

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

Proposed Product Name:	
Pharmaceutical Form(s):	
Active substance(s):	
ATC code:	
Proposed indication(s):	
Legal basis of application: <input type="checkbox"/> Art. 14 <input type="checkbox"/> Art. 16(1) <input type="checkbox"/> Art. 16(2)	
Duplicate/multiple applications will be submitted: <input type="checkbox"/> Yes <input type="checkbox"/> No Indicate the number of duplicates:	
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)	<input type="checkbox"/> CEP <input type="checkbox"/> ASMF <input type="checkbox"/> N/A
2)	<input type="checkbox"/> CEP <input type="checkbox"/> ASMF <input type="checkbox"/> N/A
3)	<input type="checkbox"/> CEP <input type="checkbox"/> ASMF <input type="checkbox"/> N/A
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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Applicant's preferred submission date (month/year):	
Scientific advice received: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details (from which MS, scope and outcome):	
Applicant:	
Authorised contact person:	
Address:	
Phone:	
E-mail address:	
Date:	