<Date>

<Reference>

Vet Applications

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

**Subject: Letter of intent for the submission of a worksharing procedure to the European Medicines Agency according to Article 65 of Regulation (EU) 2019/6**

**Worksharing Applicant details:**

|  |  |  |
| --- | --- | --- |
| Name: |  |  |
|  |  |  |
| **Address:** |  |  |
|  |  |  |
| **Contact person details:** (i.e. name, address, e-mail address, phone number) |  |  |

**Application details**:

This letter of intent for the submission of a variation requiring assessment <group of variations requiring assessment> following a worksharing procedure according to Article 65 of Regulation (EU) 2019/6, concerns the following veterinary medicinal products:

|  |  |  |  |
| --- | --- | --- | --- |
| **Veterinary Medicinal product** | **Active substance(s)** | **CVMP Rapp.  / RMS** | **EU/MRP number** |
| <(invented)Name> | <INN/common name> |  |  |
| <(invented)Name> | <INN/common name> |  |  |
| <(invented)Name in RMS> | <INN/common name> |  |  |
| <(invented)Name in RMS> | <INN/common name> |  |  |

The following variation(s) are intended to be part of the worksharing procedure:

| **Variation scope number[[1]](#footnote-1)** | **Title of the variation1** | **Recommended timetable (R, S, E):** |
| --- | --- | --- |
| <Number> | <Title of variation as in the classification guidance> | <Recommended timetable> |
| <Number> | <Title of variation as in the classification guidance> | < Recommended timetable > |
| <Number> | <Title of variation as in the classification guidance> | < Recommended timetable > |

|  |  |
| --- | --- |
| Justification for worksharing: | *[Include here (or as an Annex 1) a more detailed ‘scope’ description and background of the proposed change(s).*  *The justification for worksharing should be provided in a separate paragraph, addressing its suitability and including the applicant’s view on the absence or limited need for assessment of product specific impact.]*    <As provided in Annex 1> |

|  |  |
| --- | --- |
| Justification for grouping**:** | *[If the worksharing consists of a group of variations, please provide here (or as an Annex 2) a justification for the proposed grouping of the variations]*    <As provided in Annex 2> |

|  |  |
| --- | --- |
| Intended submission date**:** |  |

|  |  |
| --- | --- |
| Explanation that all MAs concerned belong to the same MA holder**:** | *[Explain here (or in Annex 3) how all MAs concerned are considered to belong to the ‘same marketing authorisation holder’]*    <As provided in Annex 3>  {Conclusion statement}  I hereby confirm that the marketing authorisations concerned by the worksharing procedure belong to the same marketing authorisation holder. |

<Signature>

<Contact person WS procedure>

<Title>

Please send this letter electronically to the European Medicines Agencyvia [*ServiceNow*](https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=24bc74171b576150bde8dac8b04bcb24) (Business Services → Veterinary Regulatory → Post-Authorisation - Vets → Intention to submit variations requiring assessment (Standard, Extended, worksharing) – Vets).

1. As per Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations [↑](#footnote-ref-1)