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Change history

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02	30.11.2017	Content revised and updated	mra
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	26.04.2017	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	Authorisations Division

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 Access to the Swissmedic eGov Portal

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

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.

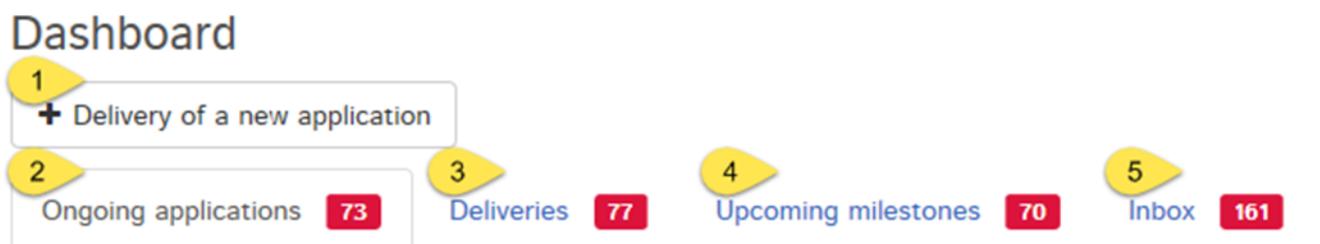
Please note: the screenshots shown in this document do not always show the full screen area.

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*.



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.

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.

Select application category

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

Enter medicines

Name

test

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

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

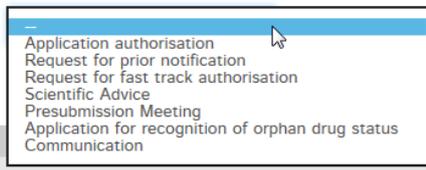
Name

TestPraeparat

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

6) Now select the *Delivery type*

Select delivery type



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.
- All fields with a red star are mandatory fields.**

- 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 *Save and exit*. The delivery can then be completed later. The dashboard will 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	▶ 🔍 🗑️

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: a paused delivery will be deleted automatically after 30 days and can no longer be edited.

- 9) In the next step, you should specify the type of document you are uploading and the format to be submitted (eDok or eCTD). 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 length of the file name is limited to a maximum of 90 characters. If this is exceeded, the following message appears:

Files

Add file

❗ File name cannot be longer than 90 characters

As with the product name in point 4), only certain characters are permitted.

Files

Add file

❗ File name contains invalid characters. The following characters are permitted: 'A' to 'Z', 'a' to 'z', '0' to '9', '.' (no successive multiple use), '-', and '_'.

Dossier ▼

eDok (CTD) ▼

eDok AE 100KB - PMF.zip

Choose file
📁

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 after the application has been recorded by Swissmedic.

The files are transferred with the *Upload* button.

Files

Add file



 Upload

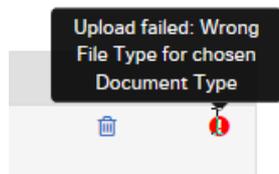
Please note: If possible, very large files should be uploaded to the Portal during off-peak times (Swissmedic core time is between 8 a.m. and 6 p.m.) as this will usually speed up processing.

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	 

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 *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.

Delivery overview

Enter delivery
Submit delivery

Service

Subject

Medicines

Delivery type

Features

Files

Delivery overview

Delivery overview

Please check the entries below for correctness before submission.

Service
Authorisation

Subject
Human medicines

Application category
Application for new authorisation

Medicines

Authorisation / Case no.	Name
0	TestPraeparat

Delivery type
Application authorisation

Features

Request for procedure with prior notification/fast track authorisation procedure is approved	ODS recognised	Art.13
No	No	No
	Company reference	

Files

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

< 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.

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.

5.2.2 Correcting an invalid delivery

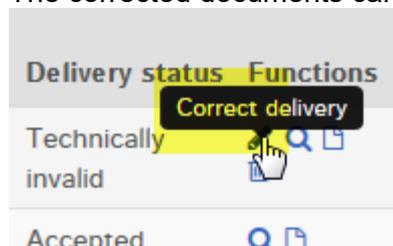
If technical problems are noticed during the delivery, the user is informed about the error via the Dashboard, the confirmation of rejection and a Validation Report. The system does not usually accept technically invalid deliveries.

Ongoing applications 0 Deliveries 2 Upcoming milestones 0 Inbox 5

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: 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 existing case/authorisation* is selected for a variation.
- 2) 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.

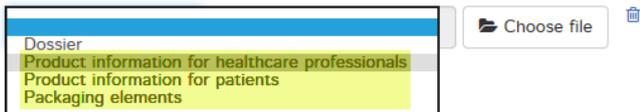
5.2.4 Submission of working documents

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.

Files

Add file



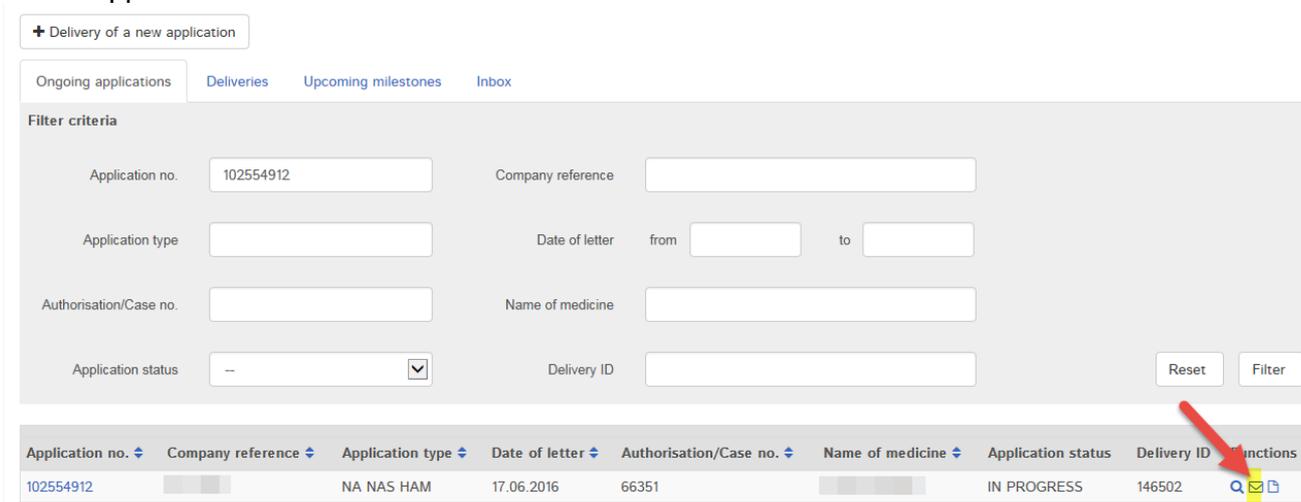
Please note: These documents should not be inserted directly into the structure of an eCTD or eDok dossier.

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

Authorisation / Case no.	Name	eCTD Dossier	Action
			<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

Dossier eCTD

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 technical validation is performed here, and the result displayed straight away. However, the reference dossier does not undergo more extensive technical validation.

Select delivery type

Application authorisation

Features

ODS recognised

Yes No

Art.13 *

Yes No

Company reference

UnserZeichen

Hash algorithm *

Message-Digest Algorithm 5

Files

Document type			File name		
Dossier	eCTD	TestPraeparat	0000.zip	<input type="button" value="trash"/>	<input checked="" type="checkbox"/>

Add file

Reference dossier

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

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 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

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 for which the authorisation number of an existing product is entered:

Select application category

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

Enter medicines

Announced or authorised medicines Medicines no longer authorised

Authorisation / Case no.

Name

+ Add medicine

< Back

Cancel

Next >

2) In the next step, the Portal correctly shows that an eCTD dossier does not yet exist for the preparation:

Authorisation / Case no.	Name	eCTD Dossier	Action
0			

3) Under *Add file* you should type in the eCTD dossier name

Add file

Dossier eCTD NEW...



 Upload

< Back

Cancel

Save and exit

Next >

where it says “*enter product name*”

Please note: It is essential that within the *enter product name* field no other entries – e.g. notification, variation etc. – are entered. Otherwise the dossier cannot be created correctly, which may potentially 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. Where there is an error, the field will be outlined in red and you cannot continue without correcting the error.
- 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).

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

Please note that a *baseline* is not displayed under *Ongoing applications*. Since Swissmedic does not regard a conversion to eCTD via the *baseline* as an application, no entry appears in *Application Tracking*.

5.2.11 Submission of follow-up measures

Where conditions are imposed (follow-up measures), Delivery Type “variation/new application” should be selected.

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.

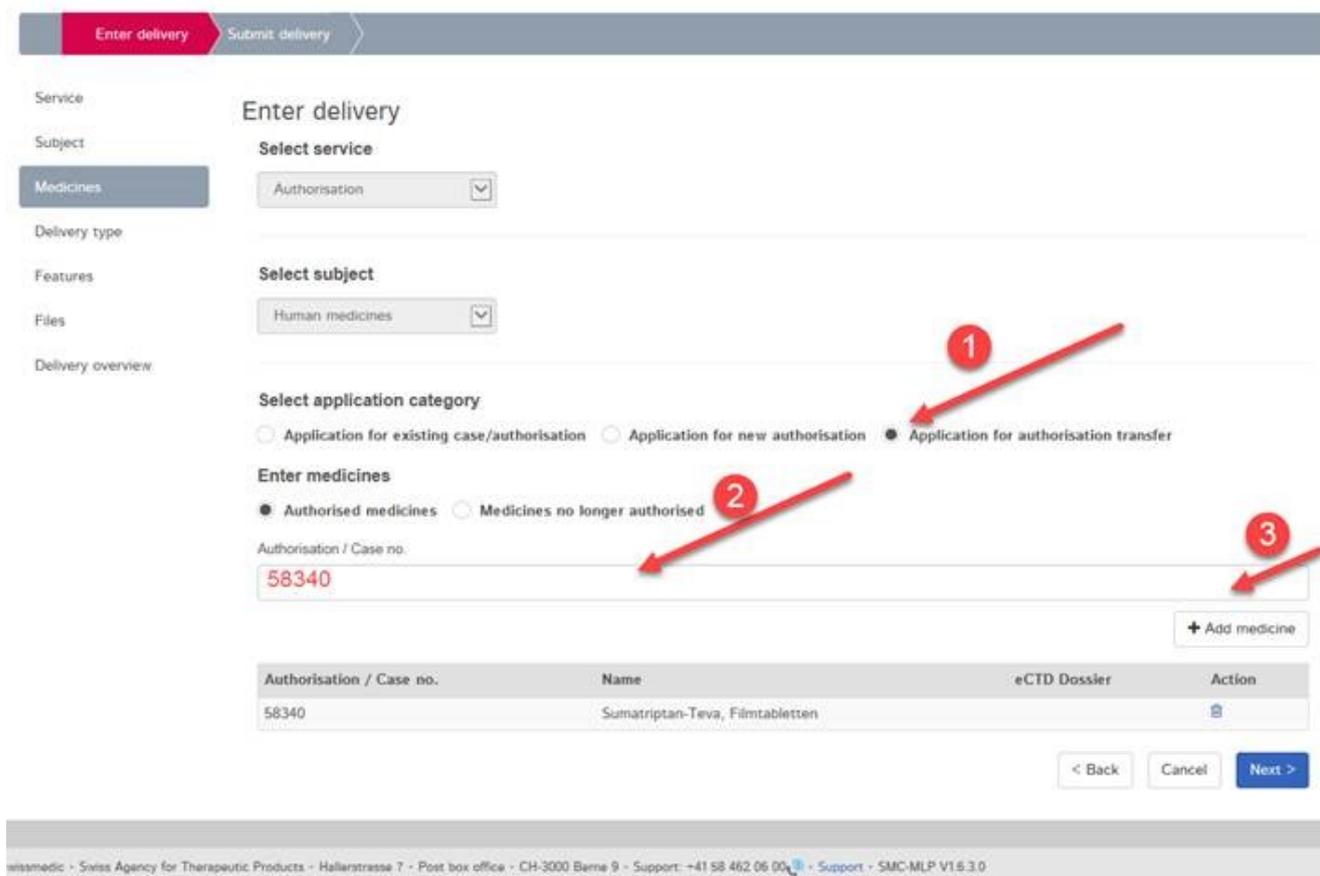
These communications can be sent to Swissmedic as a *New delivery* using the Delivery Type *Communication*.

Please note: This delivery type of *Communication* may not be used for submissions of regular applications or conditions (*Follow-up Measures*).

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 and adds it to the list via *Add medicine*. For collective applications, several preparations can be selected and added.

3) 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.

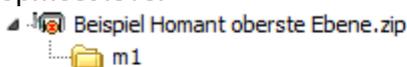
Please note: During the 5 days prior to the submission of the authorisation transfer, no other application may be submitted by the existing authorisation holder. Only after the reregistration is complete may the new authorisation holder submit new applications.

5.2.14 Submission of a HOMANT preparation report

HOMANT preparation notifications can be submitted in eDok format and hence via the eGov Portal.

Please proceed as follows:

- Create an eDok according to the Template and Formal Requirements.
- The zip file required for the upload must be structured as follows:
 - o In parallel with the module structure, the HOMANT XML file must appear at the topmost level



Name	Typ
m1	Folder
KPAExportFile.xml	XML-Dokument

- Create a delivery in the Portal Dashboard with Delivery Type "Reporting HOMANT" 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:

1. When the application is initiated, Swissmedic draws up the time schedule in accordance with the time limits specified in the corresponding Administrative Ordinance.
2. 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.
3. 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.
4. 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 Time limits

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

The Terms of Use, section 3.2 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 eCTD or eDok, 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 observed.
- 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, 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

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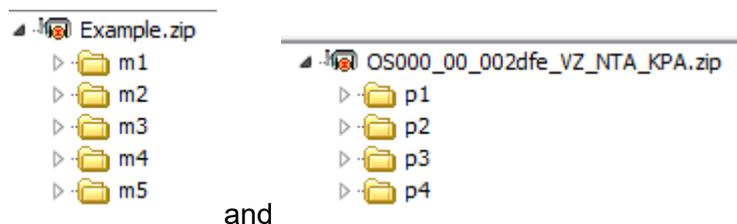
Please note: The file extension of the documents listed above must always be written in lower case, e.g. Document.docx. The use of Document.DOCX will lead to an error message on uploading.

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

Specification of the ISO files: must be created in accordance with ISO 9660:1999. ISO UDF does not work.

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):



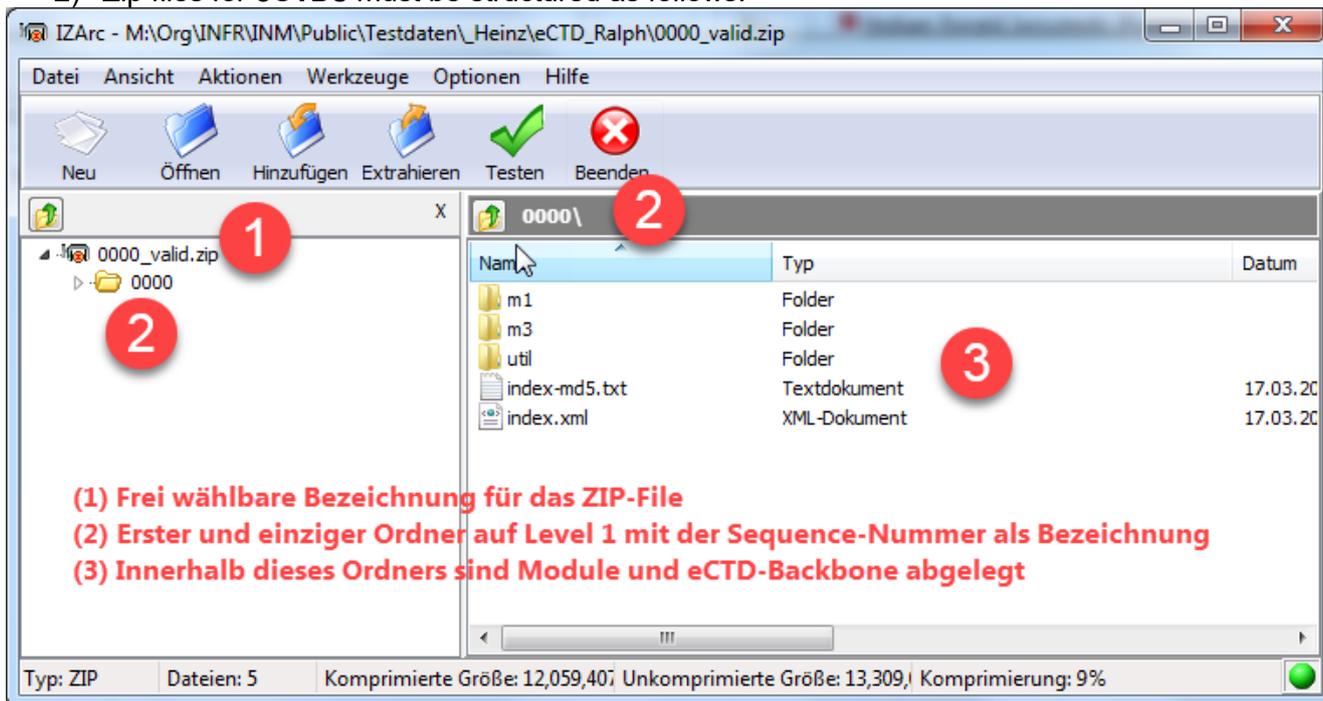
Please note: The module and part structure must appear at the topmost level in the Zip file. Incorporating an additional higher-level folder into the Zip file structure will result in a validation error when the file is uploaded to the Swissmedic eGov Portal.

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.

N.B.: No Zip files are permitted within the eDok Zip file

2) Zip files for **eCTDs** must be structured as follows:



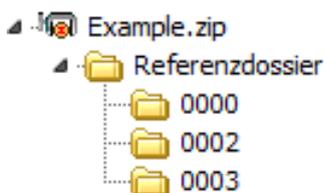
[Points 1-3 in screenshot above:]

1. Freely selected name of Zip file
2. First and only folder at Level 1, with sequence no. as name
3. Modules and eCTD backbone are filed within this folder

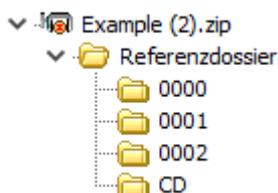
3) Zip files for **reference dossiers** must be structured as follows:

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:



Please note that no unsorted files should be saved in the zip file. If there are files that do not fit in the sequence structure, a folder "CD" must be created and all files should be saved in it.



Note: No zip files are permitted within the eDok zip file

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:

	<p>Denial of acceptance Specimen DEV</p>
<p>Delivery-ID: 100000001 Application no.: Doc-ID: 0010088727 Your reference:</p>	
<p>Data issuing platform: Swissmedic platform for electronic submissions</p>	
<p>Recipient: Swissmedic Hallerstrasse 7 3000 Bern 9</p>	
<p>Date: 2016-05-24 12:11:07</p>	
<p>Sender:</p>	
<p>User identification: Adn-TestuserREF</p>	
<p>Comment: Acceptance of delivery denied. Please consult validation report(s) and resubmit your application after correction.</p>	
<p>Checksum Delivery: MD5 3af186832ad1237fe01f738c59498573</p>	
<p>Attachments:</p>	
<p>0 0000.zip 3af186832ad1237fe01f738c59498573</p>	
<p>0 0000/index-md5.txt 8485837f9840ec2bb320512bdbc7fb7a</p>	
<p>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-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</p>	
<p>Page 1 of 3</p>	

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

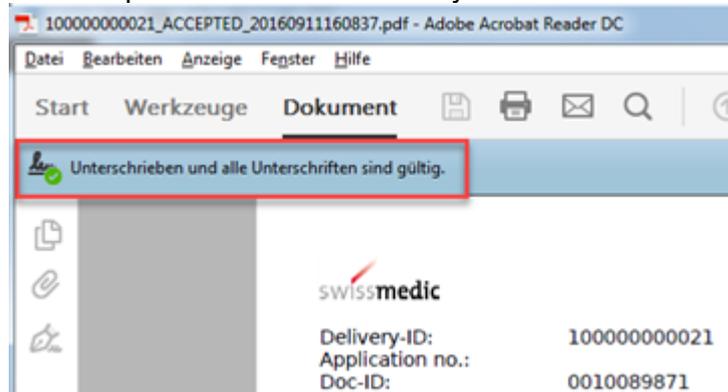
- 1) The checksum for the whole delivery, i.e. here the checksum is calculated for all documents (zip file plus any Working Documents).
- 2) The checksum for the dossier zip file
- 3) The checksum for each individual file in the delivery

Please note: If there are any discrepancies please contact Support immediately.

5.8.5 Handling of electronic / digital signatures and acknowledgements

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:

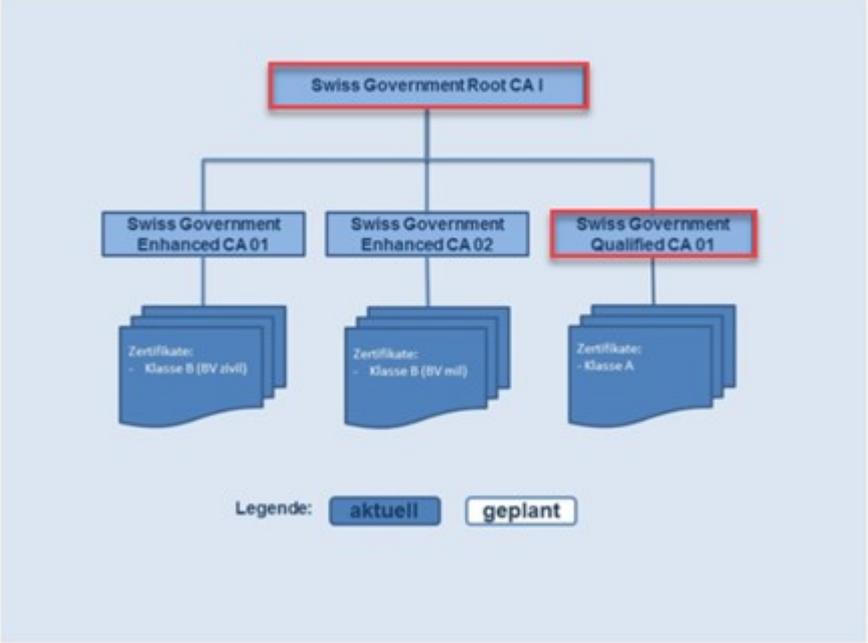
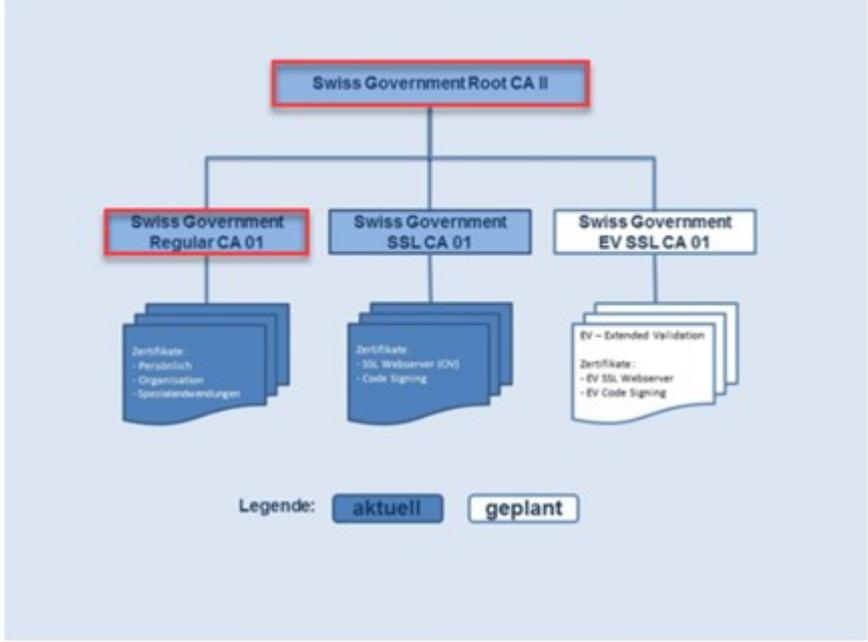


If errors are found when checking the validity of the signature, your local IT infrastructure will need to be checked. The most common cause is a missing element in the certificate chain. The following table shows which certificates must exist for each document type for a successful validity check. The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

<p>Certificates</p>	<p>Swiss Government Root CA I</p>  <p>Root: Swiss Government Root CA I Intermediate: Swiss Government Qualified CA</p>
<p>Document type</p>	<p>Acknowledgement (class C certificate)</p>
<p>Digital signature</p>	<p>Advanced electronic signature according to ZERTES</p>
<p>Link</p>	<p>https://www.bit.admin.ch/adminpki/00247/05329/index.html?lang=de</p>
<p>Certificates</p>	<p>Swiss Government Root CA II</p>  <p>Root: Swiss Government Root CA II Intermediate: Swiss Government Regular CA 01</p>

<p>Alternative checking option</p>	<p>Online Validator service of the Federal Administration https://www.e-service.admin.ch/validator/upload/all/en</p> <p>Document type: Dokument validieren</p> <p><input type="text" value="1"/></p> <p>Wählen Sie den Dokument-Typ Was für ein elektronisches Dokument möchten Sie auf seine Gültigkeit prüfen?</p> <div data-bbox="464 618 1437 837" style="border: 1px solid gray; padding: 5px;"> <p>Wählen Sie den Dokumenttyp (Liste)</p> <ul style="list-style-type: none"> BAKOM Dokumente Validator für Veranlagungsverfügungen und Rückerstattungsbelege der Eidgenössischen Zollverwaltung Dokument eines Betreibungsamtes (eSchKG) Bundesrecht Qualifizierte Signatur mit Zeitstempel gemäss ZertES Qualifizierte Signatur gemäss ZertES Strafregisterauszug Mit Swiss Government PKI Smartcard und Zertifikat signiertes und zeitgestempelttes Dokument schweizerischer Behörden Elektronische öffentliche Urkunden und elektronische Beglaubigungen </div>
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5.8.6 Submission of a DMF/ASMF via eGov Portal

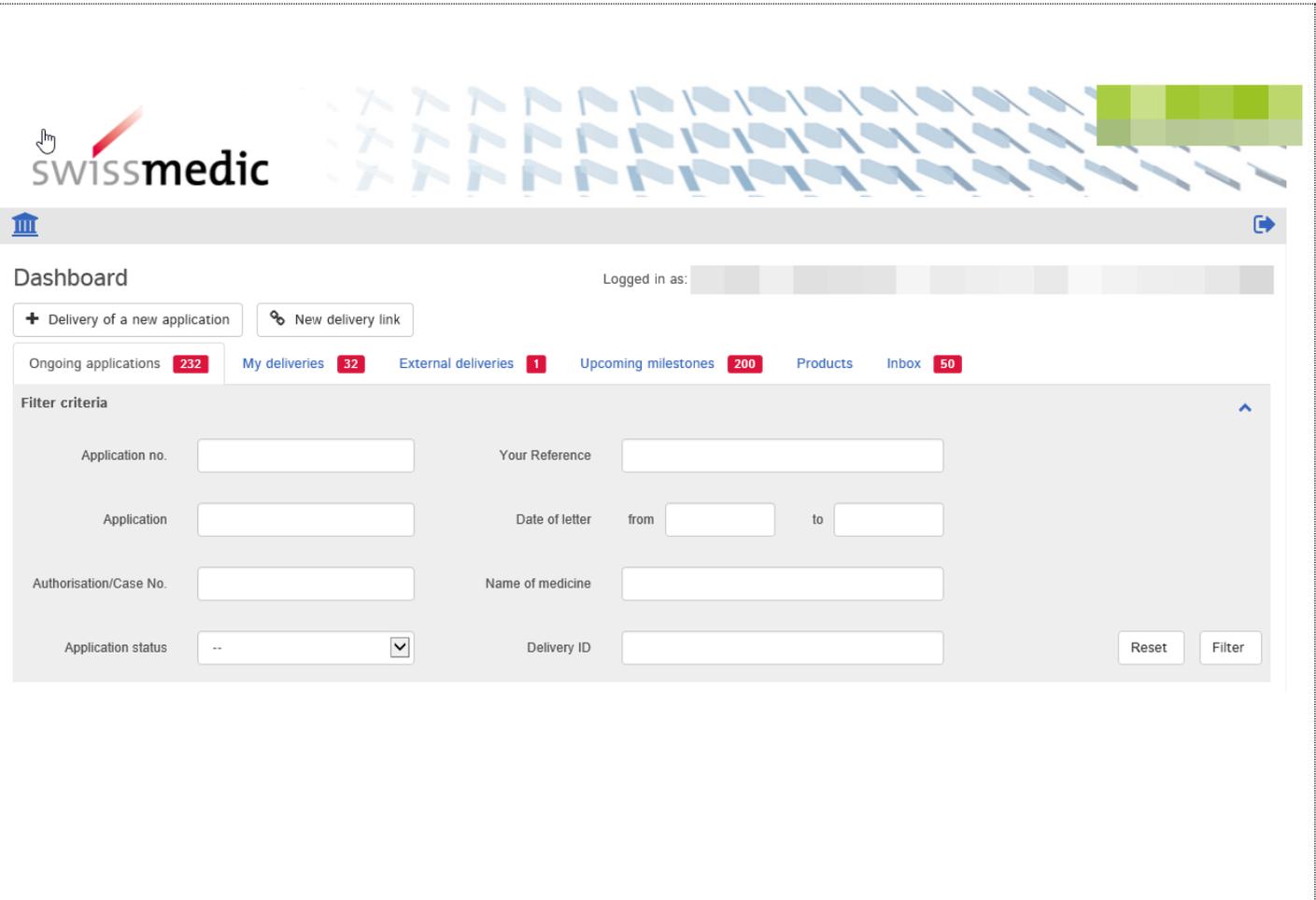
With the new function in the eGov Portal, it is now possible to submit DMF/ASMF documents electronically. Only documents in **eCTD** or **eDok** format can be submitted in this process. The authorisation holder generates a link and makes it available to the DMF/ASMF holder. The following instructions explain the process for submitting DMF/ASMF via the eGov Portal step by step.

Authorisation holder's view

Log in to the eGov Portal

1. Generate new link

Click on **“New delivery link”**.



The screenshot shows the Swissmedic eGov Portal dashboard. At the top left is the Swissmedic logo. Below it is a navigation bar with a home icon and a user profile icon. The main content area is titled 'Dashboard' and shows the user is logged in. There are two main buttons: '+ Delivery of a new application' and 'New delivery link'. Below these are several status indicators: 'Ongoing applications 232', 'My deliveries 32', 'External deliveries 1', 'Upcoming milestones 200', 'Products', and 'Inbox 50'. A 'Filter criteria' section is visible, containing several input fields: 'Application no.', 'Your Reference', 'Application', 'Date of letter' (with 'from' and 'to' sub-fields), 'Authorisation/Case No.', 'Name of medicine', 'Application status' (a dropdown menu), and 'Delivery ID'. There are 'Reset' and 'Filter' buttons at the bottom right of the filter section.

2. Choose product

If the product already exists, click on “Yes” under “Case”; select the product number under “Case no.” or enter the product name under “Name”. Only the products assigned to the user can be selected. If no product exists, click on “No” under “Case”.

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

A link is generated (1). Copy this link into the clipboard and e-mail it to the DMF/ASMF holder.

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 DMF Holder at a time and enables them to upload the DMF directly to the Swissmedic.

Case * No Yes

Enter case *

Case no. *

Name *

Comment

Link

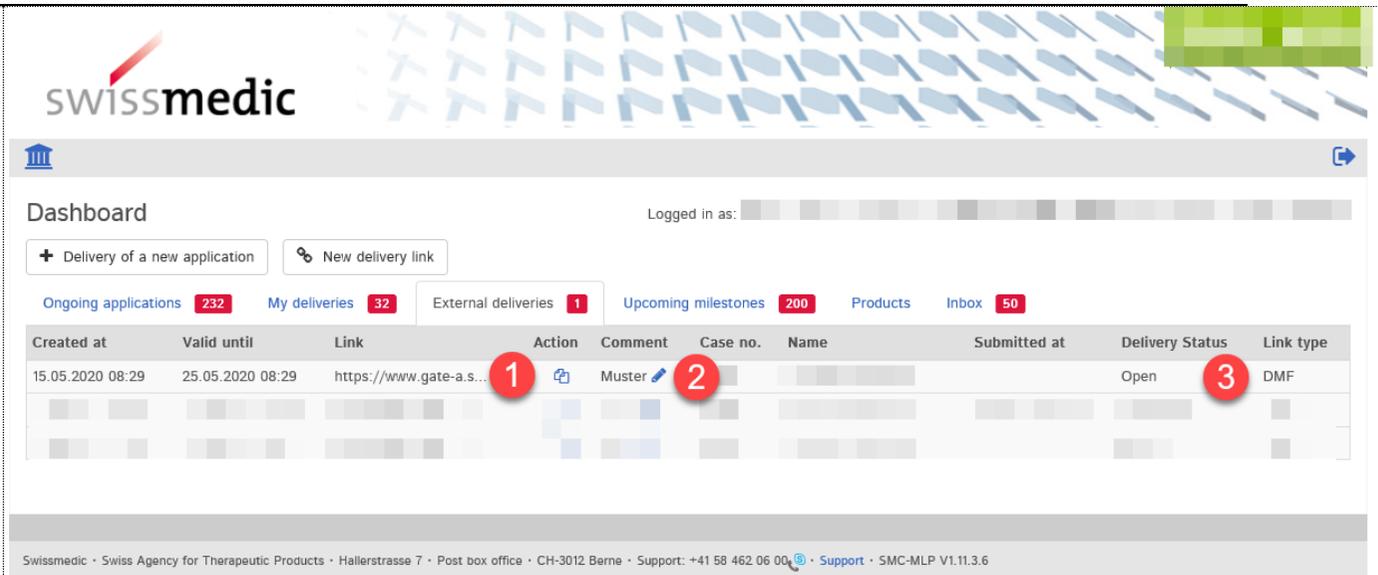
<https://www.gate-a.swissmedic.ch/dmf/dmf.xhtml?token=8U6wDEnnzjys7NH3zOqboY7ixNgqqo0>

Go to "External deliveries"

Close

4. Overview of external submissions

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



The screenshot shows the Swissmedic eGov Portal dashboard. At the top, there is a navigation bar with the SWISSmedic logo and a user profile icon. Below the navigation bar, the dashboard displays various statistics and a table of external deliveries. The table has columns for Created at, Valid until, Link, Action, Comment, Case no., Name, Submitted at, Delivery Status, and Link type. A red circle with the number 1 highlights the Link column, a red circle with the number 2 highlights the Comment column, and a red circle with the number 3 highlights the Delivery Status column.

Created at	Valid until	Link	Action	Comment	Case no.	Name	Submitted at	Delivery Status	Link type
15.05.2020 08:29	25.05.2020 08:29	https://www.gate-a.s...	1	Muster 2				Open 3	DMF

DMF/ASMF holder's view

1. Submission of the DMF/ASMF documents by the DMF/ASMF holder

Once the link has been loaded by the DMF/ASMF holder, the following view is displayed (see picture). The following actions must be performed:

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

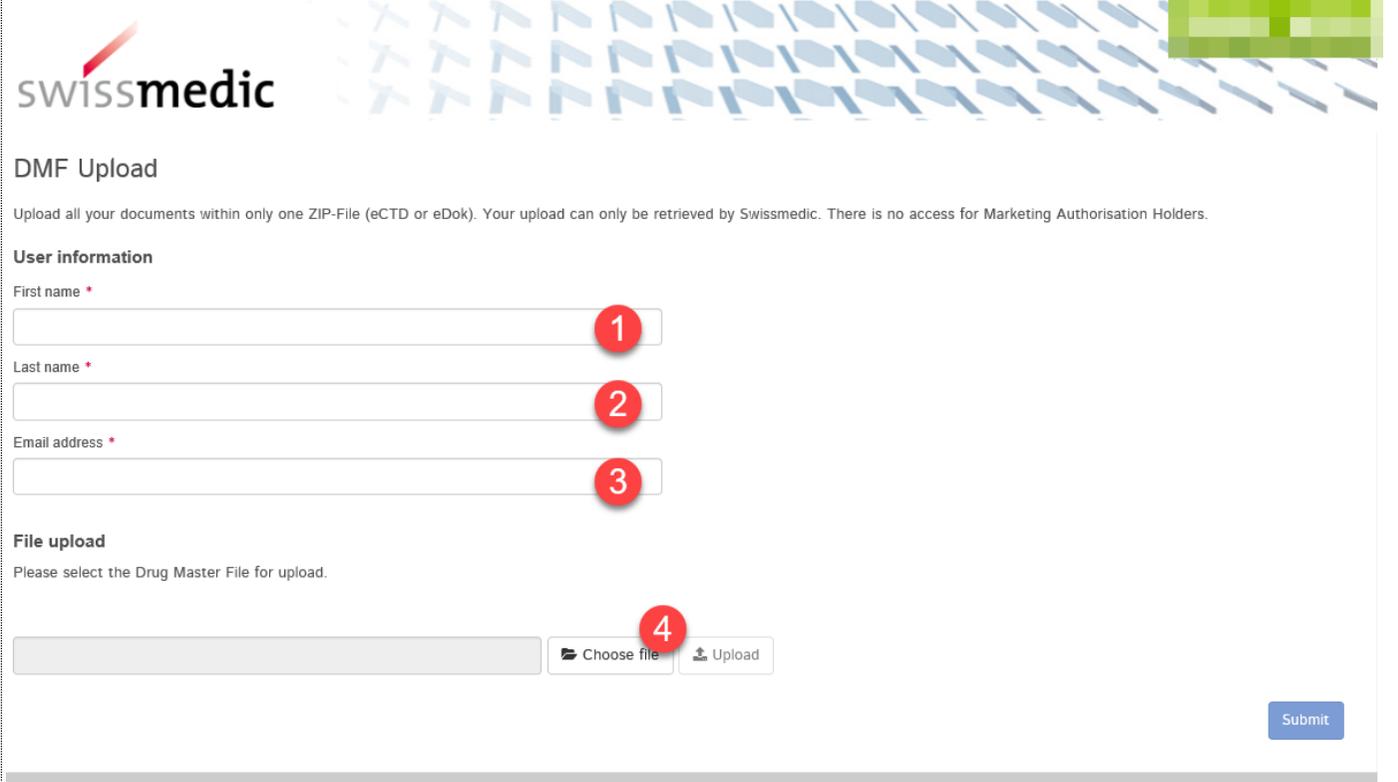
Choose the DMF/ASMF document on the PC.

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

You can obtain further information about these two formats at the following links:

<https://www.swissmedic.ch/swissmedic/en/home/services/submissions/ectd.html>

<https://www.swissmedic.ch/swissmedic/en/home/services/submissions/papiereinreichung---edok.html>



SWISSmedic

DMF 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 * 1

Last name * 2

Email address * 3

File upload

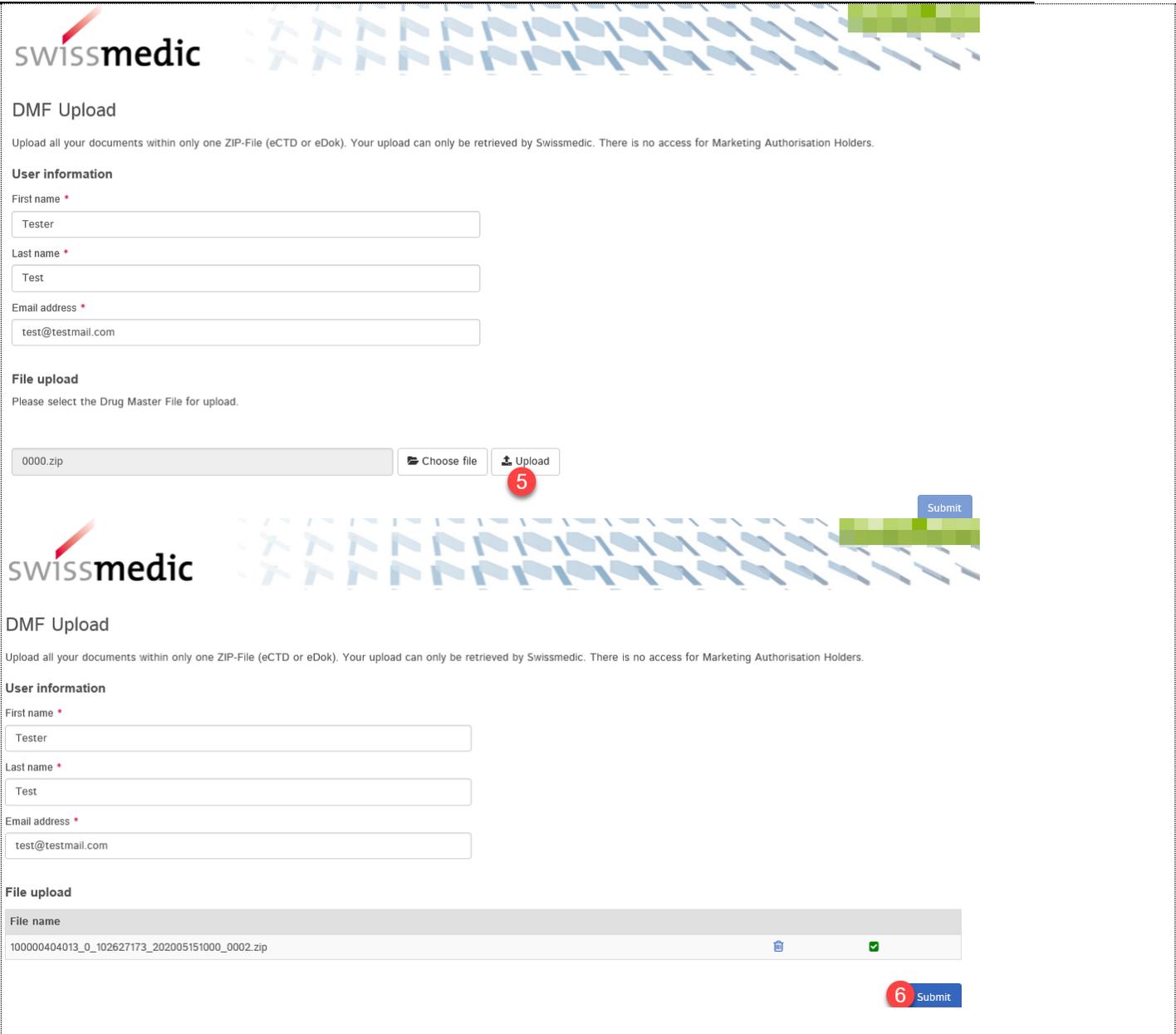
Please select the Drug Master File for upload.

4

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.



DMF 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 Drug Master File for upload.

0000.zip

DMF 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 *

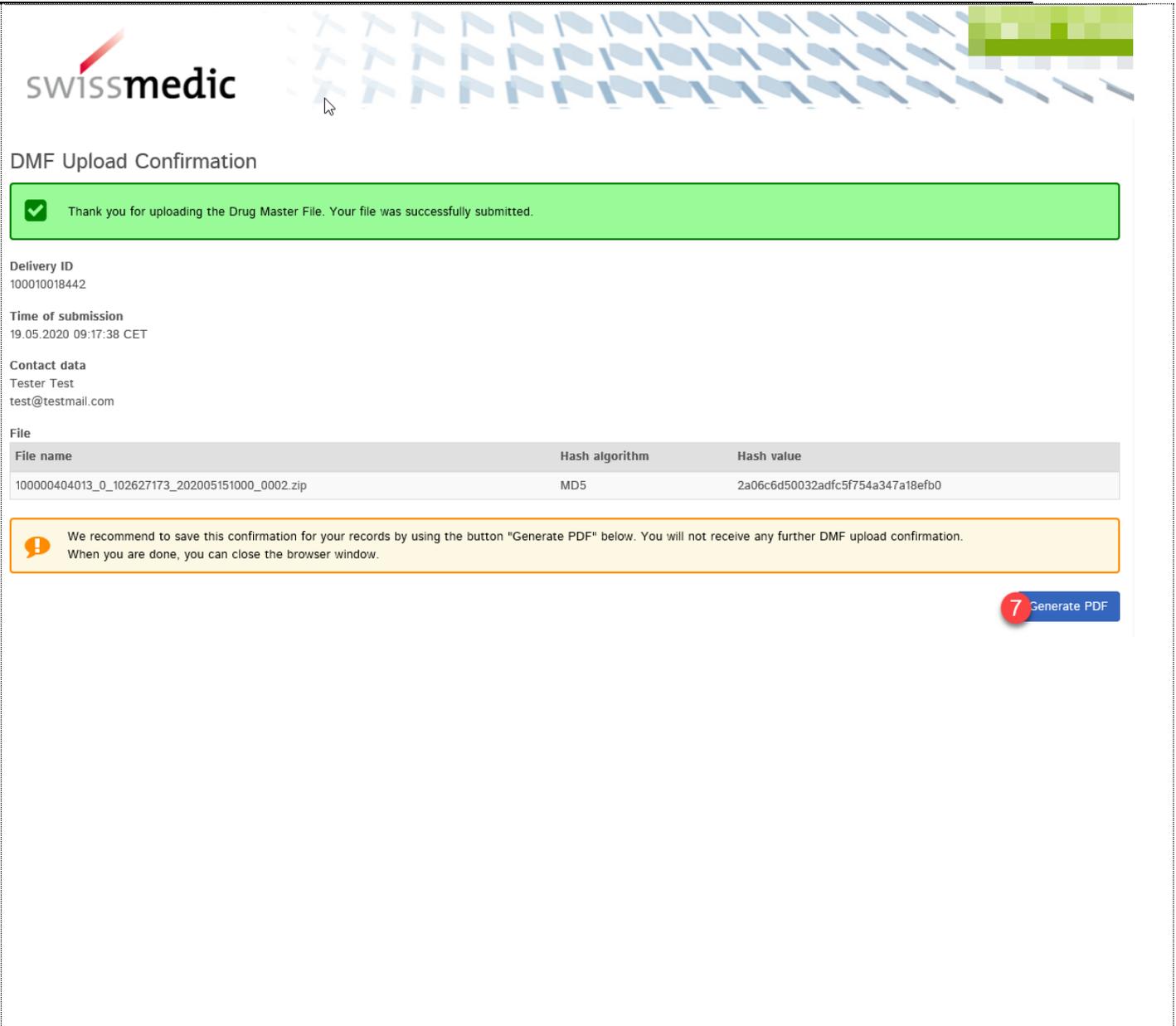
Email address *

File upload

File name		
100000404013_0_102627173_202005151000_0002.zip	<input type="button" value="Delete"/>	<input checked="" type="checkbox"/>

3. Generating the confirmation

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



DMF Upload Confirmation

Thank you for uploading the Drug Master File. Your file was successfully submitted.

Delivery ID
100010018442

Time of submission
19.05.2020 09:17:38 CET

Contact data
Tester Test
test@testmail.com

File

File name	Hash algorithm	Hash value
100000404013_0_102627173_202005151000_0002.zip	MD5	2a06c6d50032adfc5f754a347a18efb0

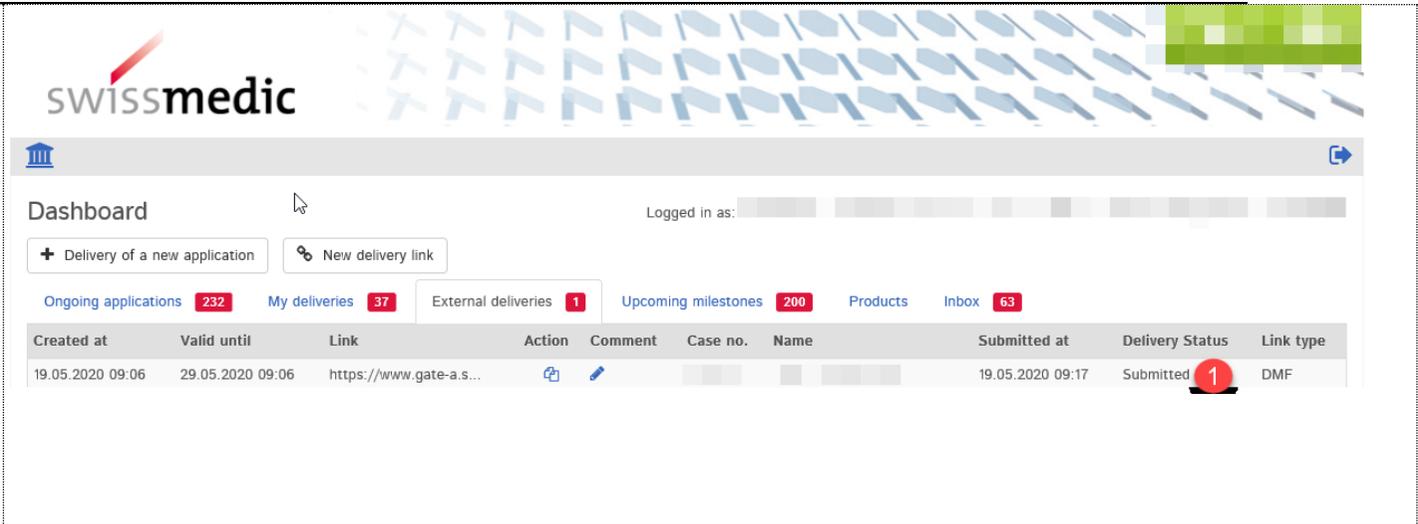
 We recommend to save this confirmation for your records by using the button "Generate PDF" below. You will not receive any further DMF upload confirmation. When you are done, you can close the browser window.

7 Generate PDF

Authorisation holder's view

5. Status change of external submissions

The status changes from Open to Submitted (1) as soon as the DMF/ASMF holder has submitted the documents. In that way, the authorisation holder can check when the DMF/ASMF submission took place.



The screenshot shows the Swissmedic eGov Portal dashboard. At the top, there is a navigation bar with the SWISSmedic logo and a home icon. Below the navigation bar, the dashboard displays several widgets: '+ Delivery of a new application', 'New delivery link', and a row of summary cards for 'Ongoing applications' (232), 'My deliveries' (37), 'External deliveries' (1), 'Upcoming milestones' (200), 'Products', and 'Inbox' (63). A table below these cards lists delivery records. The table has columns for 'Created at', 'Valid until', 'Link', 'Action', 'Comment', 'Case no.', 'Name', 'Submitted at', 'Delivery Status', and 'Link type'. One record is shown with a 'Submitted' status and a red notification badge with the number '1'.

Created at	Valid until	Link	Action	Comment	Case no.	Name	Submitted at	Delivery Status	Link type
19.05.2020 09:06	29.05.2020 09:06	https://www.gate-a.s...					19.05.2020 09:17	Submitted 1	DMF

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

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.