*December 2022*

*CMDh/096/2009, Rev.6*

<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

<National Agency>

<Address>

<Address>

<Post code> <Town>

<Country>

**Subject: Submission of Variation Application Dossier(s) for <Product Name(s) in the MS where the application(s) for variation is submitted> <Procedure Number(s)>**

Dear Sirs,

We are pleased to submit our Variation Application Dossier(s) for <Type IAIN / Type IA / Type IB unforeseen / Type IB foreseen / Type II > Procedure(s).

The application concerns <Single variation / Grouping of variations / Grouping of variations including an extension application / Worksharing>.

The 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):**

**National Marketing Authorisation Number(s):**

**Type of the Variation Application(s)**:

When appropriate, please indicate type of change (for Type IB and Type II variations only):

[ ]  Indication

[ ]  Paediatric Indication

[ ]  Safety

 [ ]  Following Urgent Safety Restriction

[ ]  Quality

[ ]  Annual variation for human influenza vaccines

[ ]  Other

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

The variation application concerns a new/updated ASMF.

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

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

eCTD Sequence number: < Four-digit number >

- The submission is checked with an up-to-date and state-of-the-art virus checker

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

<- The relevant fees have been paid.>

<The variation application affects the SmPC, labelling and/or package leaflet. Clean and tracked versions has been enclosed as word files in the working documents. All changes in the text, in comparison with the previously approved version of product information, has been marked with track-changes in the highlighted versions.>

<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 intend to apply multilingual packaging for the following new ‘clusters’ of member states:2*free text*>

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

Yours sincerely,

<Signature>

<Name>

<Title>

1. *When duplicates are submitted, a reference to the first application should be given*

*2Add here which ‘clusters’ of MS 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-1)