Agence nationale de sécurité du médicament et des produits de santé

Submission of confidential file for the active substance (or the "European Active Substance Master File (ASMF)") to ANSM

Under the terms of the decree of 23 April 2004 ("standards and protocols"), applicants for marketing authorization, when compiling their dossier, should take into consideration the guidelines published by the European Commission and by the European Medicines Agency (EMA).

Accordingly, in conformity with the European note for guidance 'GUIDELINE ON ACTIVE SUBSTANCE MASTER FILE PROCEDURE' CHMP/QWP/227/02 Rev 3/ Corr. – adopted on 21 June 2012 (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/07/WC500129994.pdf)

it is recommended that any confidential file for the active substance (or the "European Active Substance Master File (ASMF)") submitted to ANSM obeys the format of the relevant parts

- Module1 including
  - Part 1.0: Submission Letter and Administrative Details, Letter(s) of Access , List of changes (between 2 versions of ASMF, if relevant),
  - Part 1.2: ASMF Application Forms
  - Part 1.4 Information concerning the experts containing a summary of the curriculum vitae, dated and signed by the expert who drafted module 2 of the CTD,
- Module 2- part 2.3.S – Active substance Quality Overall Summary,
- Module 3 –part 3.2.S - Active substance Documentation

of the Common Technical Document (or CTD) (see EU CTD : http://ec.europa.eu/health/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf)

I – Which type of documents should be submitted?

		Initial submission of ASMF	Update or Variation of ASMF	Response to questions	Administrative change (Change of ASMF Holder- Change of Name and/or Address of ASMF Holder/ Active Substance Manufacturer)	Withdrawal of ASMF
Module 1	Submission Letter includ. Administrative Details[1]	+	+	+	+	
	Letter(s) of Access[2]	+	+			+ Withdrawal Access Letter[3]
	List of changes[1]		+			
	Copy of Deficiency Letter			+		
	Copy of certificate of Suitability					+ (if relevant)
	ASMF Application Form[4]	+	+	+	+	+
	Information concerning the expert(s)[5]					
Module 2[6]	Applicants Part	+	+ (if updated)			
	Restricted Part	+	+ (if updated)			
Module 3[7]	Applicants Part	+	+ (if updated)	+ (if relevant)		
	Restricted Part	+	+ (if updated)	+ (if relevant)		

[1] = the template of Cover Letter is in the Annex 3 of 'GUIDELINE ON ACTIVE SUBSTANCE MASTER FILE PROCEDURE' CHMP/QWP/227/02 Rev 3/ Corr'

[2] the template of Letter of Access is in the Annex 2 of 'GUIDELINE ON ACTIVE SUBSTANCE MASTER FILE PROCEDURE' CHMP/QWP/227/02 Rev 3/ Corr'

[3] the template of Withdrawal of Access Letter is in the Annex 4 of 'GUIDELINE ON ACTIVE SUBSTANCE MASTER FILE PROCEDURE' CHMP/QWP/227/02 Rev 3/ Corr'

[4] = a tabular comparison between the old and the new contents of the "ASMF",

[5] one copy of the application form of the "ASMF" file including the relevant annexes should be provided; this form is available for downloading at the following link:
http://www.ansm.sante.fr/Activites/Autorisations-de-mise-sur-le-marche/Substances-actives-a-usage-pharmaceutique-Active-Substance-Master-File

(3) = a copy of part 1.4 of CTD module 1 containing a summary of the curriculum vitae, dated and signed by the expert who drafted module 2 of the CTD.

(6) = one copy of part 2.3.S of CTD module 2 (or the Quality Overall Summary) distinguishing between the open part (Applicants Part) and the closed part (Restricted Part) in two separate documents.

(7) = one copy of part 3.2.S of CTD module 3 distinguishing between the open part (Applicants Part) and the closed part (Restricted Part) in two separate documents.

II- Which format of documents should be submitted?

The eCTD format is mandatory.

The implementation of eCTD to ASMF follows the European note for guidance 'PRACTICAL GUIDELINES ON THE USE OF THE eCTD FORMAT FOR ASMFs FOR ACTIVE SUBSTANCE MASTER FILE HOLDERS AND MARKETING AUTHORISATION HOLDERS' EMA/43526/2010 v 1.0 (http://esubmission.ema.europa.eu/eASMF/index.htm)

A copy of Ansm's ASMF Application Form (PDFtext or WORD format) should be included in Module 1 of the ASMF.

III-When and where should the documents be submitted?

All documents relative to an ASMF to be sent only via CESP and at least one month before the submission of Marketing Authorization Application or Marketing Authorization Variation

All information regarding ASMF submission to ANSM via CESP is available in the "Notice to ASMF Holders for Electronic Submission of ASMF to ANSM via CESP" **(mettre lien hypertexte pour la notice)**

IV- How to obtain additional information?

Any request should be sent to the following Internet address: DMF-ASMF@ansm.sante.fr