C B G
M E B

Request for timeslot for national Marketing Authorisation Application for herbal medicinal product for human use

Proposed Product Name:	
Pharmaceutical Form(s):	
Strength(s):	
Active substance(s):	
ATC code:	
Proposed indication(s):	

Legal basis of application:

☐ Art. 8(3) ☐ Art. 10a ☐ Art. 16a

Application based on a EU herbal monograph:	☐ Yes ☐ No
Line extension application: Indicate product name and RVG number of the existing authorisation:	☐ Yes ☐ No
Duplicate/multiple applications will be submitted: Indicate the number of duplicates:	☐ Yes ☐ No

Name(s) and address(es) of the manufacturer(s) of active substance:	Has a Ph.Eur. Certificate of suitability (CEP) been issued for the active substance and/or will an Active Substance Master File (ASMF) be used?
1)	☐ CEP ☐ ASMF ☐ N/A If ASMF, will ASMF worksharing be used? ☐ Yes ☐ No EU ASMF number, if already allocated:
2)	☐ CEP ☐ ASMF ☐ N/A If ASMF, will ASMF worksharing be used? ☐ Yes ☐ No EU ASMF number, if already allocated:
3)	☐ CEP ☐ ASMF ☐ N/A If ASMF, will ASMF worksharing be used? ☐ Yes ☐ No

College ter Beoordeling van Geneesmiddelen
Graadt van Roggenweg 500 | 3531 AH Utrecht
POSTADRES Postbus 8275 | 3503 RG Utrecht
088 224 80 00 | www.cbg-meb.nl

Medicines Evaluation Board
Graadt van Roggenweg 500 | 3531 AH Utrecht | The Netherlands
CORRESPONDENCE ADDRESS P.O. Box 8275 | 3503 RG Utrecht | The Netherlands
+31 (0)88 224 80 00 | www.cbg-meb.nl

Request for timeslot for national Marketing Authorisation Application for herbal medicinal product for human use

	EU ASMF number, if already allocated:
Name(s) and address(es) of the manufacturer(s) of finished product:	Does the manufacturer of the finished product have an EU GMP certificate?
1)	☐ Yes ☐ No
2)	☐ Yes ☐ No
3)	☐ Yes ☐ No

Applicant's preferred submission date (month/year):	
Scientific advice received: ☐ Yes ☐ No If yes, provide details (from which MS, scope and outcome):	
Applicant:	
Authorised contact person:	
Address:	
Phone:	
E-mail address:	
Date:	