

Voluntary “prior notification of new application with new active substance” via eGov portal

Voluntary prior notification of applications with a new active substance (NA NAS) is of considerable help to Swissmedic in resource planning. The possibility of early resource planning supports efficient processing of applications and is therefore in the interests of all concerned.

These short instructions describe the process for prior notification of an NA NAS via the eGov portal. Alternatively, the prior notification can be made by letter or by e-mail to eSubmissions@swissmedic.ch. Whichever communication channel is used, Swissmedic then enters a dummy application in the planning system and assigns it an **application identifier (application ID)**. The application and corresponding application ID then become visible to the applicant in the eGov portal.

Time for prior notification

- Once the approximate submission date (+/-2 weeks) is known (ideally 4-6 months before submission)
- Follow-up message to SMC in the event of lengthy postponement of the submission date or a change to the intention to submit

Step 1: Procedure for prior notification of an NA NAS application

Prior notification of NA NAS application via eGov portal

So that Swissmedic can enter a dummy application in the planning system, the applicant must submit a “prior notification” including the required information.

Please proceed as follows if you need to submit this type of prior notification:

- 1) Dashboard -> Delivery of a new application
- 2) Subject, i.e. the area concerned (human, veterinary or complementary medicine)
- 3) As this is a prior notification for a new medicinal product, “Application for new case/authorisation” must be selected as the application case type.
- 4) Enter the product name, if known (max. 20 characters)
- 5) The product is added via “Add case”, then click “Next”.

Select application case type

Application for existing case/authorisation
 Application for new case/authorisation
 Application for case/authorisation transfer

Enter cases

Case title

New_case

+ Add case

- 6) Select “Communication” as the delivery type for prior notification of NA NAS.

Select delivery type

Communication

- 7) Upload your cover letter (in PDF format) under “Add file” as “Letter”.

Files

Add file

Letter

Choose file

Upload

Cover letter

The cover letter must include the following elements:

- Subject: "Prior notification of NA NAS"
- Active substance(s)
- Product name (if known)
- Month of planned application submission
- ATC code (if known)
- Indication
- Indication wording applied for (if known)
- Pharmaceutical form

Once Swissmedic has entered the pre-announced application in the planning system, this and the application ID become visible for the applicant in the eGov portal. The application ID assigned to the application must be used in Step 2 when submitting the actual NA NAS application.

Step 2: Submission of the NA NAS application after prior notification

Submission of the NA NAS application after prior notification.

The applicant uses the application ID visible in the eGov portal to submit the actual NA NAS application.

Please proceed as follows to submit this type of application:

- 1) The existing dummy application can be found under "Ongoing applications" using the application ID issued by Swissmedic.
- 2) Submission of the application can now be started by clicking on the mail symbol under "Functions".
- 3) Select "Response to Swissmedic Correspondence" under "Application Type".

+ Delivery of a new application

Ongoing applications | Deliveries | Upcoming milestones | Inbox

Filter criteria

Application no. Company reference

Application type Date of letter from to

Authorisation/Case no. Name of medicine

Application status Delivery ID

Reset Filter

Application no. ▾	Company reference ▾	Application type ▾	Date of letter ▾	Authorisation/Case no. ▾	Name of medicine ▾	Application status	Delivery ID	Functions
102554912		NA NAS HAM	17.06.2016	66351		IN PROGRESS	146502	