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

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| **Type of veterinary medicinal product**  Chemical (other than biological)  Biological other than immunological  Immunological  Homeopathic (acc. to Art. 85 (2) of Reg. (EU) 2019/6)  Other (please specify) | | | | |
| **Type of application**:  MRP  SRP  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 SRP**  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):** |
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| **Legal basis of application:** | | | | |
| Art. 8 (Full dossier) | Art. 18 (Generic) | | | |
| Art. 19 (Hybrid) | Please choose from the list below | | | |
| Art. 20 (Combination product) | Art. 21 Informed consent | | | |
| Art. 22 (Well-established use) | Art. 23 (Limited markets) | | | |
| Art. 25 (Exceptional circumstances) | | | | |
| This application concerns a change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species to an existing marketing authorisation? | | | Yes  No | |
| Identify the existing product(s) to which the change relates | | | | |
| Indicate the nature of the change(s) that result in this being considered a change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species to an existing marketing authorisation:  Please choose from the list below  Comments: | | | | |
| 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 8 years in the EEA** | | | | |
| Product name, strength, pharmaceutical form: | |  | | |
| Target species: | |  | | |
| Marketing authorisation holder: | |  | | |
| Date of first authorisation: | |  | | |
| In Member State (EEA/Community): | |  | | |
| Is there any additional protection period? If yes, please clarify: | |  | | |

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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., preservative, colouring matter, other 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/or  Will 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  No  If yes explain:  Is there any other regulatory procedure foreseen until the intended MRP/SRP submission date:  Yes  No  If 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 & Pharmaceutical  form(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 |  |  |  |  |  |  |  |  |  |
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| HR |  |  |  |  |  |  |  |  |  |
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| IS |  |  |  |  |  |  |  |  |  |
| IT |  |  |  |  |  |  |  |  |  |
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| LT |  |  |  |  |  |  |  |  |  |
| LU |  |  |  |  |  |  |  |  |  |
| LV |  |  |  |  |  |  |  |  |  |
| MT |  |  |  |  |  |  |  |  |  |
| NL |  |  |  |  |  |  |  |  |  |
| NO |  |  |  |  |  |  |  |  |  |
| PL |  |  |  |  |  |  |  |  |  |
| PT |  |  |  |  |  |  |  |  |  |
| RO |  |  |  |  |  |  |  |  |  |
| SE |  |  |  |  |  |  |  |  |  |
| SI |  |  |  |  |  |  |  |  |  |
| SK |  |  |  |  |  |  |  |  |  |
| UK (NI) |  |  |  |  |  |  |  |  |  |