Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Updated procedure for submitting applications according to HMV4 before 01.01.2019

03.12.2018

As of 1 December 2018 Swissmedic will accept submissions with the documents updated according to HMV4.

- For eDok submissions, the corresponding cover sheets and templates will be available online on 1 November 2018. These new templates are intended for submissions according to HMV4. Submissions that do not yet correspond to HMV4 should continue to use the currently available templates. From 1 January 2019, only eDok submissions using the updated templates will be accepted by Swissmedic.
- For eCTD submissions, a transitional solution will be provided for authorisation holders that have not yet updated to the latest M1 Specification and the corresponding Validation Set. In the transitional solution, submissions according to HMV4 will still be able to use the current structure of the M1 Specification, v1.3. In M1 Specification v1.4, certain eCTD sections will be renamed, deleted or additionally inserted as a result of the new and updated forms required for HMV4. Until the end of the transitional phase on 30 June 2019, submissions will be accepted according to Validation Sets 1.3 and 1.4.
- The following procedure applies to the transitional solution:

  1. Documents for 1.2.2.25 should be filed under 1.2.2.99
  2. Documents for 1.2.2.26 should be filed under add-info
  3. Documents for 1.12 (incl. 1.12.1/1.12.2/1.12.3/1.12.4) are to be filed under add-info
  4. The covering letter must explicitly mention the procedure and the filing of the new documents in the old M1 structure.
  5. The documents should have meaningful names (variable part of file name), and the titles themselves should be meaningful.
  6. The following sections will be renamed in connection with HMV4, but the content will remain unchanged. Documents can be filed in the usual way:

a) 1.2.1
b) 1.2.2
c) 1.2.2.19
d) 1.2.2.20
e) 1.5.1
f) 1.7.6

7. Application Type

In the table below you will find a comparison of the Application Types as per the new M1 Specification v1.4 with the existing Specification and the Types to be used during the transition phase.
Only Application Types that have been changed are shown in this table.

M1 Specification v1.4 (ab 01.01.2019 gültig)	Übergangslösung (neue Formulare im eCTD gem. M1 Spec v1.3 ablegen) Gültig von 01.12.2018 bis 30.06.2019
na-co-marketing	co-marketing
na-pi	pi
var-type1a	**notification**
var-type1ain	**notification**
var-type1b	**notification**
var-type2	**var-authorisation-scientific**
extension	**na-ngf, na-nko, na-ndo**
advice	**na- nas, na-bws, na-ngf, na-nko, na-ndo,**

https://www.swissmedic.ch/content/swissmedic/en/home/services/submissions/news-submissions/aktualisierungvorgehensweisezureinreichungvongesuchennachhmv4.html