**Presubmission request form to the European Medicines Agency for veterinary medicinal product in accordance with
Regulation (EU) 2019/6**

Complete for all types of Requests:

Scope of Request: Choose from the list

Date of Request: Click or tap to enter a date.

EMA Product Number:

(Provide if already allocated)

Intended submission date of Marketing Authorisation Application after 28 January 2022: Click or tap to enter a date.

For eligibility for the centralised procedure requests (according to Regulation (EU) 2019/6)

Proposed basis for eligibility: Choose an item.

Additional information on the request:

**Information on the Applicant:**

Complete for all types of request:

**Applicant:**

|  |  |
| --- | --- |
| Company Name: |  |
| Address:  |  |
| City: |  |
| Post Code: |  |
| Country: |  |

SME Status: Yes [ ]  No [ ]

Expiry date of SME Status:

SME Number:

**Contact Person (Section is mandatory):**

|  |  |
| --- | --- |
| Title: |  |
| Last name: |  |
| First Name: |  |
| Company Name: |  |
| Address: |  |
| City: |  |
| Post Code: |  |
| Country: |  |
| Telephone: |  |
| Email: |  |

**Information on the product**

Product Name:

Product (invented) name status: Choose an item.

Non-prescription product (OTC): Yes [ ]  No [ ]

Vaccine Yes [ ]  No [ ]

Vaccine common name:

Additional information on strength(s) with units, pharmaceutical form(s) and route of administrations(s):

**Active substance(s)[[1]](#footnote-1):**

|  |  |
| --- | --- |
| INN |  |
| Common Name: |  |
| Chemical name: |  |
| Company code: |  |
| Substance Type[[2]](#footnote-2): | Choose an item. |
| Method of Manufacture[[3]](#footnote-3): | Choose an item. |
| Biological Source[[4]](#footnote-4): |  |
| Tissues: |  |

*Add active substance- if required copy the table and complete for another active substance*

Contains GMO: Yes [ ]  No [ ]

Nanotechnology: Yes [ ]  No [ ]

ATCvet Classification[[5]](#footnote-5):

Therapeutic indication[[6]](#footnote-6):

Other relevant information on the product:

**Information on future Marketing Authorisation Application(s) (MAA) for a veterinary medicinal product:**

*For eligibility to the centralised procedure request and Intent to submit a Marketing Authorisation Application: The application will be submitted in accordance with the following Article in Regulation (EU) 2019/6*

Legal basis[[7]](#footnote-7): Choose an item.

If Application under Article 23 of Regulation (EU) 2019/6:

Are the conditions as referred under Article 23 (a) and (b) positively confirmed by CVMP Yes [ ]  No [ ]

If yes, indicate reference of evaluation procedure and date:

If legal basis is Article 18, Article 19, Article 21 of Regulation (EU) 2019/6, or if it is a multiple (duplicate) application:

Name of proposed reference medicinal product[[8]](#footnote-8):

Is it centrally authorised product? Yes [ ]  No [ ]

If “No”, information on reference product:

Strength(s), pharmaceutical form(s):

Marketing Authorisation Holder:

Authorisation Date (dd-mm-yyyy):

Member State (EEA)[[9]](#footnote-9):

Target Species: (Provide all target species)

Additional relevant information on the future MAA:

# Supplementary information for veterinary medicinal products:

Target Species: (Provide all target species)

Status of MRLApplication: Choose an item.

CVMP scientific advice: Yes [ ]  No [ ]

If yes, provide CVMP scientific advice reference number:

1. For INN, Common name, Chemical name and company code, provide all available names [↑](#footnote-ref-1)
2. Select a relevant term at the lowest possible level [↑](#footnote-ref-2)
3. Select a relevant term at the lowest possible level [↑](#footnote-ref-3)
4. Select a relevant term at the lowest possible level [↑](#footnote-ref-4)
5. Complete the ATCvet code to the lowest applicable level even if an ATCvet code has not been approved [↑](#footnote-ref-5)
6. As included in the Summary of Product Characteristics (SPC), when available [↑](#footnote-ref-6)
7. If Application under Article 8 of Regulation (EU) 2019/6 – Full application – New/known active substance in relation to structure and properties, not in relation to cut-off dates for eligibility to the centralised procedure. For VMPs other than biologicals, the ‘CVMP Reflection paper on new active substance (NAS) status of chemical substances for VMPs ([EMA/CVMP/QWP/3629/2016](https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-chemical-structure-properties-criteria-be-considered-evaluation-new-active_en.pdf))’ is available for reference. [↑](#footnote-ref-7)
8. This refers to all centrally authorised products, MRP, DCP and Nationally authorised products. The term “reference product” applies to multiple (duplicate) applications by analogy [↑](#footnote-ref-8)
9. 9 For marketing authorisations via MRP or DCP, provide the Reference Member State [↑](#footnote-ref-9)