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Change history

Version	Valid and binding as of	Description, comments	Author's initials
2.1	13.09.2019	Link and phrase “The current system requirements are available under www.swissmedic.ch/egov-req ” deleted	anm
2.0	01.01.2019	Corrections	seb
01	19.09.2017	First version	seb

1 Terms, definitions, abbreviations, glossary

Acceptance of...	Acknowledgement for a specific step
Hash algorithm, hash code	Checksum calculated for a submission or for individual files
Company reference	Reference, your reference
CPP	Certificate of a Pharmaceutical Product
Dashboard	Work environment and input screen
Delivery	Delivery for new or ongoing applications
Delivery ID	Specific identification number of uploaded file
Doc ID	Identification number of transmitted file
Delivery status	Status of a delivery
eGov	eGovernment

eGov Service	Individual service within the eGov Portal
eSubmissions	Service for entering deliveries
Swiss authorisation human	Human medicinal products
Inbox	Mailbox in dashboard
mTAN	Mobile transaction number via SMS
Notification	Notification by e-mail
Release	Version of the Portal software
Subject no., subject number	Identification number for applications, corresponds to delivery ID
Export or Swiss veterinary authorisation	Export preparation or veterinary medicinal product
Upload	Upload process

2 Objective and scope

This information sheet contains the basic information needed to use the Swissmedic eGov Portal, particularly the eGov **CPP** services.

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. The new user will then receive an e-mail from Swissmedic (it@swissmedic.ch) with a link for setting up an initial password.

4 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.

5 Use of the eGov Portal

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

The home page displays the *Administration*, *CPP* and *eSubmissions* areas (depending on the user's authorisation).

The individual areas are explained in greater detail below.

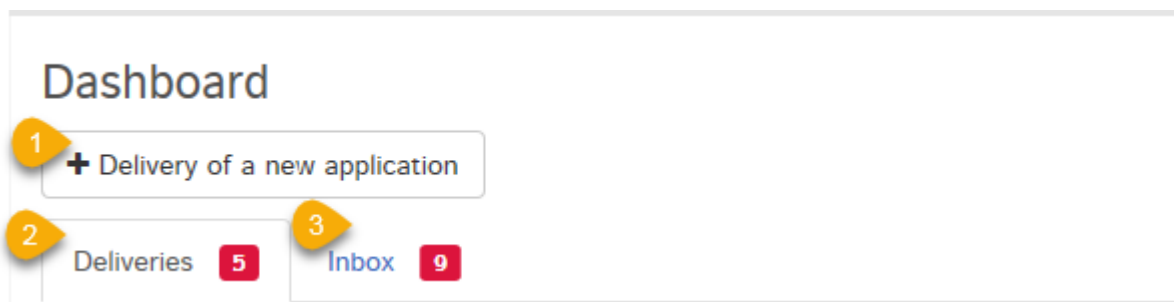
5.1 Administration area

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

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

5.2 eGov CPP area

Excel files for CPP applications can be uploaded here together with the related files in a screen-guided process. A dashboard (see diagram below) is provided for users:



The Swissmedic eGov Service CPP offers the following options:

1	Delivery of a new application with file.
2	List of most recent CPP deliveries.
3	List of delivery confirmations from Swissmedic (identified by a doc ID)

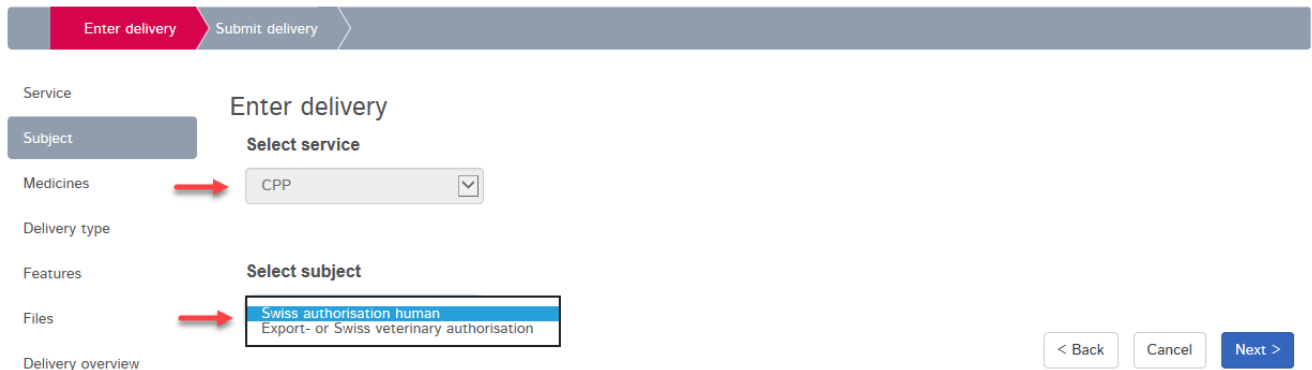
5.2.1 Delivery of a CPP application

The complete process is illustrated below by means of an example.

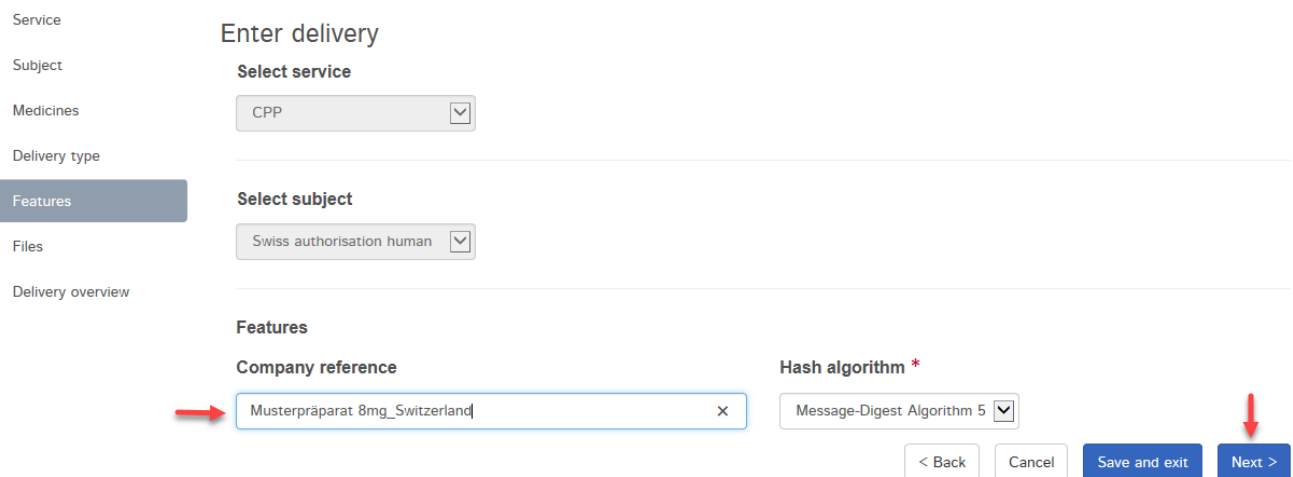
In the *dashboard*, click on *Delivery of a new application* to initiate the process.

Subsequent steps: From the *Select service* dropdown menu choose “CCP” and under *Select subject* pick either “Swiss authorisation human” or “Export or Swiss veterinary authorisation” and click Next to confirm.

Deliveries



A *company reference* can optionally be provided under *Features*. This will appear in the dashboard, in the inbox and on the delivery confirmation and the acceptance of delivery acknowledgement as “Your reference”. The *company reference* is solely to help the user to keep track of applications delivered and will not be entered on the CPP certificate.



Next step: Under files click on **+Add file**. Under *Choose file* select the input file in xlsx format.



In the case of applications for an export preparation/veterinary medicinal product where information for healthcare professionals (IHP) is required as an attachment to the certificate, following upload of the input file the IHP is also to be uploaded. To do so, click on **+Add another file**, in place of *CPP request form* choose *Product information for HCP*, and under *Choose file* select the PDF of the IHP.

Files

Add file



Click on *Upload* to transmit the files.

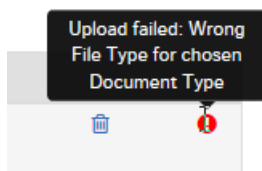
During the *upload* an automatic technical check is performed (including a virus check and a correct file format check). NB: This is not the same as a technical validation or structural check on the CPP form. These will be carried out later as part of the process for issuing the certificate.

The result of this automatic technical check will be displayed on screen. A green tick indicates that the *Upload* has been successful. Depending on the size of the delivery, this step may last several seconds.

Files



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.

If everything is correct, the delivery can be completed (Next) 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
CPP

Subject
Swiss authorisation human

Features

Company reference
Musterpräparat 8mg_Switzerland

Files

Document type	File name	Hash
CPP request form	xyz 8 mg_fct.xlsx	8673a069aeafb845acd33684aea8a079

< Back
Cancel
Submit

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

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.

A message confirming the successful submission is then displayed.

Submitted delivery

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

The delivery will remain in the *Deliveries* area while it is being processed. The delivery confirmation has been created and the delivery status is set to “Transmitted”. It may take several minutes to transmit the data. Once this process is complete and the documents have been transmitted, the acceptance of delivery acknowledgement will be created and the delivery status changed to “Accepted”.

Delivery status provides information on the processing status.

The following statuses are possible:

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

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

Dashboard

+ Delivery of a new application

Deliveries **6** Inbox **11**

Delivery ID	Your Reference	Service / Subject	Delivery type	Last updated at	Last updated from	Delivery status	Functions
100010002452	Musterpräparat 8...	CPP/Swiss authorisation human		12.09.2017 10:38		Accepted	Q D

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

Delivery details x

Delivery details

Delivery ID	100010002452	Application No.	8087776
Dok ID	0010106445	Application Type	Firma_Demo_CPP
Service	CPP	Company/User Name	
Subject	Swiss authorisation human	Application category	
		Delivery Type	

Medicines

Features

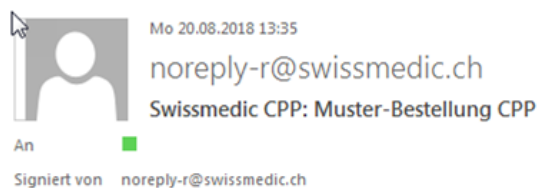
Company reference	Musterpräparat 8mg_Switzerland	Hash algorithm	MD5
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Submitted files

File name	Document type	Structure format	eCTD dossier	File Status	Functions
xyz 8 mg_fct.xlsx	CPP request form			Valid	D

OutDok ID	Subject	Subject no.	Your reference	Document type	File name	Received on	Retrieved on	Func.
	Delivery	100010002452	Musterpräparat ...	Delivery Confirmation	100010002452_SENT_20...	12.09.2017		D
	Delivery	100010002452	Musterpräparat ...	Acceptance of delivery	100010002452_ACCEPTE...	12.09.2017		D

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



Dear Sir or Madam,

Swissmedic has uploaded a document to your account:

User-ID:

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

Service: CPP
Subject: Swiss authorisation human
Your reference: Muster-Bestellung CPP

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

Best Regards,

Swissmedic - Swiss Agency for Therapeutic Products

Swissmedic will then begin processing the application.

5.2.1.1 Further options when entering a CPP application

Change *hash algorithm*: The *hash algorithm* option can be used to select the method for calculating the checksum (techn. control mechanism to identify transmission errors).

Pause application: If necessary, the delivery can be temporarily saved by clicking




without having to complete the process. The delivery can be completed later. The dashboard will show the status as *Paused*.

Dashboard

+ Delivery of a new application

Deliveries **6** Inbox **9**

Delivery ID	Your Reference	Service / Subject	Delivery type	Last updated at	Last updated from	Delivery status	Continue delivery
100010002452	Musterpräparat 8...	CPP/Swiss authorisation human		12.09.2017 09:06	cpp_seb_cpponly	Paused	

To resume delivery, click on 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 after 30 days and can no longer be edited.

5.3 Inbox area

The inbox shows delivery documents for downloading. By entering various search terms, the filter function can be used to find and download a document. The *Retrieve status* function shows whether documents have already been downloaded or not yet retrieved. CPP users will see their own applications only.

5.4 Acknowledgements and notifications

During the delivery process, the Portal automatically issues acknowledgements or so-called notifications containing e.g. important information on status, errors or confirmations.

5.4.1 CPP application 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 delivery and forwarded to the specialist department for checking and processing
- Denial of acceptance -> Portal cannot process documents

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

Acceptance of delivery is considered to be an acknowledgement of receipt.

5.5 Technical details

The following section addresses certain technical details.

5.5.1 File formats

Document type	Authorised file formats
CPP request form	XLSX
Product information for healthcare professionals	PDF

Please note: This list shows only those formats authorised for uploading the input file and attachment. However, the key factor for correct delivery of the application is compliance with the requirements of the *Guidance document for requesting product certificates (CPP)*.

5.5.2 Doc ID

A Doc ID is created for every submission. In cases of doubt or if an unexpected problem is encountered with the Portal, Swissmedic can verify on the basis of the Doc ID number if an application has been received. The DocID is displayed as soon as the acceptance of delivery acknowledgement has been created.

The number can be seen in the delivery details and in the acceptance of delivery acknowledgement.

Delivery details			
Delivery details			
Delivery ID	100010002452	Application No.	Company/User No. 8087776
Dok ID	0010106445	Application Type	Company/User Name Firma_Demo_CPP
Service	CPP	Application category	
Subject	Swiss authorisation human	Delivery Type	

6 Cancellation of applications

As soon as the application has been confirmed and forwarded by clicking “Submit”, it can no longer be cancelled.

7 Support

E-mail it@swissmedic.ch

Tel: 058 462 06 00

www.swissmedic.ch/gate-support

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