*This template should be sent via email with the following header:*

***COVID-19, ECMP Step 3- Notification of implementation*** *procedure number (e.g. NL/H/nnnn/001)*

Applicant>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

<National Agency>

<Address>

<Address>

<Post code> <Town>

<Country>

**Subject: Notification of implementation for a Covid-19 emergency change management process (ECMP)**

Dear Sirs,

We wish to inform you of implementation of a change for the below referenced product(s) on this date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [add date of implementation] under the previously agreed ECMP.

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):**

**EU Procedure Number (*where applicable):***

**Involved CMS’s (*where applicable*)**

The application of ECMP has been agreed by the RMS with the following RMS reference details\*:

Reference number:\_\_\_\_\_\_\_\_\_\_\_\_ Date of acceptance:\_\_\_\_\_\_\_\_\_\_\_

*[\*Include any RMS reference numbers where advised in the ECMP acceptance email, and date of RMS acceptance].*

In support of this application the applicant has completed section 1 of this template outlining the relevant information in each section.

**Section 1 – Changes being implemented**

Under the proposed ECMP the applicant is implementing the following changes, as outlined in our previously submitted Step 1 template submitted, and has selected all options which apply.

Addition of a source for the following:

Starting materials

Reagents

Intermediates of active substance

Active substances\*

Other material as further described below

A summary description of changes including brief information on the source(s) proposed, including address, and the material(s) to be sourced have been provided below:

|  |
| --- |
|  |

*\*When a new manufacturing site for the API is notified the MAH should state the full name and address of this manufacturer and state the ASMF number and version when an ASMF is used or the CEP number in case the new manufacturer owns a CEP.*

Addition of a finished product manufacturing/control site for the following:

Manufacture of finished product or finished product intermediates

Primary Packaging

Secondary Packaging

Batch Release

Batch Control Testing

Other manufacturing operation as further described below

A summary description of changes including brief information on the site(s) proposed, including address, and the operations to be conducted have been provided below:

|  |
| --- |
|  |

The applicant has reviewed the information provided in the European Commission Notice to Stakeholders: Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the Covid-19 Pandemic and associated CMDh guidance (CMDh/418/2020), and understands that an agreed ECMP can cease to be valid in case one or more of the commitments provided are not fulfilled.

The relevant variations will be submitted no later than 6 months after the date of implementation above.

<Name and Signature of applicant>

<Date>

**Appendix A – Relevant product name and national marketing authorisation numbers.**

|  |  |
| --- | --- |
| **Member State** | **Product Name and Marketing authorisation number(s)** |
|  |  |
|  |  |
|  |  |
|  |  |