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 a NL=RMS MRP Marketing Authorisation Application for medicinal product for human use

Product Name:	
RVG number(s):	
Pharmaceutical Form(s):	
Strength(s):	
Active substance(s):	
ATC code:	
Indication(s):	

Legal basis:

☐ Art. 8(3) ☐ Art. 10(1) ☐ Art. 10(3) ☐ Art. 10(4) ☐ Art. 10a
☐ Art. 10b ☐ Art. 10c

Intended CMS(s):

☐ AT	☐ BE	☐ BG	☐ CY	☐ CZ
☐ DE	☐ DK	☐ EE	☐ EL	☐ ES
☐ FI	☐ FR	☐ HR	☐ HU	☐ IE
☐ IS	☐ IT	☐ LI	☐ LT	☐ LU
☐ LV	☐ MT	☐ NO	☐ PL	☐ PT
☐ RO	☐ SE	☐ SI	☐ SK	☐ XI

Use of European Reference Product (ERP) in any of the CMSs ☐ Yes ☐ No
If yes, please indicate which product is used as ERP for which CMS(s):

It is confirmed that the dossier complies with the current legislation/EU guidelines*: ☐ 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:	

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E-mail address:	
Date:	

*To avoid a delay the MAH must ensure that the dossier has been updated in line with current legislation/EU guidelines. If during preparation of the MRP AR it becomes apparent that the dossier is not up-to-date the procedure will be put on-hold.