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Change history

Version	Valid and binding as of:	Modified without New minor version change	Description, comments (by author)	Author's initials
4.0	01.06.2018		Section 2.31 inserted	mra
03	30.11.172017		Various changes to content	mra
02	04.09.172017		Various changes to content	mra
		26.04.17	New QM-Ident: OS000_00_002d_MB (Version 01) Old QM-Ident: ZL000_00_032d_MB (Version 09)	feh
01	03.05.17		The Q&A section will be removed from the Information sheet and hived off into a separate document.	mra

1 Objective and scope

This Q&A document should always be read in combination with the Swissmedic eGov *Portal – Standard functions* information sheet. It is designed to answer the most important questions on submissions via the Portal.

The Q&A should be updated at regular intervals and taken into account whenever updates are made to the information sheet.

2 Questions and answers (Q&A)

2.1 If I use the Portal, do I also still need to send documents by post?

No, with Portal submissions, the submission of (paper) documents by post is no longer necessary.

2.2 Do I still need to sign the letter, form, etc.?

Individual documents no longer need to be signed for a portal submission. Authentication is ensured via the portal login process.

2.3 Are acknowledgements of receipt issued for variations requiring notification?

An Acceptance of delivery is now issued as acknowledgement of receipt of these applications.

2.4 When can the result of the Technical Validation be expected in the case of eCTD submissions?

A generally applicable answer cannot be provided here since this depends on the file size and input volume on the server.

As a rule, however, you should receive an acknowledgement of the delivery within 24 hours.

If this does not occur, please contact Support.

2.5 Can I submit a sequence 0001 immediately after creating a new eCTD dossier, i.e. when switching from paper to eCTD?

A sequence 0000 can only be submitted if an eCTD dossier does not yet exist. In this scenario you will have to wait until Swissmedic has completely recorded, created and processed the new preparation or new eCTD dossier.

A new sequence (for example Sequence 0001) can be submitted only if you are able to select the corresponding preparation via the *Enter medicines* menu when making a new submission.

2.6 Can consecutive eCTD sequences generally be uploaded in parallel when there is no baseline?

If a dossier already exists, a parallel upload of several eCTD sequences (e.g. 0002 and 0003) can, in theory, be started.

However, in view of possible life cycle errors, we recommend that you wait until you receive the Acceptance of delivery before you upload the next sequence.

2.7 What information is binding if the entries in the eGov Portal are not the same as the details on the form?

Swissmedic considers the details on the form to be authoritative.

2.8 How does the required confirmation of identity for submission without a signature work now?

Please check the *n/a* box in the form *Application for authorisation/variation*.

2.9 How are the confirmation of identity and the confirmation for the virus check handled for eCTDs?

The eCTD Guidance for Industry has hitherto required two confirmations, one to confirm that the paper version and the eCTD are identical and one to confirm the virus check in the cover letter.

- Since paper documents no longer apply with a Portal submission, this confirmation is no longer required.
- The Portal performs its own virus check during the upload. The required confirmation can be replaced by a new text module in the cover letter: **Virus check performed by Portal**.

2.10 Orphan drug or MUMS. What should you be aware of?

If a product is also authorised as an *orphan drug* or *MUMS*, Swissmedic assigns two different authorisation numbers to the same product name. Currently, the only way to differentiate these when submitting an application or assigning rights is by their authorisation numbers. In an upcoming release, *orphan drug* / *MUMS* products will be assigned a suffix so that they can be differentiated more easily.

2.11 Can submissions or documents be deleted?

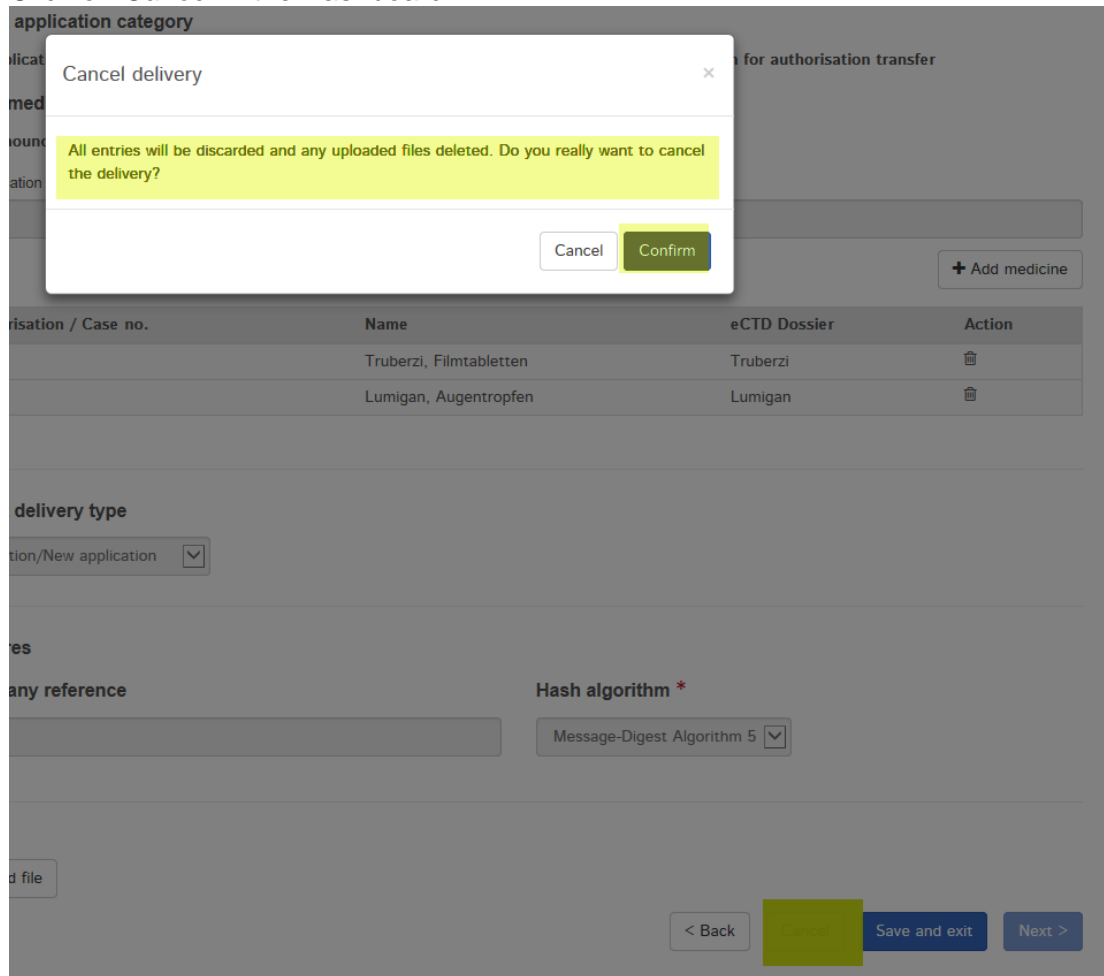
As a rule, completely uploaded submissions for which an acknowledgement has been issued can no longer be deleted. If necessary, however, a submission can be deactivated by Swissmedic Support. This will then be deleted automatically after 60 days; until that point, however, it will remain visible under *Deliveries* with the status *accepted*.

A delivery that has not yet been sent (Status Paused) but that is *Technically invalid* can still be deleted by the user.




The corresponding procedure is as follows:

Delivery is still being processed:

- Click on *Cancel* in the Dashboard



- Delivery is uploaded but identified by the system with the status *technically invalid*:

100010000792	Authorisation/Human medicines	Variation/New application	55918	Lumigan, Augentropfen	08.06.2017 16:30	Ralph.Allergan	Technically invalid	  
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- The delivery can be deleted completely via the recycle bin icon

2.12 Is it possible to submit eCTD test submissions via the Swissmedic eGov Portal?

No, you must continue to send test submissions to Department OSS by post.

2.13 How are approved manuscripts for information for healthcare professionals, patient information and packaging elements handled?

Approved manuscripts are handled differently depending on the contractual agreement with Swissmedic.

- Company does not want digitally signed documents
 - Manuscripts are sent on paper, together with the official decision document
 - In addition manuscripts are still uploaded to the inbox via the Portal
- Company wants digitally signed documents
 - Official decisions and manuscripts are only uploaded electronically to the inbox via the Portal.

Please observe the above when checking new documents in the inbox

2.14 How are text correction communications (TPS) handled?

Submissions concerning texts or text correction communications are sent as a response to an ongoing application under *Ongoing Applications*. A clear distinction must be made here depending on whether *responses to LoQ, VB or VG* are involved or, with reference to the text correction communication, individual documents are to be uploaded during the text review phase.

- The responses must be submitted as a *Response to Swissmedic correspondence* on an ongoing application and include a complete eDok or eCTD dossier.
- However, if a document is to be submitted during the text review phase, the option *Informal exchange in labelling phase (without dossier)* is selected so that individual documents can then be uploaded.

2.15 What should be done in the event of a system failure at Swissmedic or at the user's end?

Please contact Swissmedic Support immediately.

In the unlikely event of a prolonged system failure, Swissmedic will promptly and comprehensively explain the subsequent steps.

2.16 How are Company References handled?

Company References allow internal codes or responsible persons to be entered. Company References can then be viewed in Application Tracking.

Swissmedic does not specify any conditions for their use.

As an *External Reference*, any entries in this field will always be transferred to the *Your reference* line of letters. Entries in your covering letter or under *PO number* in the forms will be ignored.

Exception: If the *Company Reference* consists of several entries because several applications have been uploaded at the same time (e.g. application A, application B, application C), Swissmedic will split the reference up in such a way that each application can be unequivocally identified. Ideally, the *PO number* field in the form should correspond to the relevant part of the entry, e.g. application A, so that entries can be matched up correctly. If it is not possible to match them up unequivocally, the entire entry will be transferred to *Company Reference*.

2.17 How can text be copied from the Swissmedic documents?

Swissmedic sends documents in PDF/A format. Since this is a protected format, it is not possible to extract and re-use text by copying and pasting.

However, it is possible to use software such as Adobe Acrobat Pro to convert the PDF files into Word documents. The text can then be edited as normal.

2.18 What is the procedure if a submission is to be sent on paper by post despite the Portal?

Switching between submissions via the Portal and by post is possible at any time. However, in the event of submissions by post, the Information for healthcare professionals, Patient information texts and the package inserts must also be submitted on a CD as Working Documents. The rules concerning confirmation of identity, virus checking and the necessary signatures must be observed accordingly.

2.19 What is the procedure if an eDok and eCTD have been submitted together but either the eCTD or the eDok is invalid?

In such cases Swissmedic will decide on the validity of the submission and will usually already be in contact with the user. The invalid part must then be corrected as agreed.


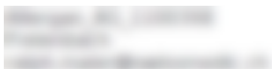
If the eCTD is invalid, but the eDok is valid, both the eCTD and the eDok, incl. any Working Documents will need to be uploaded again, i.e. the submission will be corrected via the small pencil icon under *Functions*.

If, on the other hand, the eCTD is valid and the eDok is invalid, a completely new delivery will need to be recreated and uploaded as agreed with Swissmedic. This is necessary because of the special processing required for the eCTD sequence.

2.20 How should the Validation Report for an invalid eDok be read?

If an eDok is invalid, a Validation Report is automatically issued by the system and the delivery receives the status *Technically invalid*.

A specimen Validation Report is shown below:

	Validation report eDok																
<table border="0" style="width: 100%;"> <tr> <td style="width: 25%;">Delivery-ID:</td> <td>100010001084</td> <td style="width: 50%;"></td> <td style="width: 25%; text-align: right;">Specimen REF</td> </tr> <tr> <td>Delivery sent date:</td> <td>2017-06-28 19:08:17</td> <td></td> <td></td> </tr> <tr> <td>Upload-ID:</td> <td>0</td> <td></td> <td></td> </tr> <tr> <td>File name:</td> <td>invalid02.zip</td> <td></td> <td></td> </tr> </table>	Delivery-ID:	100010001084		Specimen REF	Delivery sent date:	2017-06-28 19:08:17			Upload-ID:	0			File name:	invalid02.zip			
Delivery-ID:	100010001084		Specimen REF														
Delivery sent date:	2017-06-28 19:08:17																
Upload-ID:	0																
File name:	invalid02.zip																
Data issuing platform: Swissmedic platform for electronic submissions																	
Recipient: 																	
Validation end: 2017-06-28 19:08:58																	
Sender: Swissmedic Hallerstrasse 7 3000 Bern 9																	
Comment: Please also check delivered document "Denial of acceptance".																	

Validation report:

The following folder name(s) are not named according to the guidelines:

```

CTD
m1
  125-andere
    1251-smpcprofcompar
  
```

Validation report:

The following folder name(s) are not named according to the guidelines:

CTD ← either CTD or NTA (not in the zip file)
 m1 ← folder is valid, mentioned due to invalid sub-folders
 10-coverDingens ← invalid folder naming
 125-andere
 1251-smpcprofcompar ← folder is valid, mentioned due to invalid parent-folder

2.21 Why are ALL my preparations suddenly selected in the Dashboard under *Enter medicines*?

If a new *Delivery* for already authorised preparations is created and nothing is then entered under *Enter medicines* in the fields *Authorisation / Case no.* or *Name*, but the user nevertheless clicks on *Add medicine*, all preparations registered to the user will be imported into the list.

Therefore, please be sure to select only those preparations in the corresponding fields that are affected by your submission for importing into the list.

Nevertheless, if the list has been filled with unwanted preparations, individual preparations can be deleted via the trashcan icon, or else the delivery must be newly created.

2.22 Why is my application not shown under *Ongoing Applications*?

Depending on urgency and workload, Swissmedic records applications within 5 days at most. After these 5 days have elapsed, a submission should be displayed under *Ongoing applications*.

If this is not the case, please contact Support.

In the following cases, however, applications are not generally shown under *Ongoing applications* (non-conclusive list):

- Baseline
- Waiver of extension
- Submission of manufacturer information
- Submission of manufacturer information

2.23 I can see a concluded milestone in Application Tracking, but no documents (official decision, notification) appear in my inbox.

Changes made by Swissmedic to application planning (application conclusions, official decision documents, milestones reached, etc.) are displayed immediately in Application Tracking.

The actual processing of outgoing mail (both on paper and electronically) only takes place overnight. Accordingly, announced official decision documents are only available in the inbox on the following day.

2.24 How can an eCTD consolidation sequence be submitted via the portal?

No specific delivery type currently exists for this operation. Please use *Variation/New application*.

2.25 Zip file was created on a Mac and now the delivery is invalid.

By default, invisible system files are used in the Mac operating system and these are saved in zip files. However, the eGov Portal cannot handle these system files and issues a Validation Report with an invalid eDok.

Please use the *WinZip* program for creating zip files on a Mac. This program suppresses the creation of invisible system files and produces a zip file that is compatible with the portal.

2.26 How can time limit extensions be submitted via the portal?

For an ~~existing preparation~~ ongoing application, a letter about the time limit extension ~~and any attachments~~ can be uploaded via the delivery type *Extension of the time limit of an application* under *Ongoing Applications*.

Please note: The delivery type *Communication* cannot be used for this purpose.

2.27 Can DMF and ASMF files be submitted via the portal?

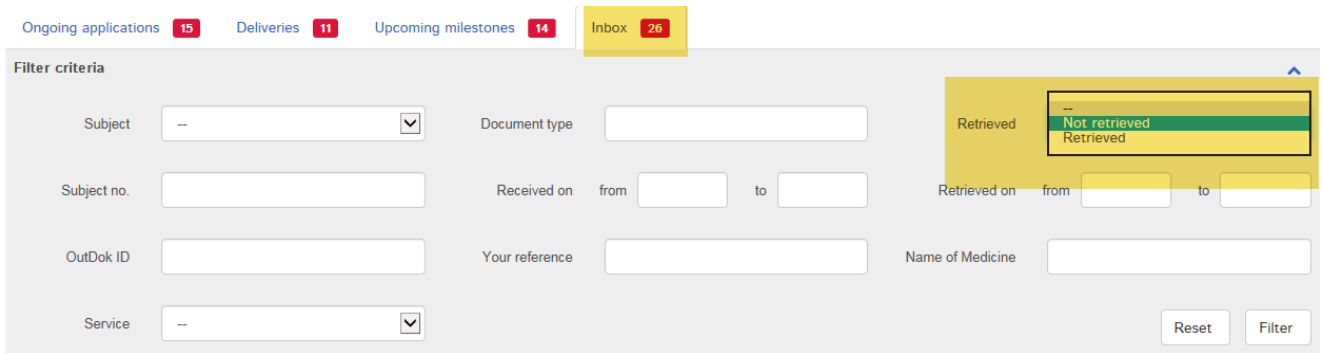
There are no plans at present to enable DMFs to be submitted via the portal. This is only permitted, and possible, in connection with an authorisation application via the authorisation holder.

2.28 Can PMF files be submitted via the portal?

The delivery type PMF and the document type PMF exist for PMF submissions, and these can be used for submissions for an existing preparation.

2.29 I can no longer find documents in my inbox after I have downloaded them.

Please check the setting for the *Retrieved* filter in your inbox. By default, this is set to *Not retrieved*. As soon as a document has been downloaded, it disappears from the list as a result of this setting.



Ongoing applications 15 Deliveries 11 Upcoming milestones 14 **Inbox 26**

Filter criteria

Subject -- [v] Document type [] Retrieved [] **Not retrieved** Retrieved

Subject no. [] Received on from [] to [] Retrieved on from [] to []

OutDok ID [] Your reference [] Name of Medicine []

Service -- [v] [Reset] [Filter]

However, these retrieved documents can, of course, continue to be downloaded while the application is available in the portal. To this end, simply change the setting to *Retrieved* via the drop-down menu.

2.30 I have forgotten to submit working documents. How can I submit them now?

If you have forgotten to upload working documents, proceed as follows:

- Create a subsequent delivery of missing documents as soon as Swissmedic has recorded the submission.
- In the dashboard, a subsequent delivery for this new application can be created under *Ongoing applications*.







- To commence processing, click the *Enter delivery for this application* button in the *Functions* area.

Dashboard

+ Delivery of a new application

Ongoing applications **8** Deliveries **2** Upcoming milestones **10** Inbox **2**

Filter criteria

Application no.	Company reference	Application type	Date of letter	Authorisation/Case no.	Name of medicine	Application status	Delivery ID	Functions
		NA NAS HAM	16.10.2014		njektionslösung	IN PROGRESS		  
		G-AE mwB AI klein HAM	03.07.2015		Augentropfen	IN PROGRESS		  

- The screen now gives you the option to state that a subsequent delivery of documents is involved (*Concerns subsequent delivery*).

Features

Informal exchange in labelling-phase (without dossier) *

Yes No

Art.13 *

Yes No

Subsequent delivery *

Yes No

Hash algorithm *

Message-Digest Algorithm 5

< Back

Cancel

Save and exit

Next >

- Subsequent deliveries of documents should never be submitted as a *Communication* delivery type, since they cannot then be assigned to an application when the application is recorded by Swissmedic.

2.31 Can one preparation (one authorisation number) have more than one eCTD life cycle?

If a preparation already has an eCTD dossier and life cycle, it is not possible to start an additional life cycle with a new Seq. 0000. The portal can only manage a single eCTD dossier per preparation. Additional pharmaceutical forms or indications must therefore be presented within the existing eCTD life cycle.