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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
3.0	01.01.2023	Chapter 1, Terms,...: complemented with OBPR, HAM, TAM/ITAM, etc. Chapter 2: Description of the cases in which the eGov Service OCABR is applied. Chapter 5.2: Clarification that the term "submissions under OCABR" refers to both OCABR and OBPR. Chapter 5.2.1: Clarifications in connection with the immunological TAMs, description of the convention for naming the uploaded files.	gim
2.0	24.08.2020	Table in section 5.5.1, additional file format added	gim
1.0	01.10.2018	First version	gim

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
OCABR	Official Control Authority Batch Release (OCABR is as well used as a summary term for all activities related to regulatory batch testing at Swissmedic).
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
HAM	Human medicinal product
TAM, ITAM	Veterinary medicinal product, immunological veterinary product
Inbox	Mailbox in dashboard
mTAN	Mobile transaction number via SMS
Release	Version of the Portal software
Subject no., subject number	Identification number for applications, corresponds to delivery ID
Upload	Upload process

2 Objective and scope

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

The eGov Service OCABR is used for the submission of applications for batch release or plasma pool testing with laboratory analysis to immunological HAMs, for applications for batch release without laboratory analysis to HAMs or ITAMs (OBPR) and for applications for notification of batches (ITAMs and HAMs).

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

Minimum system requirement: the latest version of Microsoft Internet Explorer (version 10 or higher) or Firefox (version 43 or higher).

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.

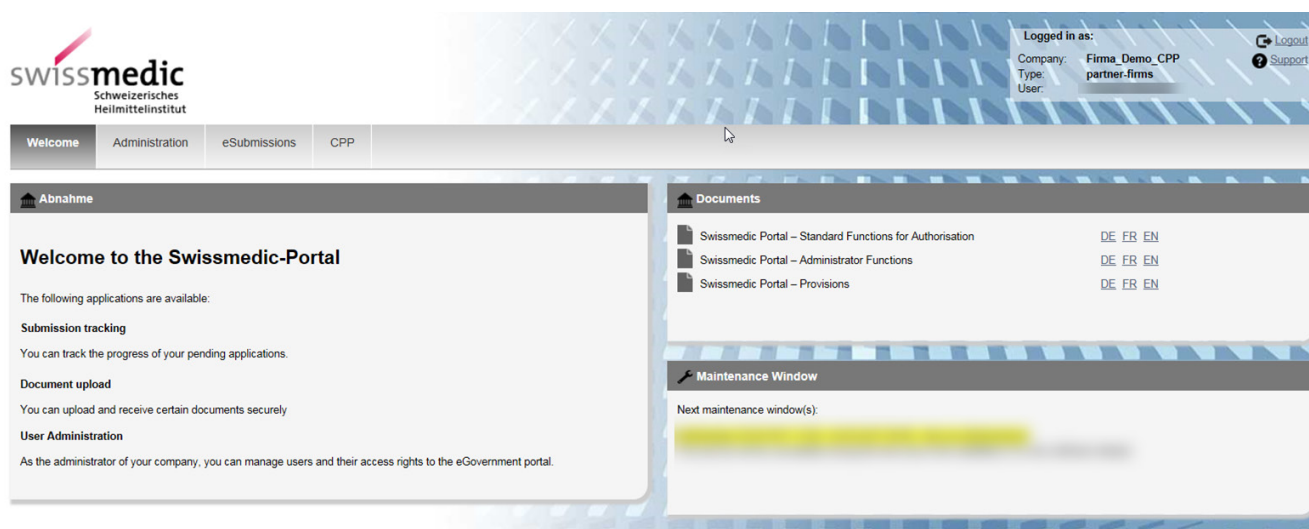
When a user logs in for the first time, and also following software updates, the user must agree to the latest terms of use.

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.

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

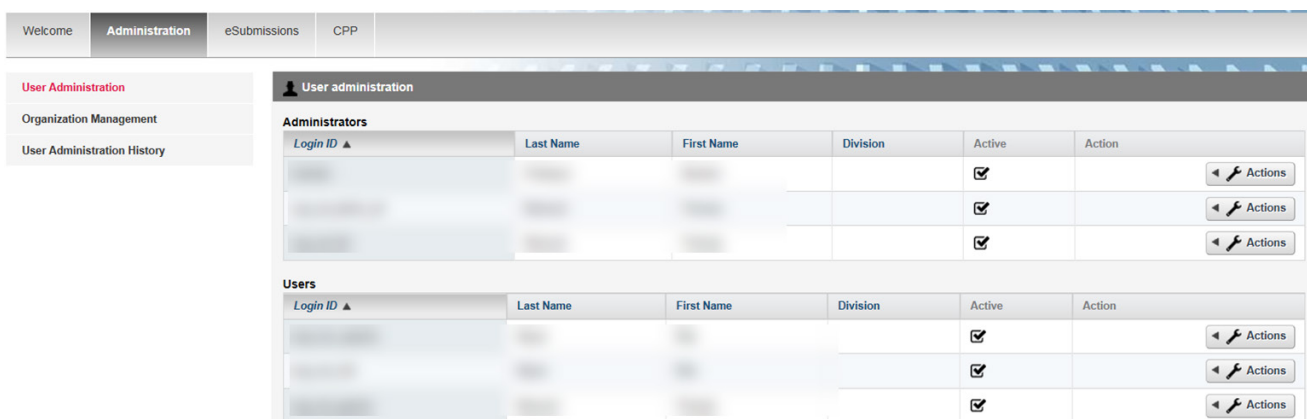
This section explains the basic functions and processes of the Swissmedic eGov Portal in greater detail. The Portal is the central access point for other eGov Services. The default language of the Swissmedic eGov Portal is English. The information sheets are available in German, French and English.



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

The individual areas are explained in greater detail below.

5.1 Administration area

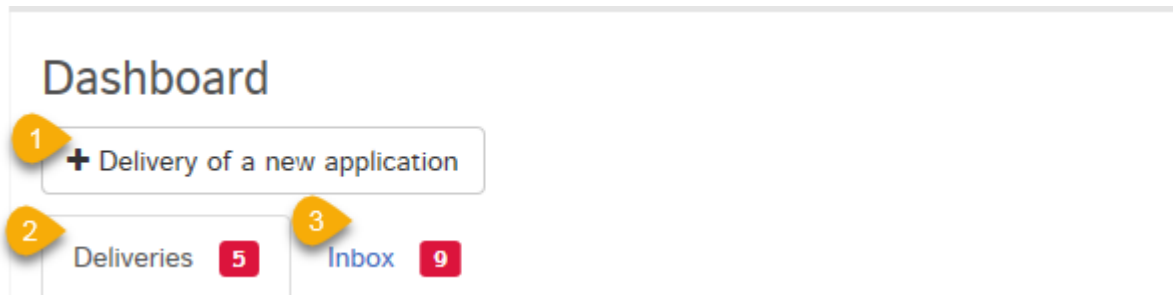


Accessible to registered Portal administrators, this area is for configuring the necessary settings and, for example, creating users.

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

5.2 eGov area OCABR

The applications for OCABR submissions (Batch Release [=OCABR or OBPR], Plasma Pool Testing, Notification) and related files can be uploaded here in a screen-guided process. A "dashboard", explained in greater detail in the following graphic, is provided for users:



The Swissmedic eGov Service OCABR offers the following options:

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

5.2.1 Submission of an OCABR 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 "OCABR" and under *Select subject* pick either "Batch Release", "Notification" or "Plasma Pool Testing" and click *Next* to confirm.

Deliveries



Service: Enter delivery

Subject: Select service

Medicines: OCABR

Delivery type: [Empty]

Features: Select subject

Files: Batch Release

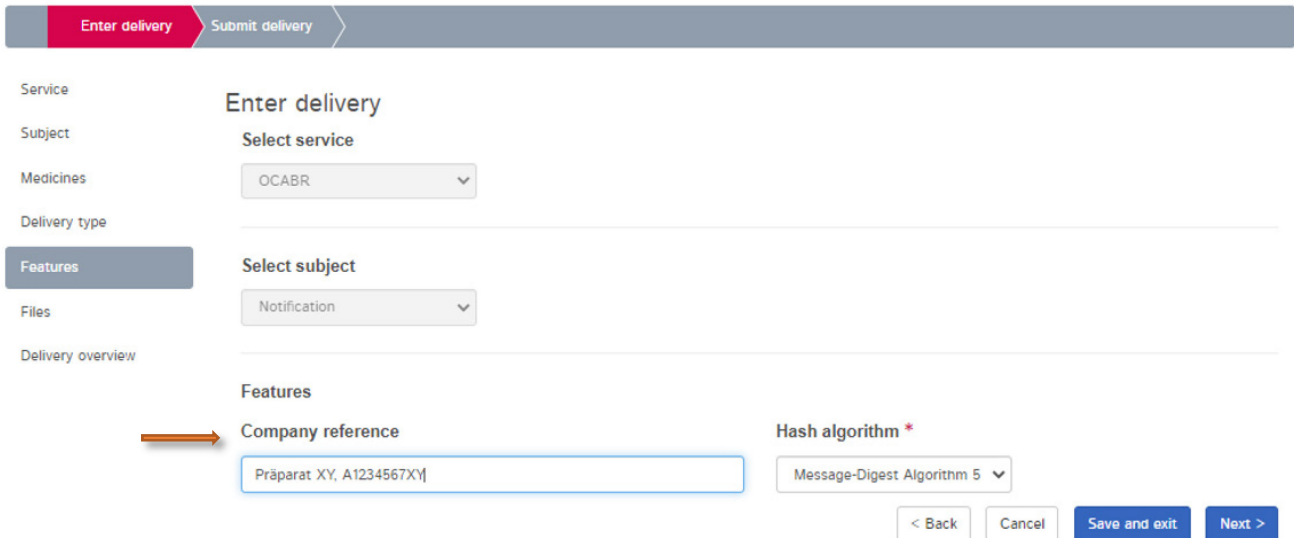
Delivery overview

< Back Cancel **Next >**

A *Company reference* can 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".

At least the following entries should be made under Company Reference:
[Drug Name], [Batch Number].

Deliveries



Next step: Under files click on **+Add file**. Under *Choose File* select the desired file.



Ideally, please use the following conventions for file names:

OCABR/OBPR:

Request for Batch Release: [BatchNumberFilling]_[DrugName].pdf

Manufacturer's documentation (summary protocol) + EU certificate (if available in special cases):
[BatchNumberFilling]_Summary.pdf

Notification HAM (Required documents: MIF and EU Release Certificate):
Ideally submitted in a document called [BatchNoPacking]_[DrugName].pdf.

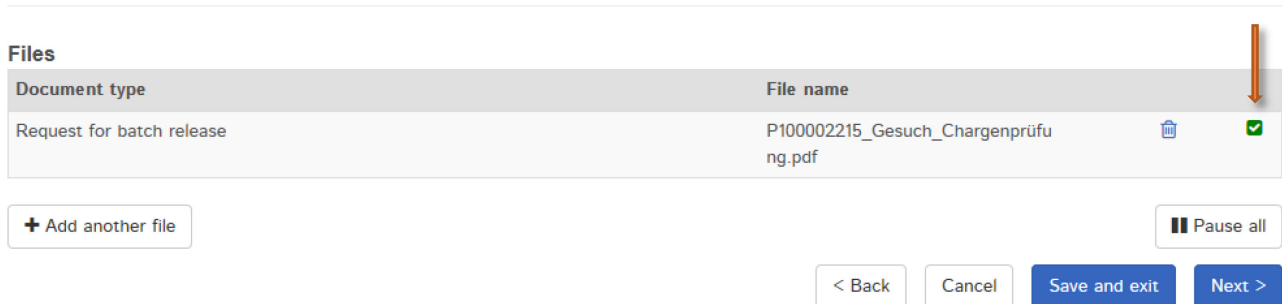
Notification TAM (Required documents: MIF, EU Release Certificate and Summary Protocol
[BatchNoPacking]_[DrugName]_TAM.pdf

Alternatively, submission is possible in several documents, which are named accordingly with supplements (e.g. with supplements _MIF.pdf, _EUcert.pdf, _SP.pdf)
Summary Protocols for the notifications TAM can be uploaded as "attachment".

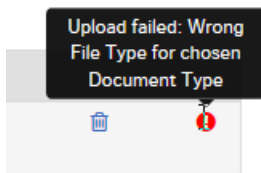
Click on *Upload* to transmit the files.

During the *upload* an automatic technical check is performed (including a virus check and a correct file format check). However, this is not the same as a technical validation, which is only carried out later on as part of the checking of submitted applications and documents.

The result of this automatic technical check will be displayed to the applicant 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.



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
OCABR

Subject
Batch Release

Features

Company reference
Einreichung vom 08.08.2018

Files

Document type	File name	Hash
Request for batch release	P100002215_Gesuch_Chargenprüfung.pdf	4a8c30ea9ee7dbfe63ec28271dc7bbde

< 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 changes 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 **1** Inbox **15**

Delivery ID	Your Reference	Service / Subject	Delivery type	Last updated at	Last updated from	Delivery status	Functions
100010007701	Einreichung vom ...	OCABR/Batch Release		14.08.2018 11:30		Transmitted	 

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

Delivery details


Delivery ID	100010007701	Application No.	Company/User No.	1001745
Dok ID	0010135884	Application Type	Company/User Name	
Service	OCABR	Application category		
Subject	Batch Release	Delivery Type		



Medicines

Features

Company reference	Einreichung vom 08.08.2018	Hash algorithm	MD5
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Submitted files

File name	Document type	Structure format	eCTD dossier	File Status	Functions
P100002215_Gesuch_Chargenprüfung.pdf	Request for batch release			Valid	

OutDok ID	Subject	Subject no.	Your reference	Document type	File name	Received on	Retrieved on	Func.
	Delivery	100010007701 	Einreichung vom...	Delivery Confirmation	100010007701_SENT_20...	14.08.2018		

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

 Di 12.09.2017 10:38
 noreply-r@swissmedic.ch
 Swissmedic eSubmissions: Correspondence
 An 
 Signiert von noreply-r@swissmedic.ch

Dear Sir or Madam

Swissmedic has uploaded a document to your account:

User-ID:

Log on to the Swissmedic portal to download the appropriate document.

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

Best Regards

Swissmedic eSubmissions - Swiss Agency for Therapeutic Products

Swissmedic will then begin processing the application.

5.2.1.1 Further options when entering a OCABR application






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



Dashboard

+ Delivery of a new application

Deliveries **3** | Inbox **16**

Delivery ID	Your Reference	Service / Subject	Delivery type	Last updated at	Last updated from	Delivery status	Functions
100010007705	asd	OCABR/Plasma Pool Testing		14.08.2018 12:01	Michael.Gilgen@swissmedic.ch	Transmitted	 
100010007703	Einreichung 08.0...	OCABR/Batch Release		14.08.2018 11:41	Michael.Gilgen@swissmedic.ch	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. OCABR 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 OCABR 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 it 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

Application type	Document type	Authorised file formats
Batch Release	Request for batch release	pdf
Batch Release	Summary Protocol incl. related docs	pdf
Plasma Pool Testing	Request for Plasma pool testing	pdf
Plasma Pool Testing	EU plasma pool certificates	pdf
Notification	MIF + OMCL batch release certificate	pdf
Notification	MIF	pdf
Notification	OMCL Batch release certificate	pdf
All application types	Attachment / Attachment ZIP	pdf, docx, xlsx, csv

Please note: This list shows only those formats authorised for uploading the files. However, the key factor for correct delivery is compliance with the requirements of [23 VZ 06 Official batch release of vaccines and blood products](#).

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 Doc ID 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	100010007701	Application No.	Company/User No.	1001745
Dok ID	0010135884	Application Type	Company/User Name	
Service	OCABR	Application category		
Subject	Batch Release	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 8 a.m. and 6 p.m.