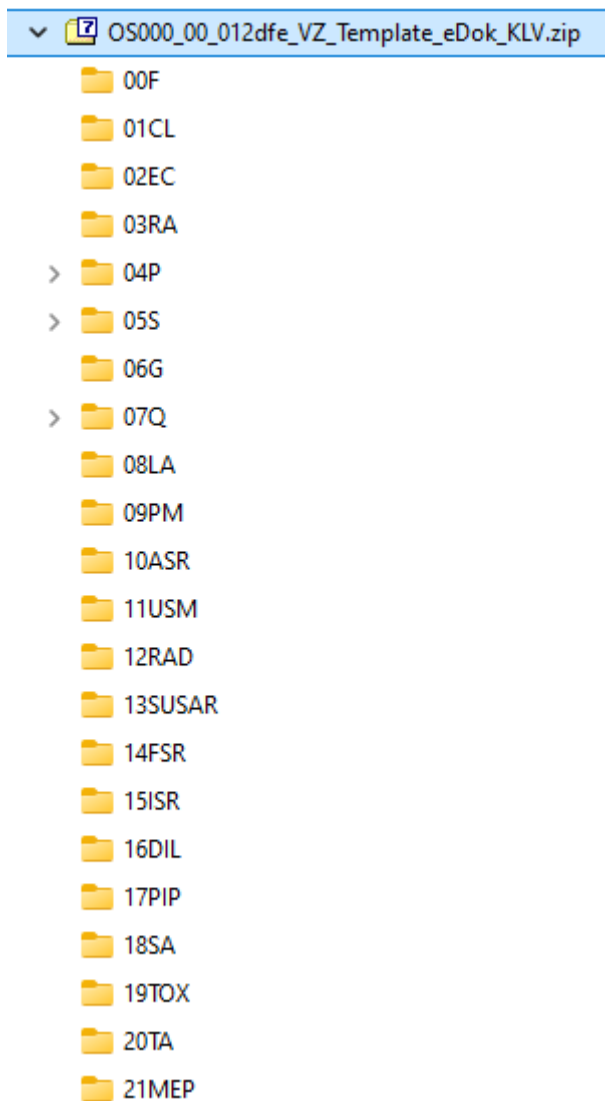
## 5.8.2 File formats

Document type	Authorised file formats
Dossier in eDok_KLV structure format	ZIP
Messages containing <ul style="list-style-type: none"> <li>- Letter</li> <li>- Attachment</li> </ul>	PDF, doc, docx

**Please note: The file extensions of the documents listed above must always be written in lower case, e.g. Document.pdf. The use of Document.PDF will lead to an error message on uploading.**

## 5.8.3 Structure of ZIP files

- 1) ZIP files for **eDoks** must be structured as follows:



**Please note: The folders must appear at the topmost level in the ZIP file. Incorporating an additional and higher-level folder into the ZIP file structure will result in a validation error when the file is uploaded to the Swissmedic eGov Portal.**

Any name can be given to the ZIP file but it is limited to 40 characters.

**Note: No ZIP files may be included in the eDok ZIP file, and the structure of Portal deliveries may not be modified, i.e. additional parent folders or subfolders are not permitted.**

#### **5.8.4 Checksum**

The Portal calculates a *checksum* for every delivery, including every file. This *checksum* allows the user to check the uploaded documents.

For each delivery you make, you can select the type of *checksum* to be calculated and used. MD5 and SHA-256 are two popular methods, and SHA-256 is the more modern and more secure algorithm.

A checking option is available post-delivery, using the general *checksum* for the whole delivery and the individual *checksum* for each delivered file, both in the Dashboard when the files are delivered and in the acknowledgement generated by the system.

SWISSmedic

Denial of acceptance  
**Specimen DEV**

Delivery-ID: 100000001  
Application no.:  
Doc-ID: 0010088727  
Your reference:

Data issuing platform: Swissmedic platform for electronic submissions

Recipient: Swissmedic  
Hallerstrasse 7  
3000 Bern 9

Date: 2016-05-24 12:11:07

Sender:



User identification: Adn-TestuserREF

Comment: Acceptance of delivery denied.  
Please consult validation report(s) and resubmit  
your application after correction.

Checksum Delivery: MD5  
3af186832ad1237fe01f738c59498573

Attachments:

0 0000.zip  
3af186832ad1237fe01f738c59498573

0 0000/index-md5.txt  
8485837f9840ec2bb320512bdbc7fb7a  
0 0000/index.xml  
a327dd146b9f2bf2389b71d20b2df7d9  
0 0000/m1/ch/ch-regional.xml  
dd2f955e939ca4a668a43f3e0ad708ea  
0 0000/m1/ch/tablets/10-cover/ch-cover.pdf  
fa3278df193f43319ce4bb4a42313eb1  
0 0000/m1/ch/tablets/12-foapplvar/121-foapplvar/ch-foapplvar.pdf  
fa3278df193f43319ce4bb4a42313eb1  
0 0000/m1/ch/tablets/12-foapplvar/122-ann-form/1221-formfulldeclaration/ch-fofulldecl.pdf  
fa3278df193f43319ce4bb4a42313eb1  
0 0000/m1/ch/tablets/19-fasttrack/ch-fasttrack.pdf  
fa3278df193f43319ce4bb4a42313eb1  
0 0000/m2/23-qos/drug-product.pdf  
ab3fb370b9fd6aa232842aab646dd5dc  
0 0000/m2/23-qos/drug-substance.pdf  
ab3fb370b9fd6aa232842aab646dd5dc  
0 0000/m3/32-body-data/32p-drug-prod/wonderpil-5mgtablets/32p1-desc-comp/description-and-composition.pdf  
37c423868635c4d8debfe83012142d37

Page 1 of 3

As can be seen in the example above, various *checksums* are generated:

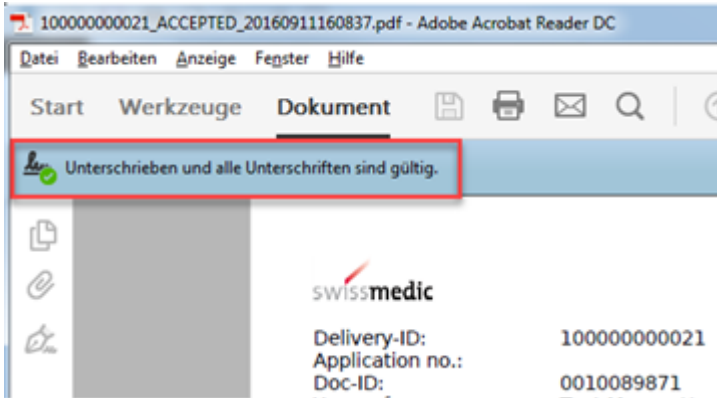
- 1) The *checksum* for the whole delivery, i.e. here the *checksum* is calculated for all documents (ZIP file plus any Working Documents).
- 2) The *checksum* for the dossier ZIP file
- 3) The *checksum* for each individual file in the delivery

**Please note: If there are any discrepancies Swissmedic Support must be contacted immediately.**

### 5.8.5 Handling of electronic / digital signatures and acknowledgements

Letters sent by Swissmedic via the eGov Portal, including official decisions or acknowledgements, are given a digital signature. Recipients can check the validity of these signatures themselves. PDF viewers (e.g. Adobe Reader) usually offer the corresponding functions.

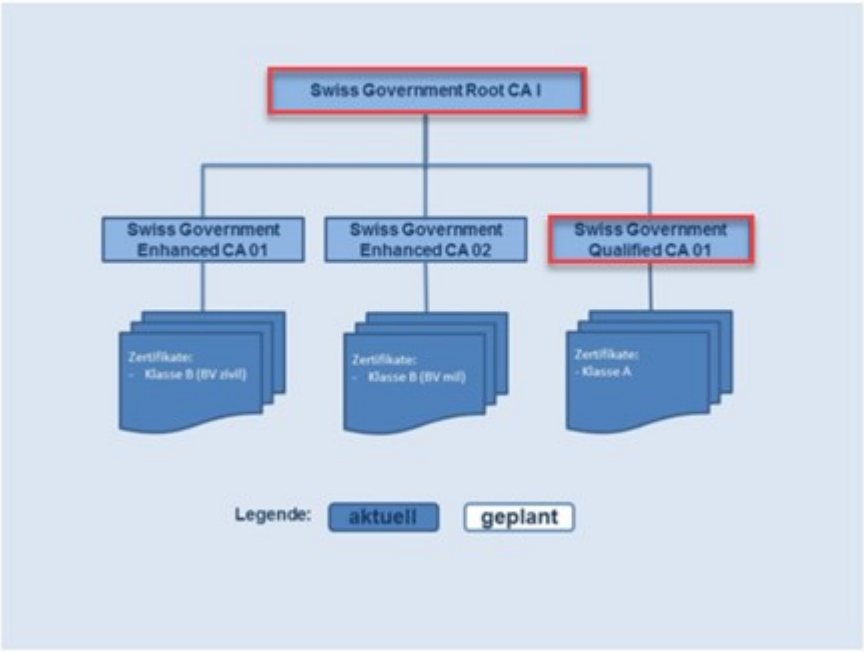
An example of a successful validity check is shown below:

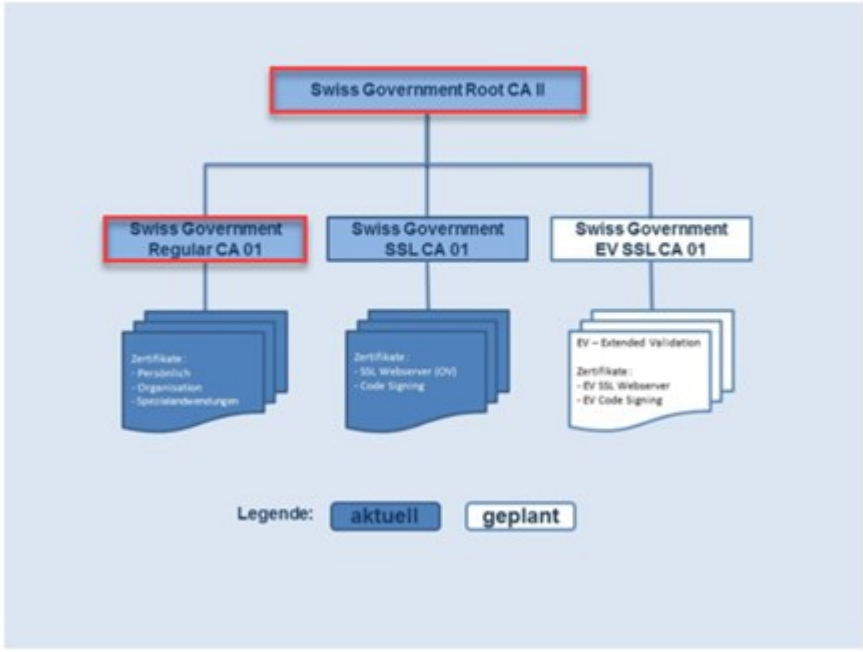


If errors are found when checking the validity of the signature, your local IT infrastructure will need to be checked. The most common cause is a missing element in the certificate chain. The following table shows which certificates must exist for each document type for a successful validity check. The certificates are made available on the *Swiss Government PKI* website.

For class A certificates (document type: official decision), an alternative option for validity checking is the *Online Validator service provided by the Federal Administration* (see table below).

Please contact your IT department if you need help with the installation of the certificates or any other issues.

<b>Document type</b>	<b>Official decision</b> (class A certificate)
<b>Digital signature</b>	Qualified electronic signature according to ZERTES
<b>Link</b>	<a href="https://www.bit.admin.ch/en/sg-pki-class-a">https://www.bit.admin.ch/en/sg-pki-class-a</a>
<b>Certificates</b>	<p>Swiss Government Root CA I</p> 

	<p>Root: Swiss Government Root CA I Intermediate: Swiss Government Qualified CA</p>
<b>Document type</b>	<b>Acknowledgement</b> (class C certificate)
<b>Digital signature</b>	Advanced electronic signature according to ZERTES
<b>Link</b>	<a href="https://www.bit.admin.ch/en/sg-pki-class-c-en">https://www.bit.admin.ch/en/sg-pki-class-c-en</a>
<b>Certificates</b>	<p>Swiss Government Root CA II</p>  <p>Root: Swiss Government Root CA II Intermediate: Swiss Government Regular CA 01</p>
<b>Alternative checking option</b>	<p>Online Validator service of the Federal Administration <a href="https://www.validator.admin.ch/">https://www.validator.admin.ch/</a></p> <p>Validate document</p> <p>Here you can check electronically signed documents. If an official function is assigned to the signature of an authorized agency, it will be displayed.</p> <p>1 Upload document</p> <div style="border: 1px dashed blue; padding: 10px; text-align: center;"> <p>↑</p> <p>Please drag your document to this window or click here and select an electronically signed file you wish to verify. Allowed documents .pdf / .xml</p> </div> <p>&gt; <a href="#">Data privacy statement, Protection of information and professional or administrative secrecy</a></p>



## 5.8.6 Submission of a Delivery Link via eGov Portal

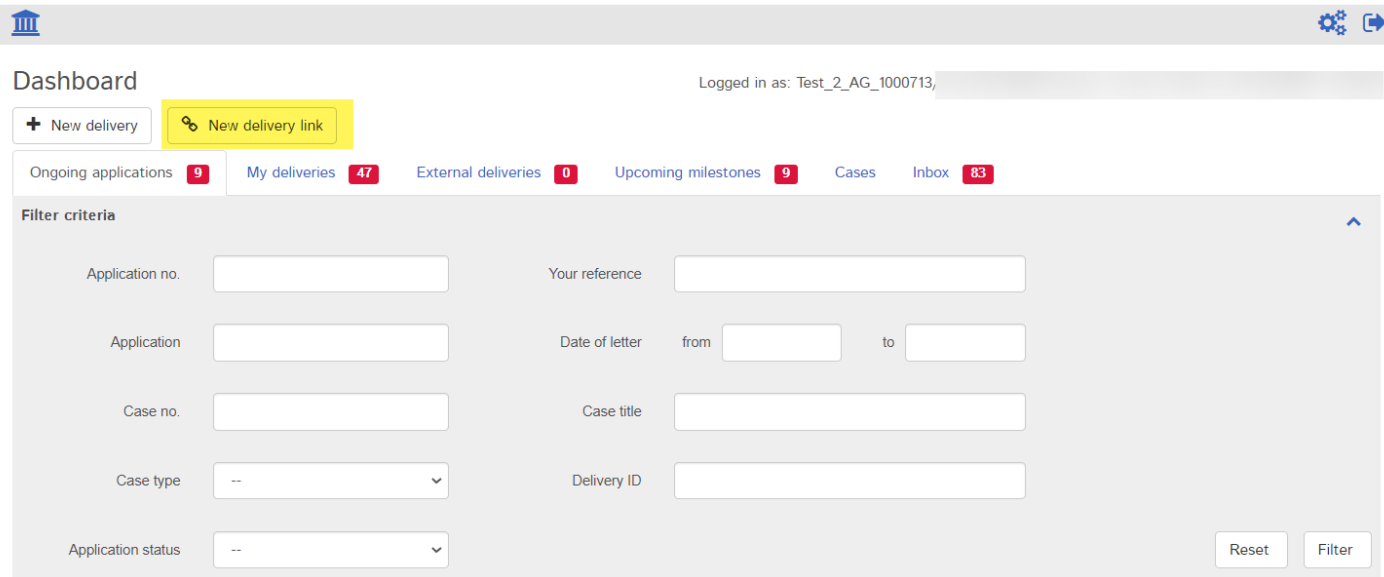
Confidential third-party documents can be delivered electronically by sending a Delivery Link through the eGov Portal. Only documents in **eDok** format can be submitted in this process. The sponsor generates a link and provides it to the party delivering the documents. The following instructions explain the process for delivering via the eGov Portal step by step.

### Sponsor's view

Log in to the eGov Portal

#### 1. Generate new link

Click on **“New delivery link”**.



The screenshot shows the eGov Portal dashboard. At the top, there is a header with a blue icon of a building and a gear icon. Below the header, the word "Dashboard" is displayed. To the right of "Dashboard", it says "Logged in as: Test\_2\_AG\_1000713". Below this, there are two buttons: "+ New delivery" and "New delivery link", with the latter being highlighted in yellow. Below the buttons, there are several status indicators: "Ongoing applications 9", "My deliveries 47", "External deliveries 0", "Upcoming milestones 9", "Cases", and "Inbox 83". Below these indicators is a "Filter criteria" section with several input fields: "Application no.", "Your reference", "Application", "Date of letter" (with "from" and "to" sub-fields), "Case no.", "Case title", "Case type" (a dropdown menu), "Delivery ID", and "Application status" (a dropdown menu). At the bottom right of the filter section, there are "Reset" and "Filter" buttons.

## 2. Select link type

Select “KLV Link” as the *Link type* for KLV deliveries.

### Delivery link generation

The generated link can be forwarded to one External Partner at a time and enables them to upload the document directly to Swissmedic.

**Link type \***

DMF Link

KLV Link

### 3. Select case

For an existing application, select the “Application no.”. Only the cases / applications assigned to the user can be selected.

Completing the “Comment” field is optional. A comment then appears in the overview list.

A link is generated (1). Copy this link to the clipboard and e-mail it to the party who will be delivering the documents.

Clicking on “Go to External deliveries” (2) generates an overview of external submissions. The view then switches to the overview of all links created to date.

#### Delivery link generation ×

The generated link can be forwarded to one External Partner at a time and enables them to upload the document directly to Swissmedic.

**Link type \***

DMF Link  
 KLV Link

#### Enter Application \*

Application No. \*

102566920

#### Comment

Test\_Link

**Link** 1

<https://www.gate-r.swissmedic.ch/ext/ext.xhtml?token=6sXNu6sHTnicneOu9MyC4ufxOjEIOFk> 

2

Go to "External deliveries"





Close

3

## Dashboard

+ New delivery
New delivery link

Ongoing applications 9
My deliveries 47
External deliveries 0
Upcoming milestones 9
Cases
Inbox 83

Created at	Valid until	Link	Action	Comment	Case no.	Case title	Application no.	Submitted at	Delivery status	Link type
08.05.2023 15:04	09.05.2023 15:04	<a href="https://www.gate-r.s...">https://www.gate-r.s...</a> <span style="background-color: orange; border-radius: 50%; padding: 2px 5px;">1</span>		Test  <span style="background-color: orange; border-radius: 50%; padding: 2px 5px;">2</span>					Open <span style="background-color: orange; border-radius: 50%; padding: 2px 5px;">3</span>	KLV
08.05.2023 15:00	09.05.2023 15:00	<a href="https://www.gate-r.s...">https://www.gate-r.s...</a>		Test_Link 					Open	KLV

### 4. Overview of external submissions

In the Dashboard you can view the Link (1), the Comment (2) and the Delivery Status (3).

### Third-party view

#### 1. Delivery of the documents by a third party

Once the link has been loaded, the following view is displayed (see image). The following actions must be performed:

Complete the fields marked with a \* (mandatory fields, 1-3) and continue with "Choose File" (4).

Select the ZIP file containing [the documents] on your PC.

**N.B.: Only documents in eDok format can be submitted.**

### Document upload

Upload all your documents within only one ZIP-File (eCTD or eDok). Your upload can only be retrieved by Swissmedic. There is no access for Marketing Authorisation Holders.

#### User information

First name \*

Last name \*

Email address \*

#### File upload

Please select the file for upload.

4
5

Choose file
Upload

6  
Submit

## 2. Uploading and submitting the documents

Continue with “Upload” (5).

As soon as the upload has been successfully completed, a green tick appears. Click on “Submit” (6) to complete the submission.

## 3. Generating the confirmation

Use “Generate PDF” (7) to obtain a PDF confirmation of the upload.



### Document upload confirmation

Thank you for uploading the document. Your file was successfully submitted.


**Delivery ID**  
100010042564

**Time of submission**  
08.05.2023 15:19:38 CET

**Contact data**  
Test Test  
swisspill1@gmail.com

#### File

File name	Hash algorithm	Hash value
eDok_KLV_Test.zip	MD5	42545e98da2dcddb071e6ad1a5aacaba

 We recommend to save this confirmation for your records by using the button "Generate PDF" below. You will not receive any further upload confirmation. When you are done, you can close the browser window.

**7**  
Generate PDF

## Dashboard

Logged in as: Test\_2\_AG\_1000713/

+ New delivery

🔗 New delivery link

Ongoing applications **9**

My deliveries **47**

External deliveries **1**

Upcoming milestones **9**

Cases

Inbox **83**

Created at	Valid until	Link	Action	Comment	Case no.	Case title	Application no.	Submitted at	Delivery status	Link type
08.05.2023 15:04	09.05.2023 15:04	https://www.gate-r.s...	📄	Test <a href="#">✎</a>	66462	hro_test_2018	102566920	08.05.2023 15:19	Submitted	KLV
08.05.2023 15:00	09.05.2023 15:00	https://www.gate-r.s...	📄	Test_Link <a href="#">✎</a>	66462	hro_test_2018	102566920		Open	KLV

### Sponsor's view

### 5. Status change of external submissions

The status changes from “Open” to “Submitted” as soon as the third party has delivered the documents. This enables the sponsor to check when the delivery was made.

## 6 Other eGov services

The Swissmedic eGov Portal also provides other services not discussed in this information sheet. For further details please refer to the corresponding guidance documents and information sheets on this website: <https://www.swissmedic.ch/swissmedic/en/home/services/egov-services.html>

## 7 Support

Support messages can be sent via:

- [www.swissmedic.ch/gate-support](http://www.swissmedic.ch/gate-support)
- [it@swissmedic.ch](mailto:it@swissmedic.ch)

We will be happy to help you with any technical or procedural questions about the eGov Portal. Please always contact us in writing for this purpose.

You will receive an answer or initial qualified feedback within 24 hours.

Please continue to direct questions on general subjects or pending applications through the appropriate channels. That way you will receive an answer from the responsible unit without delay.

## Change history

Version	Change	sig
1.1	New layout, no content adjustments to the previous version	tsj
1.0	Creation of content; a separate document for CT applications submitted via the eGov Portal	dms, ma, plp