May 2020

CMDh/420/2020

<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

<National Agency>

<Address>

<Address>

<Post code> <Town>

<Country>

**Subject: Submission of an application for a Covid-19 exceptional change management process (ECMP)**

Dear Sirs,

We wish to submit an application for a Covid-19 ECMP for the below referenced product(s).

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*)**

Additionally, Appendix A has been completed where relevant, outlining the national marketing authorisation numbers in the member states.

In support of this application the applicant has completed sections 1, 2, and 3 of this template outlining the relevant information in each section.

**Section 1 – Information related to the medicinal product:**

The following information is being provided to support the proposed designation of the medicinal product(s) as a crucial medicine for the treatment of Covid-19 patients\*

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***\*Where applicable, information on prior discussions with MS and/or EMA related to availability can be included***

**Section 2 – Commitments provided in support of this application:**

The applicant provides the following commitments:

The applicant commits to ensuring that the quality of the finished product will not be compromised. The applicant will ensure new suppliers/sites abide by the quality standards applicable in the EU and, in particular, that the specifications (both for active substance(s) and finished product) in the marketing authorisation are respected. The applicant will also ensure that where required by EU legislation, that the manufacturing/control site used under the ECMP will have an EU GMP certificate or have been certified by the authorities of a country with whom the EU has concluded a mutual recognition agreement.

The applicant commits to notify the implementation of the changes made to the relevant competent authorities within 48 hours after the change is implemented by the MAH. A notification and the supporting summary description of changes should be submitted then for each supplier and/or manufacturing/control site that is implemented under the ECMP.

The applicant commits to submit the corresponding variation application to the competent authorities no later than within 6 months following the implementation of the change.

The applicant understands the limited scope of the ECMP and commits that no changes other than those outlined in section 3 below are intended under the ECMP.

**Section 3 – Changes proposed under the ECMP:**

Under the proposed ECMP the applicant proposes changes to the following, 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 and the material(s) to be sourced have been provided below:

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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 and the operations to be conducted have been provided below:

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| --- |
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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.

<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)** |
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