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** |  |