Swissmedic, Swiss Agency for Therapeutic Products

Department Operational Support Services

Hallerstrasse 7

3012 Berne

**Format:**

eCTD

CTD  incl. eDok copy or  incl. paper copy (cover sheet inserted)

NTA  incl. eDok copy or  incl. paper copy (cover sheet inserted)

Comments: °°°°°

**Submission type:**

New application(s) with scientific assessment

New application(s) without scientific assessment

Approval

Variation(s) requiring notification

Renewal/Renouncement

Answer to open application(s), application ID(s): °°°°° (whatever the type of answer)

Other: °°°°°

**Particular aspects:**

Fast-track / Application with prior notification

Scientific Advice / Pre-submission meeting

Safety-relevant change to product information

Advertising

Signals

Other: °°°°°

**Number of submitted applications:** °°°°° (of these: °°°°° Collective application(s))

Change history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Valid and binding as of: | Description, comments (by author) | Author’s initials |
| **01** | **14.02.2017** | **New QM Ident (old Ident: SU000\_00\_004e\_VL) / new address header** | **wis** |
|  | **23.01.2015** | Document technically adapted for internet publication. | sel |
| **02** | **19.06.2014** | **Inserted address field** |  |