



Swissmedic eSubmissions platform

The eSubmissions platform is used for the electronic submission of applications for authorisation or variations and the electronic delivery of correspondence from Swissmedic. The following functions are currently available:

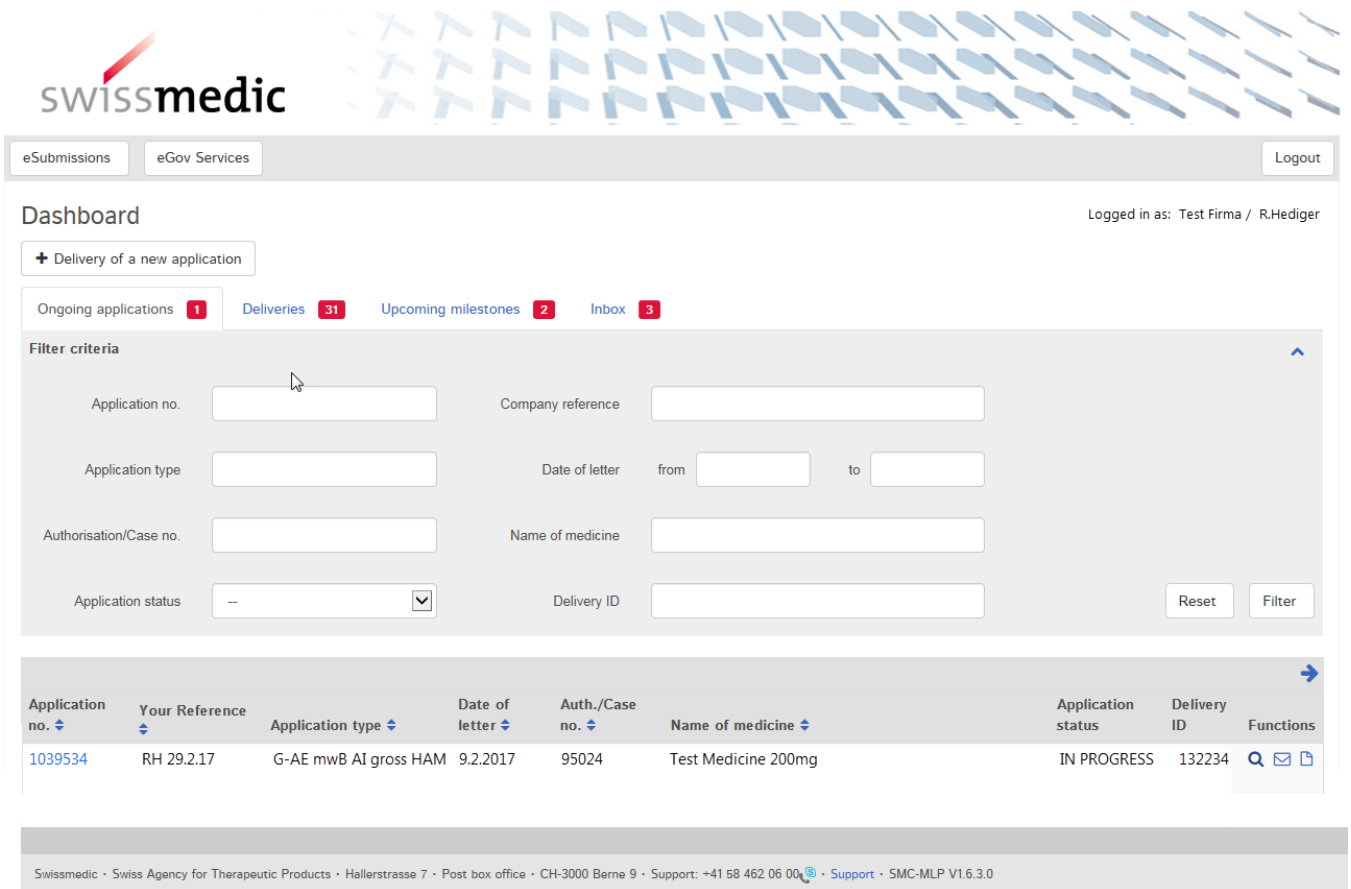
- **Electronic submission of applications**
Locally installed software is not required to submit applications in eCTD or eDok formats. However, to upload documents, you will require Internet Explorer 10 or Firefox version 43 or higher. When you submit applications via the user-friendly and intuitive web application, you will very quickly receive a response concerning your delivered data.
- **Customised granting of permissions at preparation level**
Using the platform, it is possible to grant permissions down to individual preparation level. This lets you control who has access to what data.
- **Application tracking**
You can also find an overview of your applications currently being processed by Swissmedic. You can save the latest status for each application as a PDF file using the Export function. There is also a new view that shows you the milestones for the next 30 days.
- **Central inbox for mail from Swissmedic**
The correspondence sent to you by Swissmedic can be retrieved from one central location and can also be searched according to various filter criteria.

The eSubmissions platform is available in two variants:

- **"Fully electronic"**
You submit your application documentation electronically and also receive all correspondence from Swissmedic in electronic format. Decisions come with a legally valid digital signature.
- **"Semi electronic"**
Under this option, you also submit your application documentation via the platform and receive all correspondence that is not connected with official decisions electronically. Documents with the nature of an official decision, e.g. preliminary decisions, LoQ or official decisions, will continue to be sent to you in paper form by post.



Screenshot of the eSubmissions platform:



The screenshot shows the SWISSmedic eSubmissions platform dashboard. At the top, there is a navigation bar with 'eSubmissions' and 'eGov Services' tabs, and a 'Logout' button. The user is logged in as 'Test Firma / R.Hediger'. The dashboard features a 'Delivery of a new application' button and a summary of key metrics: Ongoing applications (1), Deliveries (31), Upcoming milestones (2), and Inbox (3). A 'Filter criteria' section includes input fields for Application no., Company reference, Application type, Date of letter (with 'from' and 'to' sub-fields), Authorisation/Case no., Name of medicine, Application status (a dropdown menu), and Delivery ID. 'Reset' and 'Filter' buttons are located at the bottom right of the filter section. Below the filters is a table with the following data:

Application no.	Your Reference	Application type	Date of letter	Auth./Case no.	Name of medicine	Application status	Delivery ID	Functions
1039534	RH 29.2.17	G-AE mwB AI gross HAM	9.2.2017	95024	Test Medicine 200mg	IN PROGRESS	132234	🔍 📧 📄

At the bottom of the page, there is a footer with contact information: 'Swissmedic • Swiss Agency for Therapeutic Products • Hallerstrasse 7 • Post box office • CH-3000 Berne 9 • Support: +41 58 462 06 00 • Support • SMC-MLP V1.6.3.0'.

To activate the new platform, simply return the required contract documents. By signing these documents you accept the current user agreements, which you can order via our website: www.swissmedic.ch/gate-order