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
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Request for timeslot for national Marketing Authorisation Application for 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. 10(1) ☐ Art. 10(3) ☐ Art. 10(4) ☐ Art. 10a

☐ Art. 10b ☐ Art. 10c

Line extension application: ☐ Yes ☐ No
Indicate product name and RVG number of the existing authorisation:

Duplicate/multiple applications will be submitted: ☐ Yes ☐ No
Indicate the number of duplicates:

For applications under Art. 10(1), Art.10(3) and Art. 10(4)

Reference medicinal product (RefMP) authorised for not less than 8 years in the EEA:

Product name, strength, pharmaceutical form:

Marketing authorisation holder:

First authorisation date (yyyy-mm-dd):

In case of CAP RefMP, notification date (yyyy-mm-dd):

Member State (EEA)/Union:

RefMP for the Netherlands:

Use of European Reference Product (ERP): ☐ Yes ☐ No

Product name, strength, pharmaceutical form:

Marketing authorisation holder:

In case of use of ERP, is the product information harmonised? ☐ Yes ☐ No

For bioequivalence study, name and address of site:

Member State (EEA)/Union:

For Art. 10(3), indicate difference(s) compared to RefMP:

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?

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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 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:	