****Request for FR as RMS in a decentralised procedure**

**for veterinary medicinal products**

*This form should be sent to* *enreg@anses.fr*

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|  Type of veterinary medicinal product : [ ] Chemical [ ] Immunological [ ] Homeopathic |  [ ] Product for MUMS  |
| Applicant Name:      Authorised contact person:      E-mail address:       Phone:        |  Proposed Product Name:       Pharmaceutical Form(s):       Active Substance(s):       Strength(s):       Target specie(s) :       |
| Legal basis of application:

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| [ ] Art.12(3) 🡺  |
| [ ] Art.13(1) – Generic application [ ] Art.13(3) – Hybrid application [ ] Art.13(4) - Similar biological application *Reference product authorised for more than 8/10 years in the EEA:* [ ]  Yes [ ]  No. Product name, strength, pharmaceutical form:      . Target species:       . Marketing authorisation holder:      . First authorisation date:      . RMS : [ ] France [ ] Other :      🡺 *Reference product information in France:*  . Product name, strength, pharmaceutical form:       . Marketing authorisation holder:       . First authorisation date:      Bioequivalence demonstration : [ ] Bioavailability studies [ ] Exemption [ ] N/A |
| [ ]  Art.13a – Well established veterinary use |
| [ ]  Art.13b – Fixed combination |
| [ ]  Art.13c – Informed consent application |
| [ ]  EXTENSIONNature of extension :  |

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| Duplicate application: [ ] No [ ] Yes 🡺 Original procedure finalized: [ ] No [ ] Yes Procedure number of the original dossier:       |
| List of proposed CMS: Definitive list : [ ] No [ ] Yes[ ] AT [ ] BE [ ] BG [ ] CY [ ] CZ [ ] DE [ ] DK [ ] EE [ ] EL [ ] ES [ ] FI [ ] HR [ ] HU [ ] IE [ ] IS [ ] IT [ ] LI [ ] LT [ ] LU [ ] LV [ ] MT [ ] NL [ ] NO [ ] PL [ ] PT [ ] RO [ ] SE [ ] SI [ ] SK [ ] UK |
| Reference product is/has been authorised in all proposed CMS:  [ ] Yes [ ] No [ ] N/A Which one :       |
| Proposed Submission date (DD/MM/YYYY):   /  /     Proposed D0 date (DD/MM/YYYY):  /  /      |
| This request has already been discussed with ANSES-ANMV(FR agency): [ ] No [ ] Yes 🡺 Details (date/email/visit) :       |
| Other information:       |

*A response on the acceptability of the request by the ANSES-ANMV will be provided within* ***14 days*** *after the receipt of the request form.*

**ANSES-ANMV response**

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| FR accepts to act as RMS for this application : [ ] Yes [ ] No 🡺 comments:     Procedure Number : FR/V/     Contact point before D0 and after D210 of the procedure : enreg@anses.fr Contact point / Rapporteur during the assessment phase of the procedure:      Timetable agreed : D-14:       D0 :       Date :       |

**Applicant comment**

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| Acceptance of the proposed timetable : [ ] Yes [ ] NoNew proposed timetable : D-14:       D0 :        Date :       |

**ANSES-ANMV response**

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| Acceptance of the proposed timetable : [ ] Yes [ ] NoNew proposed timetable : D-14:       D0 :        Date :       |