<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(s)>**

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a <Mutual Recognition><Decentralised> Procedure which details are as follows:

**Name of the medicinal product(s) (in the RMS):**

**Pharmaceutical form(s) and strength(s):**

**INN/active substance(s):**

**ATC Code(s):**

**Legal Basis of the Application(s)**:

*When appropriate, please indicate:*

- Use of European Reference Medicinal Product [ ]  Yes [ ]  No

- If the strength(s) of the Reference MP differs between RMS/CMS [ ]  Yes [ ]  No

- If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS [ ]  Yes [ ]  No

- If the indication(s) of the Reference MP differs between RMS/CMS [ ]  Yes [ ]  No

**Active Substance Master File (ASMF):**

An ASMF is used for this application: [ ]  Yes [ ]  No

- if yes: The ASMF is participating in the EU/ASMF worksharing procedure: [ ]  Yes [ ]  No

- if yes: EU/ASMF reference number: <EU/ASMF/XXXXX>\_\_\_\_\_\_\_\_\_\_\_

**You will find enclosed the submission dossier as specified hereafter:**

[ ]  eCTD Sequence number: <Four-digit number>

[ ]  We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

<- Multiple/duplicate applications are submitted.>**[[1]](#footnote-2)**

<- A transfer of ownership (MAH) for the medicinal product is to take place in the national step after finalisation of the procedure.>**[[2]](#footnote-3)**

<- The relevant fees have been paid.>

<- The Risk Management Plan in module 1.8.2 is similar to the one <submitted><approved> in the procedure(s) <Full procedure number(s).>

 <- We intend to apply multilingual packaging and the following clusters will apply: 3free text>

*< When appropriate, please indicate:*

 We intend to prepare EU full/reduced harmonised labelling text for a multilingual packaging.

 We intend to use EU full harmonised labelling text (no text reductions required) for a multilingual packaging. >

< - In Annex 5.19 we have provided three proposals for the invented name for assessment listed in order of preference, for the member states involved in each multilingual packaging cluster >

<- 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.>

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number>

<Email address>

<Email address for technical validation issues>

1. *When duplicates are not submitted simultaneously, a reference to the first application should be given.* [↑](#footnote-ref-2)
2. *Confirmation that transfer during that step is possible, to be obtained from MSs concerned.*

*3 Add here which ‘clusters’ of MSs will be grouped on each multilingual pack e.g. IE/NL/MT, IS/NO/EE, this does not preclude further clusters later on request.* [↑](#footnote-ref-3)