List of contents

Change history

Version	Valid and binding as of:	~~Modified without~~New minor version ~~change~~	Description, comments (by author)	Author's initials
3.1		01.09.2018	Time limits section: Incorrect examples have been reset to their status as per Version 02 of the document. No change regarding handling of time limits.	mra
~~02~~3.0	~~30.11.17~~01.06.2018		**Deadlines section revised,** content revised and updated	**mra**
02	30.11.2017		**Content revised and updated**	mra
01	03.05.~~17~~2017		**Content revisions; the Q&A section is hived off into a separate document; removal of section on the old portal**	**mra**
		26.04.~~17~~2017	New QM-Ident: OS000_00_001d_MB (Version 01) Old QM-Ident: ZL000_00_032d_MB (Version 09)	feh

1   Terms, definitions, abbreviations, glossary

Department OSS	Swissmedic Department Operational Support Services
Acceptance of…	Acknowledgement for a specific step
Application authorisation, New application	Authorisation application
Application category	Selection: Authorised preparations, preparations no longer authorised, etc.
Application no., Application number	Application ID, service order number
Application Tracking	Application tracking for ongoing applications
Art.13	Article 13 submission
Baseline	Switching from paper-based to eCTD submission
Basic company dossier	Basic company dossier
Case / Authorisation / Name of Medicine	Preparation, preparation name
Checksum, Md5-Checksum, Hash algorithm, hash code	Checksum calculated for a submission of individual files
Communication	Communication to Swissmedic
Communication not concerning authorisation	Communication to Swissmedic that is not related to the authorisation (NZL)
Company Reference	Reference, your reference
Concerns subsequent delivery	Subsequent delivery of documents for an ongoing application
Dashboard	Work environment and input screen
Delivery	Delivery for new or ongoing applications
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
eCTD	International submission format for authorisation applications

eDok	Swissmedic submission format for authorisation applications
eGov	eGovernment
eGov Service	Individual service within the eGov Portal
eMessage	Service eMessage
eSubmission	Service for recording submissions
Extension of authorisation	Extension of authorisation
Extension of the time limit for an application	Extension of the time limit for an application
Fast track authorisation	Fast-track authorisation procedure
Follow-up Measures	Conditions
HAM	(Department) Human medicinal products, Human medicine
Inbox	Inbox for Swissmedic correspondence in the Dashboard
KPA	(Department) Complementary and Herbal Medicines
LoQ	List of questions
Milestone	Breakpoints between the application phases
mTAN	mobile transaction number via SMS
New authorisation	First Authorisation, New Application
Notification	Notification by e-mail
NZL	Non-Authorisation
Procedure with prior notification	Procedure with prior notification
Q&A	Questions and Answers
Reference dossier	Reference dossier for an Article 13 submission
Release	Version of the Portal software
Renewed authorisation	Renewed authorisation
Renunciation of an application	Renunciation or withdrawal of an application
Response to Swissmedic correspondence	Response to Swissmedic correspondence
Sequence	Component of an eCTD submission
Subject	Division (HAM, TAM, KPA)
Subject no., Subject number	Identification number for applications, corresponds to Delivery ID
TAM	(Department) Veterinary Medicines
Text correction communication	Text correction communication, TPS
Transferring authorisation	Transferring authorisation
Upload	Upload process
Validation Report	Validation Report in the event of mistakes during submission
Variation	Variation application
Withdrawal of authorisation	Withdrawal of an authorisation for a medicinal product
Working Documents	Working documents, including Information for healthcare professionals, Patient information and packaging elements
Zip file, ISO file	Packed file for upload
ZL	Authorisation

2   Objective and scope

This Information sheet contains the basic information needed to use the Swissmedic eGov Portal, particularly the eGov **eSubmissions services.** A separately managed Questions and Answers document (Q&A) covers additionally arising questions and problems. Both documents are updated at regular intervals and are available on the login screen.
User administrators should refer to the *Swissmedic Portal – Administrator functions* information sheet.

3   Conditions for the use of the Swissmedic eGov Portal

A User Agreement with Swissmedic must be signed in order to use the Portal.
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.

Minimum system requirement: the latest version of Microsoft Internet Explorer (version 10 or higher) or Firefox (version 40 or higher).

4   ~~Using~~Access to the Swissmedic eGov Portal

The Swissmedic eGov Portal is accessed via the address www.portal.swissmedic.ch. Once the user has entered their user ID and previously established password, an SMS message containing a mobile transaction number (mTAN) will be sent to the user's registered mobile phone number. This transaction number must be entered on the following screen in order to complete the login process. When a user logs in for the first time, and also following software updates, the user must agree to the latest terms of use.

The Portal includes an option for resetting the password. Once the user has entered their registered e-mail address, the system will send a new password to that address. This password should then be changed immediately by the user.

Please note: the login screen shows the latest versions of the Information sheet and the Q&A, as well as important information on any maintenance time windows.

5   ~~New Swissmedic~~Using the eGov Portal ~~from 2016 (pilot phase) / 2017 (regular operation)~~

This section explains the basic functions and processes of the new Swissmedic eGov Portal in greater detail. The Portal is also the central access point for other *eGov Services*. Although the default language of the Swissmedic eGov Portal is English, the information sheets are available in several languages.

Please note: the screenshots shown in this document do not always show the full screen area.
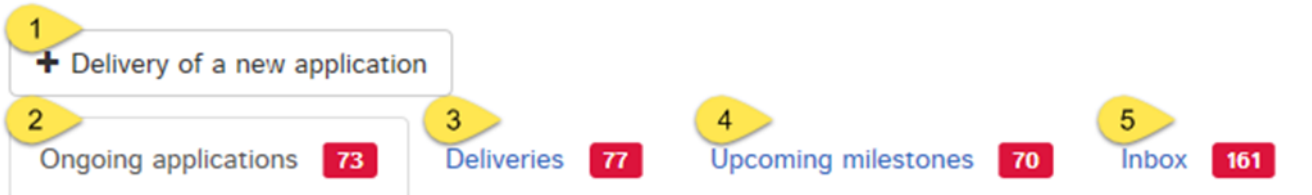
5.1   Administration area

This view is only accessible to user administrators. For further details please refer to the information sheet for administrators.

5.2   eGov eSubmission area

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

Dashboard

1	Deliver documentation for a new application. This includes deliveries relating to existing or new preparations.
2	List of entered applications in progress at Swissmedic. Answers to correspondence, with reference to a specific application, are also delivered here.
3	List of deliveries to Swissmedic that have been submitted electronically by the authorisation holder but that have not yet been entered.
4	List of tasks relating to all applications due within the next 30 days, with planned finish dates.
5	List of all correspondence from Swissmedic relating to a delivery (identified by a delivery ID), an application (identified with an application no.) or an authorisation (identified by an authorisation number)

5.2.1 Example of a submission for first authorisation

The complete process is illustrated below for a first authorisation.

1) *Dashboard -> Delivery of a new application*
2) *Subject,* i.e. the area concerned (human, veterinary or complementary medicine)
3) *Application category.* Options here include deliveries relating to a *notified* or *authorised medicinal product*, *deliveries for a new medicinal product or deliveries for an authorisation transfer.*
4) Enter the name of the new preparation

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 potentially lead to delays.

~~Please note that entries in the *Name* field under *Enter medicines* are subject to the following rules.~~ 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 *Name of medicine* is entered, the field is outlined in red and the process cannot be continued until the name has been corrected.
The field length is limited to a maximum of 20 characters. Actual preparation names that are longer than 20 characters must be abbreviated. However, the Swissmedic system will use the full intended name for the preparation (taken from the information on the Authorisation/Variation application form).

5) The preparation is added via *Add medicine*. Only then will the *Next* button be enabled.

Enter delivery

Select service

Authorisation

Select subject

Human medicines

Select application category

○ Application for existing case/authorisation   ● Application for new authorisation   ○ Application for authorisation transfer
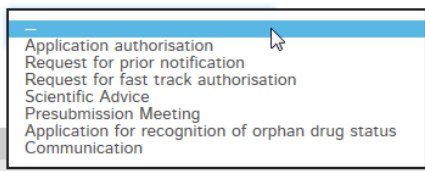
Enter medicines

Name

TestPraeparat

+ Add medicine

Authorisation / Case no.	Name	eCTD Dossier	Action
0	TestPraeparat		🗑

< Back   Cancel   Next >

6) Now select the *Delivery type* ~~and other properties for the delivery.~~

Select delivery type

—
Application authorisation
Request for prior notification
Request for fast track authorisation
Scientific Advice
Presubmission Meeting
Application for recognition of orphan drug status
Communication

7) Select other properties for the delivery, e.g. Orphan Drug Status (ODS), information relating to Article 13, Company Reference and Hash algorithm

Features

ODS recognised

○ Yes   ● No
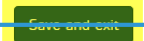
Art.13 *

○ Yes   ● No

Company reference

Hash algorithm *

Message-Digest Algorithm 5

- Swissmedic uses the information in *ODS recognised* for the internal prioritisation of deliveries.
- Entering *Yes* for Art.13 means that an Art.13 reference dossier will have to be uploaded.
- Company reference is a free field that can be used by the user for identifying the delivery.

- The Hash algorithm option can then be used to select the method for calculating the checksum.

8) If necessary, the delivery can be saved temporarily via [< Back] [Cancel] [Save and exit] [Next >] .Save and exit. The delivery can then be completed later. The dashboard will then show the status as *Paused*.

Dashboard

+ Delivery of a new application

Ongoing applications 8   Deliveries 2   Upcoming milestones 10   Inbox 2

Delivery ID	Company reference	Service / Subject	Delivery type	Authorisation/Case no.	Name of medicine	Last updated at	Last updated from	Delivery status	Functions
100000000881		Authorisation/Human medicines	Application authorisation		Test_0809	08.09.2016 14:36	Ralph.Allergan	Paused	▶ Q 🗑

To resume the delivery, click the arrow under *Functions* and *Continue delivery*.
You can also completely delete incomplete deliveries by clicking the *Trash can* icon.

Please note that: a paused delivery will be deleted automatically after 30 days and can then no longer be edited or completed.

9) In the next step, you should specify the type of document you are uploading, and the format to be submitted (eDok or eCTD) and the storage location of these documents.).
For collective applications submitted in the eCTD format, the correct preparation name (eCTD dossier column in the table of selected preparations) should be selected. This ensures that several eCTD sequences are assigned to the correct preparation.

The *Add another file* function can then be used to transfer any Working Documents. An Art.13 reference dossier, for example, can also be uploaded at his point.

Please note: The *Working Documents* should be delivered at the same time as the dossier and not only whenafter the application has been published on the Portalrecorded by Swissmedic.

The files are transferred with the *Upload* button.

Files

Add file

| Dossier ▼ | eCTD ▼ | TestPraeparat ▼ | | 📂 Choose file | 🗑 |

⬆ Upload

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.

During the *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 technical validation for an eCTD or the structural check for eDoks, which are only performed 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.
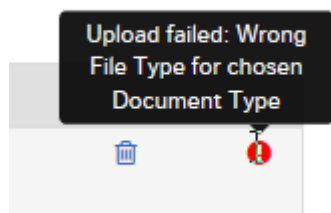
Files

Document type			File name		
Dossier	eCTD	TestPraeparat	eCTD-0000.iso	🗑	☑

+ Add another file   **II 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.

Upload failed: Wrong File Type for chosen Document Type

🗑   ❗

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

10) If everything is correct, the delivery can be completed and handed over to the system. To this end, a *Delivery overview* with a summary of the details is displayed.

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.

Please note: It is no longer necessary to send a signed and dated printout of the md5 checksum for an eCTD by post. The checksum completely replaces this procedure.

Files

Document type	Structure format	eCTD dossier	File name	Hash
Dossier	eCTD	TestPraeparat	eCTD-0000.iso	db1fb1189bc1d736dbd0090ab4b0aeb3b9b60e6f17f2c0f7d5fbbfd535388aad

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 placed in 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 for the acceptance of the delivered files, including a more detailed technical validation of the eCTD and 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 placed in your Inbox and e-mailed to the user's registered correspondence e-mail address.

Please note: The receipt of the *Acceptance of Delivery* acknowledgement is important for Portal users. It represents the confirmation of receipt and also concludes the delivery of a first authorisation.

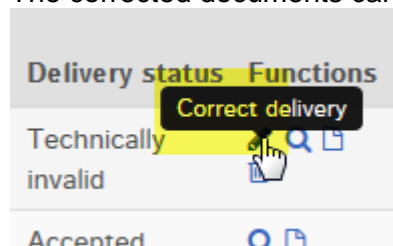### 5.2.2   Correcting an invalid delivery

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

The user can then correct the documents and restart the *Upload*. The system does not usually accept technically invalid deliveries.
The corrected documents can be re-uploaded via the *Correct delivery* function (the small pen icon).

Please note: During a correct delivery upload, all documents (corrected dossier, incl. 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 new authorisation* ~~must be selected for a first authorisation, while~~ *Application for existing case/authorisation* is selected for a variation.

2) ~~Selection of the preparations concerned.~~ Since a variation relates to an existing preparation, the corresponding preparation can be selected from the selection list via the authorisation number or the preparation name.

   Please note that a maximum of 15 products are displayed in the drop-down list. A registered preparation that is not displayed can be included via the authorisation number or name.

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

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

5.2.4 Submission of working documents

Please note: In general, the *Working Documents* should always be uploaded together with the actual delivery, see section 5.2.1.

In addition to the eDok or eCTD dossier, any Product information for healthcare professionals, Product information for patients or Packaging elements are uploaded by choosing the appropriate item from the menu.
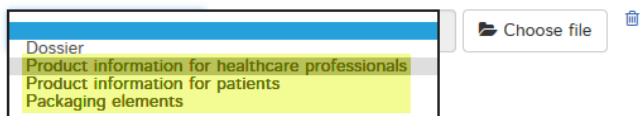
Please note: These documents should not be inserted directly into the structure of an eCTD or eDok dossier.
It is also not necessary to submit a data storage medium with the Working Documents as well.

5.2.5 Example of a reply to an ongoing application

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

1) You can search for the desired application using the *Application no.* or other information such as the *Delivery ID*.
2) For the relevant 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.

3) The preparations 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

+ Add medicine

Authorisation / Case no.	Name	eCTD Dossier	Action
			🗑

Select delivery type

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

< Back   Cancel   Next >

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

Files

Add file

| Dossier | eCTD | Praeparat2006 | | 📂 Choose file | 🗑 |

⬆ Upload

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

5.2.6   Example of a submission of an Article 13 reference dossier

Please note: This document does not address the general procedure for general deliveries according to Art. 13. The corresponding specification documents still take precedence here.

For deliveries according to Article 13, a reference dossier is usually uploaded as well. The procedure is essentially the same as that for first authorisation or a variation. If you are making a delivery under Article 13, you should also click *Yes* to start the separate process.

Please note: If a consolidated Swiss sequence is being submitted directly rather than a reference dossier, this *Art.13* option may not be selected.

Finally, you can select and upload the reference dossier, along with the regular Swiss eCTD sequence, in the *Files* area. See also section 5.8.3 for details of the structure of the zip file. A ~~rudimentary~~ technical validation is performed here, and the result displayed straight away. However, the reference dossier does not undergo more extensive technical validation.

~~Please note: This document does not address the general procedure for general deliveries according to Art. 13. The corresponding specification documents still take precedence here.~~

5.2.7 Submission of collective applications

If a delivery is created as a collective application for several preparations, all affected preparations are selected in the *Enter medicines* screen and added with *Add medicine*.

Please note: If no preparation is selected, clicking *Add medicine* will cause all preparations 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.

If the delivery only includes eDok-managed preparations, you will need to proceed as follows:
- One (1) new delivery is created
- The preparations are added to the list
- Only a single eDok dossier may/can be uploaded for all eDok-managed preparations. Therefore, all documents must be inserted into a single eDok template. If several forms, documents, etc. exist, these must be named differently as appropriate and inserted into the

folder. No parent folders within the zip file may be created for each preparation in a collective application since this would result in an invalid dossier

If the delivery only includes eCTD-managed preparations, you will need to proceed as follows:
- One (1) new delivery is created
- The preparations are added to the list
- A separate eCTD dossier must be uploaded for each eCTD-managed preparation, provided it has its own separate life cycle
  - o If an eCTD life cycle includes several preparations, the eCTD dossier is uploaded to the smallest authorisation number

If the delivery includes both eDok-managed and eCTD-managed preparations, you will need to proceed as follows:
- One (1) new delivery is created
- The preparations are added to the list
- A separate eCTD dossier must be uploaded for each eCTD-managed preparation, provided it has its own separate life cycle
  - o If an eCTD life cycle includes several preparations, the eCTD dossier is uploaded to the smallest authorisation number
- Only a single eDok dossier may/can be uploaded for all eDok-managed preparations. Therefore, all documents must be inserted into a single eDok template. If several forms, documents, etc. exist, these must be named differently as appropriate and inserted into the folder. No parent folders within the zip file may be created for each preparation in a collective application: this would result in an invalid dossier since the specified structure would no longer be correct. For the sake of clarity, it is possible to create folders at the lowest structural level

As a general rule: Splitting into several deliveries must be avoided since this can cause problems with recording and lead to delays.

5.2.8 Submission of a reply concerning multiple application IDs

Replies concerning multiple *application IDs* should be submitted under the lowest *application ID*. Please also mention this procedure briefly in the cover letter. Swissmedic will then assign the replies to the corresponding variation. The correct assignment will then be shown in Application tracking.
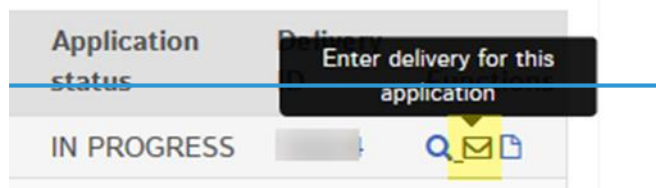
5.2.9 Example of the submission process after approval of a fast-track application and procedure with prior notification

~~The current release of the Portal does not yet incorporate a *Delivery Type* specifically for applications submitted after a fast-track application is approved. This will be amended in a future release.~~
For the time being, please proceed as follows if you need to submit such applications:
1) Swissmedic has already created a dummy application that you will have to use to submit your application after fast-track approval.
2) You will find the corresponding application under *Ongoing Applications*, using the Application no. that was sent to you.
3) You can then start the process via *Functions*.

4) Please use the *Application Type Response* ~~to Swissmedic correspondence~~ to upload your ~~eDok or eCTD dossier, depending on the preparation~~*or application to accepted fast track / prior notification*.

5.2.10 Example of a submission with conversion to eCTD or use of an eCTD baseline

~~Bei einer Umstellung von bisherigen Papier-Einreichungen auf eCTD muss bei Swissmedic zuerst ein sogenanntes eCTD-Dossier angelegt werden. Dies kann sowohl über eine Baseline als auch über eine reguläre eCTD-Sequence geschehen.~~

~~1) Es wird eine neue Einreichung gestartet, für die der Name eines neuen Präparats eingegeben wird:~~

In the event of a switch from previous paper submissions to eCTD, an "eCTD dossier" first has to be created at Swissmedic. This can be done either via a baseline or via a regular eCTD sequence.

1) A new submission is started and the name of a new preparation entered:

Select application category

◯ Application for existing case/authorisation   ⦿ **Application for new authorisation**   ◯ Application for authorisation transfer

Enter medicines

Name

[   ]

+ Add medicine

| < Back | Cancel | Next > |

~~Es dürfen dabei einzig die folgenden Zeichen verwendet werden:~~
Only the following characters may be used:

- A ~~bis~~to Z (~~Grossschreibung~~upper case)
- a ~~bis~~to z (~~Kleinschreibung~~lower case)
- 0 ~~bis~~to 9 (~~Ziffern Null bis Neun~~numbers zero to nine)
- - (~~Bindestrich~~hyphen)
- _ (~~Unterstrich~~underscore)

~~Alle anderen Zeichen, Leerschläge usw. sind nicht erlaubt. Ebenso ist die Feldlänge auf 20 Zeichen beschränkt. Sollte der tatsächliche Präparatename länger als 20 Zeichen sein, muss dieser abgekürzt werden. Das Präparat wird von Swissmedic trotzdem mit dem von Ihnen vorgesehenen vollständigen Namen geführt (gemäss Ihren Angaben im Formular *Gesuch Zulassung/Änderung*).~~

~~**Bitte beachten: Alle anderen Eingaben, wie z.B. Notification, Variation usw. sind hier nicht zulässig und führen dazu, dass das Dossier nicht korrekt angelegt werden und somit zu zeitlichen Verzögerungen führen kann.**~~

~~Das~~No other characters, blank spaces, etc. are permitted. The field length is also limited to 20 characters. Actual preparation names that are longer than 20 characters must be abbreviated. However, the preparation will be managed by Swissmedic system with the full intended name for the preparation (taken from the entries on your *Authorisation/Variation* form).

Please note: No other entries – e.g. notification, variation etc. – are permissible here and will mean that the dossier cannot be created correctly, which may potentially lead to delays.

2) In the next step, the Portal ~~zeigt im nächsten Schritt korrekt~~correctly shows that an~~, dass noch kein~~ eCTD ~~Dossier zum Präparat vorhanden ist~~ dossier does not yet exist for the preparation:

Authorisation / Case no.	Name	eCTD Dossier	Action
0			🗑

3) ~~Unter *Add file* ist als Ziel für die eCTD-Sequence automatisch der oben neu eingegebene Präparatenamen ausgewählt.~~
3) Under *Add file*, the above-mentioned newly entered preparation name is automatically selected as the destination for the eCTD sequence.

Files

Add file

| Dossier ▾ | eCTD ▾ | ▾ | | 📂 Choose file | 🗑 |

⬆ Upload

4) ~~Danach kann der Upload gestartet werden.~~
4) The upload can then be started.

Files

Document type			File name	
Dossier	eCTD	Newdossier	eCTD-0000.iso	🗑
Product information for healthcare professionals			FI_Ralph.docx	🗑
Product information for patients			26.10..docx	🗑

~~Bitte beachten Sie, dass eine *Baseline* nicht unter~~Please note that a *baseline* is not displayed under *Ongoing applications* ~~angezeigt wird. Für~~. Since **Swissmedic** ~~stellt eine Umstellung auf~~does not regard a conversion to **eCTD** ~~mittels *Baseline* kein Gesuch dar und entsprechend gibt es auch keinen Eintrag im~~via the *baseline* as an application, no entry appears in *Application Tracking*.

5.2.11 Submission of follow-up measures

At the moment, there is no specific *delivery type* for submitting *follow-up measurements*. Please use *Variation application* from the context menu until further notice. Swissmedic will then make the correct assignment based on the cover letter.
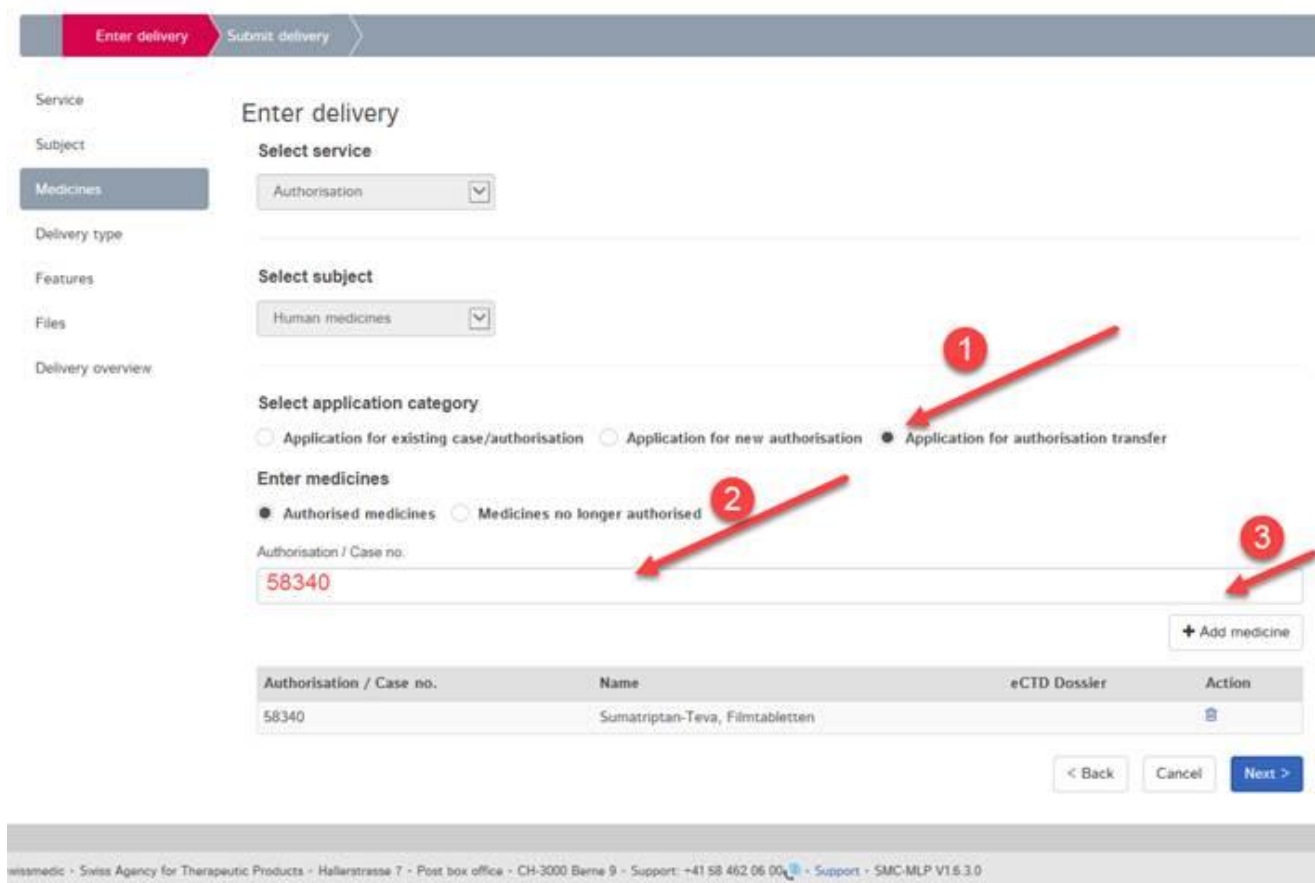
5.2.12 Submission of a communication

In the Portal, the term *Communication* applies to all submissions that are not first authorisations, variations, or responses to milestones. These include, for example, a journal article that is relevant to the application but which is not a response. However, they may also involve information stating, for example, that the preparation has now been authorised abroad or correspondence concerning a signal that has already been opened.

These communications can be sent to Swissmedic as a *New delivery* using the Delivery Type *Communication*.

~~Bitte beachten Sie: Diese~~Please note: This **delivery type** of ***Communication*** ~~darf nicht für die Einreichungen von regulären Gesuchen oder Auflagen~~may not be used for submissions of regular applications or conditions **(*Follow-up Measures*)** ~~verwendet werden.~~).

5.2.13   Submission of an authorisation transfer

1) The Delivery Type *Application for authorisation transfer* is used.
~~2)~~ The new authorisation holder selects the preparation to be transferred using the authorisation number~~,~~
~~3)~~2)   and adds ~~this~~it to the list via *Add medicine*. For collective applications, several preparations can be selected and added.
~~4)~~3)   ~~uploads~~upload the eDok or the eCTD

A separate delivery should definitely not be created for each preparation.
Swissmedic will then assign the preparations correctly when it records the application. Ideally, the PDF of the Application for authorisation/variation form should bear the corresponding preparation name. This will simplify recording.

Please note: During the 5 days prior to the submission of the authorisation transfer, no other application may be submitted by the existing authorisation holder. Only after the reregistration is complete may the new authorisation holder submit new applications.

5.2.14   Submission of a HOMANT preparation report

~~Until now~~ HOMANT preparation ~~reports could not~~notifications can be submitted ~~as an~~in eDok ~~to Swissmedic. However,~~format and hence via the ~~eDok guidance document has now been updated to add this option~~eGov Portal.

Please proceed as follows ~~in the Portal~~:
- Create an eDok according to the Template and Formal Requirements.
- The zip file required for the upload must be structured as follows:
    - In parallel with the module structure, the HOMANT XML file must appear at the topmost level
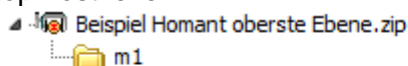
    -
- Create a delivery in the Portal Dashboard with Delivery Type "Homant Reporting" for an existing preparation

5.3   Ongoing applications -> Submission tracking area

In the *Ongoing applications* area of the dashboard users can retrieve a variety of information on ongoing deliveries 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 Submissions 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 deliveries, 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. This time limit also applies generally to special application types such as fast-track authorisations, procedures with prior notification, baseline etc. It is possible, therefore, that a delivery does not appear immediately under *Ongoing Applications*. Users do not need to query this during this 5-day period.

5.4   Area Upcoming milestones

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

Please note the following:
1st   When the application is initiated, Swissmedic draws up the time schedule in accordance with the time limits specified in the corresponding Administrative Ordinance.
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.
▪   In the case of longer delays (> 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.

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 an adjustment is carried out. When an application is first entered in the Swissmedic eGov Portal, and also in the case of changes to time limits for ongoing applications, 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 (e.g. acknowledgements, Information for healthcare professionals/Patient information and Packaging elements) can also be downloaded from this area.
The *Retrieve status* function shows whether documents have already been downloaded or not yet retrieved. 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* (preparation). 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 will have to arrange a follow-up e-mail after the time limit is 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 ~~Deadlines~~

5.6 Time limits

The Usage Contract ~~regulates~~contains the ~~handling of~~provisions relating to time limits for Portal users. ~~The date of receipt of a delivery is counted as one working day after receipt. This must be taken into account where there are time limits for certain deliveries.~~

The ~~Special~~ Terms of Use, section 3.2 of the Contract, ~~are handled as follows~~entail the following:
- Data can be submitted electronically at any time.
- The ~~date of receipt and the date for calculating time limits is considered to be~~"clock" starts running on the next working day after the issue of the *Acceptance of Delivery* acknowledgement~~, which indicates~~ indicating successful delivery. The *Delivery confirmation* acknowledgement is not in itself sufficient.
- The *Acceptance of Delivery* counts as the acknowledgement of receipt ~~of notifiable~~for specific applications.
- If the submitted dossier (ZIP file) does not satisfy the requirements for eCTD or eDok, a Validation Report is issued~~,~~ and the delivery is ~~considered as~~deemed not to have been delivered. In this case too, an *Acceptance of delivery* acknowledgement is not yet issued.

~~A few~~Two examples are listed below:

- Deadline for delivery is 25 ~~January. Delivery takes place~~Jan. Application is submitted on 25 ~~January and acknowledgement is dated 25 January -> time limit is observed if reply is sent on 25 January and the~~Jan. *Acceptance of delivery* acknowledgement is ~~sent on 25 January~~dated 25 Jan. -> Deadline is observed.
- Deadline for delivery is 25 ~~January. Delivery sent~~Jan. Application is submitted on 25 ~~January,~~Jan. But the company ~~suffers~~experiences technical problems~~,~~ and no *Acceptance of delivery* acknowledgement is ~~sent -> time limit~~issued. -> Deadline is ~~not observed~~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, mistakes, 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 for 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. If this acknowledgement is missing, Swissmedic will not process the delivery any further.

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

By way of example, the structure of the subject line for any automatic forwarding is shown below:

- Mail 1 - New Application = information about the first publication of an application
  [Swissmedic Portal: New Application; <ZL number>; <SA number>; <preparation name>; <reference>]
- Mail 2 - Application Update = information about changes in the event of changes to an important milestone for an application
  [Swissmedic Portal: Application update; <ZL number>; <SA number>; <preparation name>; <reference>]
- Mail 3 - Correspondence from Swissmedic = information about the receipt or expiry of Swissmedic correspondence
  [Swissmedic Portal: Correspondence; <ZL number>; <SA number>; <preparation name>; <reference>]

- Mail 4 - Correspondence from Swissmedic NZL = information about the receipt or expiry of Swissmedic correspondence unrelated to the authorisation (planned)

  [Swissmedic Portal: Correspondence]
- Mail 5 - Confirmation of acceptance (rejection) ZL = information about the completion of processing, incl. confirmation of acceptance or rejection

  [Swissmedic Portal: Delivery; <ZL number>; <SA number>; <DeliveryID>; <preparation name>; <reference>]
- Mail 6 - Confirmation of acceptance (rejection) NZL = information about the completion of processing, incl. confirmation of acceptance or rejection unrelated to the authorisation (planned)

  [Swissmedic Portal: Correspondence]

Please note: The subject lines of e-mail 1 and e-mail 2 will only be switched when all companies have changed over to the Swissmedic eGov Portal. Until then the existing subject lines will continue to be used:

→ Swissmedic Portal Application: <ZL number>; <SA number> - <"preparation name">

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 will be displayed here.

The following statuses are possible:

Status	Meaning
Paused	Delivery is saved temporarily
Processing	Delivery is continued
Transmitted	Delivery was sent
Technically invalid	Technically invalid
Accepted	Delivery is accepted

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

5.8.2 File formats

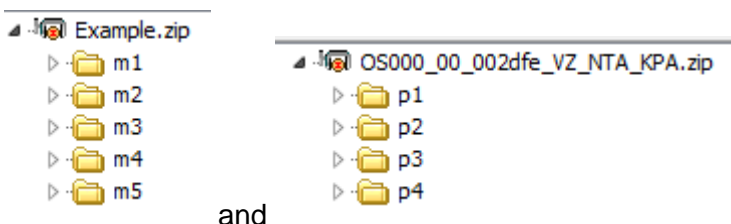| Document type	Authorised file formats
Dossier in eCTD structure format	zip, iso
Dossier in eDok structure format	zip

Information for healthcare professionals, patient information and veterinary information as working documents	doc, docx
Packaging elements as working documents	pdf, doc, docx
In the KPA notification procedure, additionally basic company dossier, master dossier, specimen quality dossier, message	zip

Messages containing
   -   Letter
   -   Attachment
	pdf, doc, docx, zip, xls, xlsx

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

Please note: **This list only shows possible formats. However, the key factor for correct delivery is compliance with the requirements in the *Guidance document Formal requirements*.**

5.8.3 Structure of Zip files

1) The Zip files for **eDoks** must be structured as follows (applies both to CTD and NTA formats):

⊿ Example.zip
  ▷ 📁 m1   ⊿ OS000_00_002dfe_VZ_NTA_KPA.zip
  ▷ 📁 m2   ▷ 📁 p1
  ▷ 📁 m3   ▷ 📁 p2
  ▷ 📁 m4   ▷ 📁 p3
  ▷ 📁 m5   ▷ 📁 p4

            and

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

For NTA structures (both for TAM and KPA), the following specifically applies: Contrary to what is stated in the eDok guidance document, the file *gtoc.pdf* must be entered under *1a-admin-info*.

The name of the Zip file is freely selectable but limited to a maximum of 40 characters.

2) Zip files for **eCTDs** must be structured as follows:
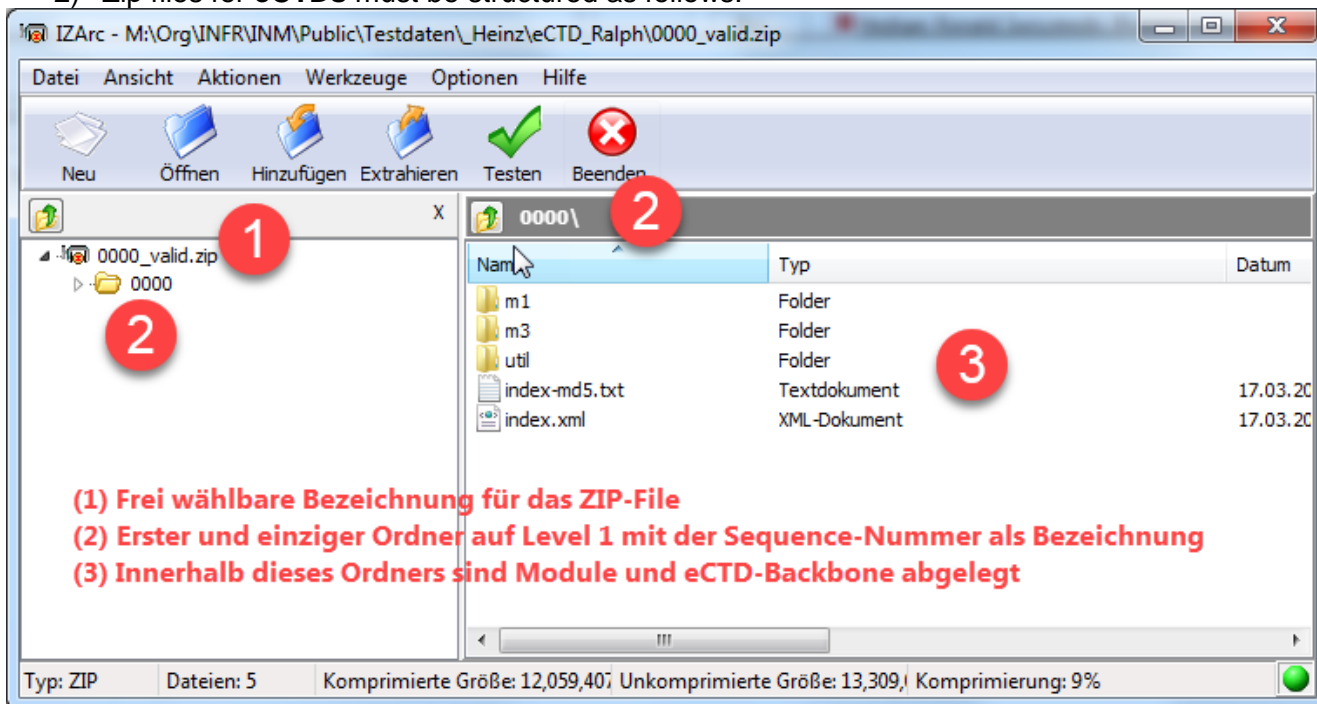
3) Zip files for **reference dossiers** must be structured as follows:
The eGov Portal only accepts a single folder at the top file level in the Zip file containing the reference dossier documents. This folder must be named *Reference dossier* in order to ensure problem-free processing in our systems.
The following structure must be observed here:
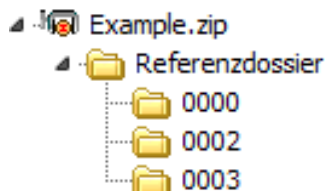
5.8.4   Checksum

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

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

The checking option is available in the confirmation issued by the system after delivery using the general *Checksum* for the whole delivery and the individual *Checksum* for each delivered file in the Dashboard:

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 please contact Support immediately.

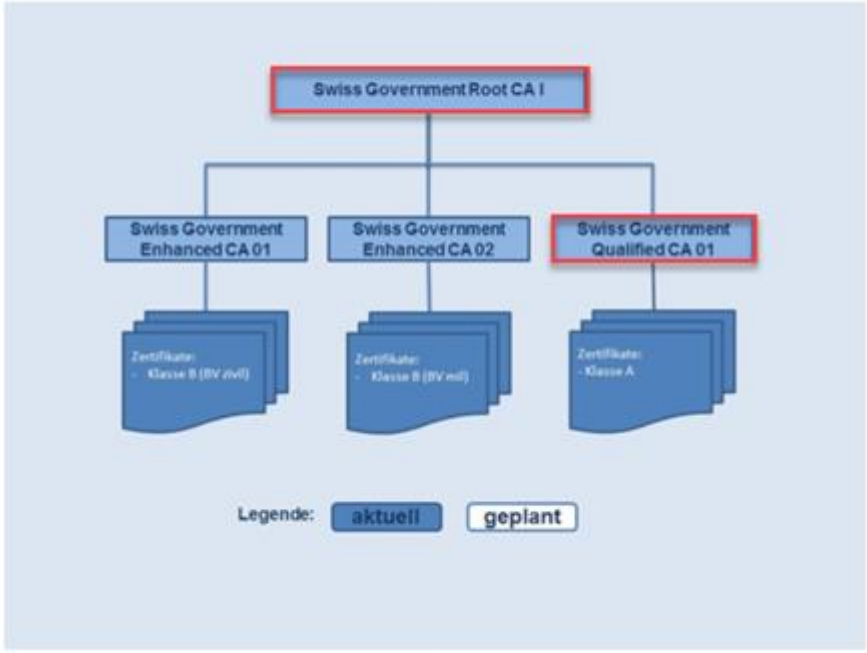### 5.8.5 Handling of electronic / digital signatures and acknowledgements

~~Documents~~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.
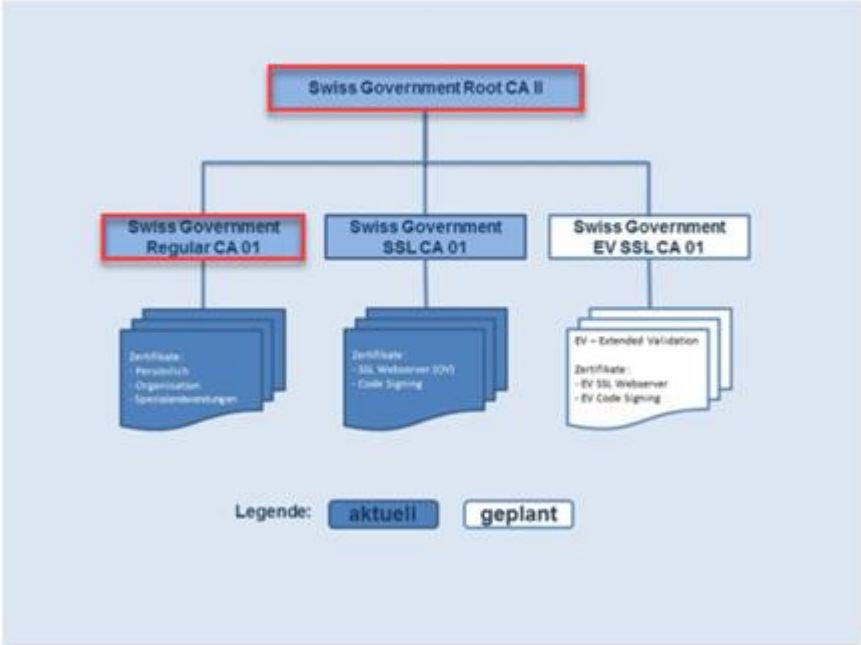An example of a successful validity check is shown below:
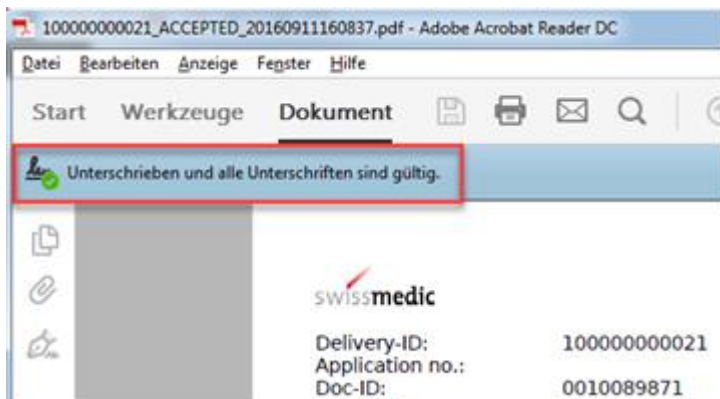
If errors are found when checking the validity of the signature, your local IT infrastructure will need to be checked. The most common cause is a missing element in the certificate chain. The following table shows which certificates must exist for each document type for a successful validity check. The certificates will then be 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.

Document type	**Official decision** (class A certificate)
Digital signature	Qualified electronic signature according to ZERTES
Link	https://www.bit.admin.ch/adminpki/00247/00790/index.html?lang=de
Certificates	Root: Swiss Government Root CA I Intermediate: Swiss Government Qualified CA
Document type	**Acknowledgement** (class C certificate)

Digital signature	Advanced electronic signature according to ZERTES
Link	https://www.bit.admin.ch/adminpki/00247/05329/index.html?lang=de
Certificates	 Root: Swiss Government Root CA II Intermediate: Swiss Government Regular CA 01
Alternative checking option	Online Validator service of the Federal Administration https://www.e-service.admin.ch/validator/upload/all/en Document type:

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 webpage: https://www.swissmedic.ch/swissmedic/en/home/services/egov-services.html

7   Support

Support messages can be sent via:
- www.swissmedic.ch/gate-support
- it@swissmedic.ch
- 058 46 20 600

~~Support is available on weekdays between 8 a.m. and 6 p.m. Queries are usually answered~~
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.