

**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***](mailto: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) | | | |
|  | | |  | | | |  | | | |
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|  | | |  | | | |  | | | |
| Legal basis of application: | | | | | | | | | | |
| Art.12(3) | Art.13(1) | | | Art.13(3) | | Art.13(4) | | | Art.13a | |
| Art.13b | Art.13c | | | Art. 13d | | Extension  Nature 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 | | | No  Which 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: | |  | | | | | | | | |