*June 2020*

*CMDh/096/2009, Rev.5*

<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 dispatch list is appended (to RMS only).

The dispatch list will be forwarded to the RMS as soon as the application has been submitted to all CMS.

<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)