<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

<National Agency>

<Address>

<Address>

<Post code> <Town>

<Country>

**Subject: Submission of application dossier(s) for marketing authorisation of <Product Name(s) in the MS where the application is submitted> <Full procedure Number>.**

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a Pick one... procedure for which the details are as follows:

**Name of the medicinal product(s) (in the RMS):** Click or type here to insert text.

**Pharmaceutical product**  **Biological product (non-immunological)**

**Immunological** **product**

**Pharmaceutical form(s) and strength(s):** Click or type here to insert text.

**INN/active substance(s):** Click or type here to insert text.

**ATC Vet Code(s):** Click or type here to insert text.

**Target species**: Click or type here to insert text.

**EU Procedure number:** Click or type here to insert text.

**National Procedure number (if appropriate)**: Click or type here to insert text.

**Legal Basis of the Application(s)**: Click or type here to insert text.

When appropriate, please indicate: use of European Reference Medicinal Product  Yes  No

You will find enclosed the submission dossier as specified hereafter. The dossier is submitted under[[1]](#footnote-1):

1. Electronic submission:

* The dossier is submitted via CESP.
* We confirm that the electronic submission has been checked with this validation tool: <Name of checker>.

<Free text field – when appropriate and if important for the validation of the application(s) additional information can be provided e.g. location of Notes to Reviewers, National file number if provided before submission etc.>

We, <Applicant>, finally hereby certify that:

The dossiers submitted to the RMS and CMS(s) are fully identical.

All the translations attached to the application and all copies are exactly the same as the originals.

An originally signed (by the manufacturer of the active substance(s)) letter of access from the ASMF[[2]](#footnote-2) addressed to the relevant national competent authority has been provided (if appropriate).

The colour mock ups will be provided during the national phase, at the end of the procedure (if required).

The relevant fees have been or will be paid, respectively.

We, <Applicant>, confirm that the complete data set according to the legal basis of the application, has been submitted with the dossier.

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number>

<Email address>

<Email address for technical validation issues>

1. See the “Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product” (http://esubmission.ema.europa.eu/tiges/vetesub.htm). Moreover, all national competent authorities have their own requirements on electronic submission for new applications: see published tables on the CMDv website (<http://www.hma.eu/568.html>). [↑](#footnote-ref-1)
2. A template for the letter of access to ASMF is available on the EMA website: <https://www.ema.europa.eu/en/active-substance-master-file-procedure>

   [↑](#footnote-ref-2)