June 2020

<MAH>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

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

To whom it may concern:

We wish to notify an application of a COVID-19 ECMP for the below referenced product.

The details are as follows:

**Name of the medicinal product:**

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

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

**EMA Product Number*:***

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

*Note: the MAH may also provide as attachments additional information on the proposed changes (e.g. a summary description of changes for each supplier and/or manufacturing/control site that is implemented under the ECMP). A separate notification form is required for each change proposed.*

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

The following information is being provided on any previous confirmation from the EMA on designation of the medicinal product(s) as a crucial medicine for use in COVID-19 patients\*

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***\* MAHs may also include argumentation on why the medicines should be considered as crucial for use in COVID-19 patients***

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

The MAH provides the following commitments:

The MAH commits to ensuring that the quality of the finished product will not be compromised. The MAH 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 MAH 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 MAH commits to notify the implementation of the changes made to EMA 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 (unless provided already with this notification).

The MAH commits to submit the corresponding variation application to EMA no later than within 6 months following the implementation of the change.

The MAH understands the limited scope of the ECMP and commits that no changes other than those outlined in section 3 below will be implemented under the ECMP.

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

Under the proposed ECMP the MAH proposes changes to the following and has selected all options which apply.

Addition of a supplier/ manufacturer 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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| --- |
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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 MAH has reviewed the information provided in the European Commission/ European Medicines Agency/ Heads of Medicines Agency Notice to Stakeholders: Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the COVID-19 Pandemic, 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 nominated contact person of the MAH>

<Date>