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

**for veterinary medicinal products**

*This form should be sent to* [*enreg@anses.fr*](mailto: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:   |  | | --- | | 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 | | EXTENSION  Nature of extension : | | | |
| 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](mailto: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 No  New proposed timetable : D-14:       D0 :  Date : |

**ANSES-ANMV response**

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| Acceptance of the proposed timetable : Yes No  New proposed timetable : D-14:       D0 :  Date : |