



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Timelines for the establishment of a European Union herbal monograph and/or a European Union list entry

Final

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Adoption by HMPC	20 September 2005
Revision 2 adopted by HMPC	15 July 2010

¹ Changed 'Community' to 'European Union'



Timelines for the establishment of a European Union herbal monograph and/or a European Union list entry

From drafting to release for public consultation

Rapporteur appointment by HMPC Peer-reviewer appointment by HMPC if possible Call for submission of scientific data (HMPC meeting report and Agency website)	HMPC meeting
Start of assessment procedure, including - market overview - comprehensive literature search - purchase of bibliographic references	6-12 months
Rapporteur presents draft monograph and/or list entry with supporting assessment report (AR) and list of references	MLWP meeting
Discussions during MLWP meetings (subsequent revision by Rapporteur of draft documents)	1 - 3 MLWP meetings
Early peer-review on a voluntary basis and if required	2 months
Adoption by HMPC of draft monograph and/or list entry with supporting AR and list of references for release for 3-month public consultation	HMPC meeting
Public consultation	3 months

From public consultation to finalisation

Rapporteur presents revised draft monograph and/or list entry with supporting AR and list of references together with overview ² of comments	MLWP meeting (End of consultation period + 1 - 2 months)
Discussions during MLWP meetings (subsequent revision by Rapporteur of draft documents)	1 - 2 MLWP meetings
Peer-review of the set of documents	2 months
Adoption by HMPC	HMPC meeting

² Overview, prepared by Rapporteur, of comments received during the public consultation period with proposed outcome for each comment (agree with comments or reject with justification)

From finalisation to publication

Quality check (editorial, linguistic) of documents For European Union herbal monographs	2 months
Publication on Agency website HMPC opinion on monograph European Union herbal monograph AR List of references Overview of comments	
Additional steps for European Union list entries	
Translation of list entry in all EU official languages (involving CdT3, QRD4 and HMPC)	1 - 2 months
Transmission to European Commission HMPC opinion on list entry European Union list entry (in all EU official languages) AR and list of references	
Publication on Agency website of link to European Commission page where to access Commission Decision	

Post-publication

Preparation of HMPC AR Summary for the public (ARSP)	
Adoption by HMPC	
Translation of ARSP in all EU official languages (involving CdT and HMPC)	

³ Translation Centre for the bodies of the European Union

⁴ Agency Working Group on the Quality Review of Documents