

**Request for BE as RMS in a decentralised procedure,
medicinal products for veterinary use**

***This form should be sent to*** ***pre.authorisation.v@fagg.be***

|  |
| --- |
| Type of the veterinary medicinal product: [ ] Chemical [ ] Immunological  |
| Intended CMSs:  |       |
| Active Substance(s):  |       |
| ATC Code:  |       |
| Target specie(s): ............................................................... |  |
| Proposed Product Name | Pharmaceutical Form(s) | Strength(s) |
|       |       |       |
|       |       |       |
|       |       |       |
| Legal basis of application: |
|  Art.12(3) |  Art.13(1) |  Art.13(3) |  Art.13(4) |  Art.13a  |
|  Art.13b |  Art.13c |  Art. 13d |  ExtensionNature of extension: |  |
| This is a duplicate of an ongoing or finalised procedure:  |       |
| Indicate the procedure number of the original dossier:  |       |
| Indicate the number of duplicates:  |       |
| **For generics only** |
| ***Reference medicinal product authorised for not less than 8/10 years in the EEA*** |
| Product name, strength, pharmaceutical form:  |       |
| Target species: |  |
| Marketing authorisation holder:  |       |
| First authorisation date *(yyyy-mm-dd):*  |       |
| Member State (EEA)/Community:  |       |
| RMS: [ ]  Belgium [ ]  Other: |  |
| ***Reference medicinal product in the proposed RMS (BE)*** |
| Product name, strength, pharmaceutical form:  |       |
| Marketing authorisation holder:  |       |
| First authorisation date *(yyyy-mm-dd):*  |       |
| Legal basis: ………………………………………………….. |  |
| Reference medicinal product is/has been authorised in all proposed CMSs | [ ]  Yes |  [ ]  NoWhich one: |   |
| Bioequivalence demonstration: [ ]  Bioavailability studies [ ]  Exemption [ ]  N/A      |
| Name(s) and address(es) of the manufacturer(s) of active substance:  |       |
| Will a Ph.Eur. Certificate of suitability (CEP) be used for the active substance and/or will an Active Substance Master File (ASMF) be used? |  [ ]  CEP |  [ ]  ASMF |  [ ]  N/A |
| Applicant´s preferred submission date:  |            |
| Proposed D0 date: ………………………………………….. |       |
| If other Member States have agreed to act as Reference Member State, please indicate the reasons for requesting BE to act as Reference Member State: |
| If Member States have refused to act as Reference Member State, please indicate the reasons: |
| This request has already been discussed with BE agency: [ ]  No [ ]  Yes* Details (date/email):
 |
| Other information:  |           |
| Applicant Name: |       |
| Authorised contact person:  |       |
| Address:  |       |
| Phone:  |       |
| E-mail address:  |       |