# Request for <EU MS> to act as RMS in a mutual recognition (MRP) or decentralised procedure (DCP)

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| **Type of veterinary medicinal product**[ ]  Pharmaceutical [ ]  Immunological [ ]  Homeopathic | [ ]  Product for MUMS |
| **Type of application**: [ ]  MRP [ ]  RUP [ ]  DCP |
| **Applicant’s Name**:      Address:      Authorised contact person:      E-Mail Address:      Phone:       |
| **Intended CMS:**      Definite list: [ ]  Yes [ ]  No |
| **In case of MRP**Product name:      Authorisation number:      **In case of RUP**Current EU procedure number:       |
| **Active substance(s):**       |
| **ATCvet code:**       |
| **Target species (as written in the proposed SPC):**       |
| **Indication(s) (as written in the proposed SPC):**       |
| **In case of DCP:****Proposed product name(s):** | **Pharmaceutical form(s):** | **Strength(s):** |
|       |       |       |
|       |       |       |
|       |       |       |
| **Legal basis of application:**  |
| [ ]  Art. 12(3) | [ ]  Art. 13c | [ ]  Art. 13(3) | Please choose from the list below |
| [ ]  Art. 13a | [ ]  Art. 13d | [ ]  Art. 13(4) |  |
| [ ]  Art. 13b | [ ]  Art. 13(1) |  |  |
| This is an **extension** application?  | [ ]  Yes [ ]  No |
| Identify the existing product(s) to which the extension relates       |
| Indicate the nature of the change(s) that result in this being considered an extension application: Please choose from the list belowComments:       |
| This is a **duplicate** of an ongoing or finalised procedure: | [ ]  Yes [ ]  No |
| Original procedure finalised: | [ ]  Yes [ ]  No |
| Complete the procedure number of the original dossier: |       |
| List the number of duplicates: |       |
| **For generics and hybrids only** |
| **Reference veterinary medicinal product authorised for not less than 6/8/10 years in the EEA**  |
| Product name, strength, pharmaceutical form: |       |
| Target species: |       |
| Marketing authorisation holder: |       |
| Date of first authorisation: |       |
| In Member State (EEA/Community): |       |

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| **Reference veterinary medicinal product in the proposed RMS** |
| Product name, strength, pharmaceutical form: |       |
| Marketing authorisation holder: |       |
| Marketing authorisation number: |       |
| Reference veterinary medicinal product has been authorised in all proposed CMSs | [ ]  Yes [ ]  No /Please specify:      [ ]  N/A |
| Demonstration of bioequivalence: [ ]  Bioavailability studies [ ]  Exemption [ ]  N/A  |
| For bioequivalence study(-ies), when performed/CRO/ used reference medicinal product: |       |
| The study(-ies) meet(s) the current guidelines: | [ ]  Yes [ ]  No If no explain       |
| Difference in the composition to the reference medicinal product (e.g. overage, excipients)? |       |
| Please provide a summary table detailing the differences between the various SPC authorised in the MS (see annex) |
| **Manufacturer(s) of Active substance(s)** |
| Name(s) and address(es) of the manufacturer(s) of the active substance(s): |       |
| Has a Ph.Eur. certificate of suitability (CEP) been issued for the active substance? And/orWill an Active Substance Master File (ASMF) be used? If relevant, EU ASMF number : | [ ]  Yes [ ]  No[ ]  Yes [ ]  No      |
| **Applicant’s preferred submission date**:      Proposed D0 date:       |
| **Other relevant information**:      |
| I hereby confirm that the dossier complies with the current legislation/EU guideline:[ ]  Yes [ ]  No |
| Is there any other regulatory procedure ongoing: [ ]  Yes [ ]  NoIf yes explain:      Is there any other regulatory procedure foreseen until the intended MRP/RUP submission date: [ ]  Yes [ ]  NoIf yes explain:       |
| I hereby declare that no other Member State has agreed to act as RMS for the above mentioned product Yes [ ]  No [ ]  |
| A request to act as RMS is pending in another MS: Yes [ ]  No [ ]  |
| This request has already been discussed with the national competent authority of the requested RMS: Yes [ ]  No [ ] If yes: Details (date/email/visit/reference number):       |

Annex: Summary table detailing the differences between the various SPC authorised in the MS

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| **Reference product:**  |
| Presentations in Member States |
| MS | Product Name & Pharmaceuticalform(s) | Strength(s) | Indication(s) | Target species | Routes of administration | Dose and duration of treatment | Withdrawal period(s) if appropriate | Contra-indications | Environmental warnings |
| AT |  |  |  |  |  |  |  |  |  |
| BE |  |  |  |  |  |  |  |  |  |
| BG |  |  |  |  |  |  |  |  |  |
| CY |  |  |  |  |  |  |  |  |  |
| CZ |  |  |  |  |  |  |  |  |  |
| DE |  |  |  |  |  |  |  |  |  |
| DK |  |  |  |  |  |  |  |  |  |
| EE |  |  |  |  |  |  |  |  |  |
| EL |  |  |  |  |  |  |  |  |  |
| ES |  |  |  |  |  |  |  |  |  |
| FR |  |  |  |  |  |  |  |  |  |
| FI |  |  |  |  |  |  |  |  |  |
| HR |  |  |  |  |  |  |  |  |  |
| HU |  |  |  |  |  |  |  |  |  |
| IE |  |  |  |  |  |  |  |  |  |
| IS |  |  |  |  |  |  |  |  |  |
| IT |  |  |  |  |  |  |  |  |  |
| LI |  |  |  |  |  |  |  |  |  |
| LT |  |  |  |  |  |  |  |  |  |
| LU |  |  |  |  |  |  |  |  |  |
| LV |  |  |  |  |  |  |  |  |  |
| MT |  |  |  |  |  |  |  |  |  |
| NL |  |  |  |  |  |  |  |  |  |
| NO |  |  |  |  |  |  |  |  |  |
| PL |  |  |  |  |  |  |  |  |  |
| PT |  |  |  |  |  |  |  |  |  |
| RO |  |  |  |  |  |  |  |  |  |
| SE |  |  |  |  |  |  |  |  |  |
| SI |  |  |  |  |  |  |  |  |  |
| SK |  |  |  |  |  |  |  |  |  |
| UK (NI) |  |  |  |  |  |  |  |  |  |