<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)