



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2014
EMA/HMPC/119889/2005 Rev.1 *Corr.*¹
Committee on Herbal Medicinal Products (HMPC)

Template for submission of a request for scientific support and advice on a traditional herbal medicinal product

Final

Adoption by HMPC	20 September 2005
Revision 1 adopted by HMPC	12 July 2011
Adopted by HMPC	January 2012

This request form should be read in conjunction with:

- the 'Guidance for companies seeking scientific support and advice on traditional herbal medicinal products' (EMA/HMPC/127670/2011)
- Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures (EMA/MB/757388/2010 or latest amendments).

¹ Change of address



Request for scientific support and advice on a traditional herbal medicinal product

1. Applicant		
Name of Company/Contact point Name of Organisation		
Contact person/telephone/e-mail		
2. Traditional herbal medicinal product		
Name of the product		
Qualitative/Quantitative composition		
Proposed indication(s) If possible, please provide a SmPC.		
3. Regulatory status		
Information on the current status of the herbal medicinal product in the EU		
Information on the current status of the herbal medicinal product outside the EU		
4. Any additional information concerning the request/product		
5. Documentation to be annexed to the briefing document		
Please specify the documentation that will be annexed to the briefing document	<ul style="list-style-type: none"> - tabulated overviews - expert report - HMPC monograph - HMPC guideline - published data - unpublished data - pharmacopoeia monograph - other 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Please specify:	

6. Specific questions to be addressed by HMPC

Indicate the extent of the request:

- Single area request
 Multiple areas request

For the fees, please consult the EMA fees implementation rules.

Quality:

- 1.
- 2.
- 3.

Safety:

- 1.
- 2.
- 3.

Long-standing use and experience:

- 1.
- 2.
- 3.

Signed and dated:

The request should be sent to: hmpc.secretariat@ema.europa.eu or by post to:
EMA, HMPC secretariat, Unit Patient Health Protection
30 Churchill Place,
Canary Wharf
UK-London E14 5EU