

Information sheet eMessage functions

Identification number:	OS000_00_005
Version:	3.0
Valid from:	30.05.2024

eMessage functions

eMessage is an eGov service through which data can be entered electronically on specific topics approved by Swissmedic.

The following services are currently approved for use:

Correspondence on the following topics:	
Medical devices	<ul style="list-style-type: none"> • Exemptions for non-conforming products • Certificates issued by Notified Bodies • Feedback on administrative proceedings in the area of marketing monitoring • Export certificates • Clinical trials

eMessage can be used both by private individuals and companies. For this, a user account must first be opened. This account is used for sending the data entries to Swissmedic and for receiving correspondence from Swissmedic. A personal user account can be opened via the following link: www.swissmedic.ch/emessage-en.

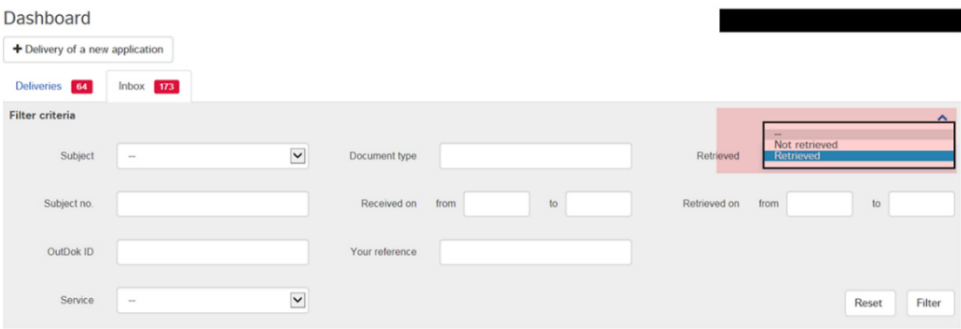
However, companies that already use another Swissmedic eGov service can arrange for their existing user account to be authorised for the service. To this end, the company must accept the "*Special terms of use for eMessage*" by submitting a signed contract for the eMessage module.


As soon as Swissmedic has released the eMessage service for use, the company's account administrator can independently issue all the other authorisations required.

An electronic mailbox is available on the eMessage platform. Correspondence from Swissmedic is signed electronically and saved in this mailbox. As soon as new correspondence becomes available here, an e-mail notification is sent.

Brief description of functions

Function	Brief description
eSubmission	Displays the start screen.
eGov Services	Displays the portal for managing user details.
Delivery of a new application	Starts the entry process for delivering documents. After the details have been entered, the corresponding documents can be uploaded. The system accepts the formats PDF, Excel or ZIP, depending on the correspondence concerned.
Response to Swissmedic correspondence	<p>Answers and subsequent submissions must also be submitted via eMessage. Submissions by e-mail will not be accepted.</p> <p>For this, please make the following selection under "Select delivery type":</p> <p>„Response to Swissmedic correspondence“</p>

	<p>Select delivery type</p> <p>Response to Swissmedic cor[...]</p>
Reference to original application number	<p>Under "Reference to original application number" it is mandatory to quote the Swissmedic reference no. (102xxxxxx) when responding or sending additional documentation.</p> <p>Reference to original application number</p> <p>102xxxxxx</p>
Deliveries	<p>The company's deliveries are displayed in this list for 20 days.</p>
Inbox	<p>Correspondence from Swissmedic is filed here and kept available for downloading:</p> <ul style="list-style-type: none"> Acknowledgements of sending and receipt of deliveries Correspondence from Swissmedic <p>If the correspondence from Swissmedic has the nature of an official decision, the delivery is displayed after download with a Download Notification.</p> <ul style="list-style-type: none"> The Inbox should not be treated as an archive. Users are required to immediately download back-ups of the documents. By default, only acknowledgements and notifications that have not yet been retrieved will be displayed. The display can be adjusted using the "Retrieved" filter. 
Acknowledgements	<p>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.</p> <p>The following acknowledgement types exist:</p> <ul style="list-style-type: none"> Delivery confirmation → Portal has received documents Acceptance of delivery → Portal has accepted documents and is starting processing Denial of acceptance → Portal cannot process documents

	<p>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.</p>
<p>Electronic / digital signatures</p>	<p>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:</p>  <p>For class A certificates (document type: official decision), an alternative option for validity checking is the <i>Online Validator service provided by the Federal Administration</i>: https://www.e-service.admin.ch/validator/upload/all/en</p> <p>Please contact your IT department if you need help with the installation of the certificates or any other issues.</p>
<p>Logout</p>	<p>Log out of the system.</p>