CBG
MEB

5.1.2e

European Medicines Agency
PO Box 5.1.2e
1008 BA Amsterdam
The Netherlands

Utrecht
26th March 2020

Our reference
20-010

Handled by
5.1.2e

Telephone
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Subject
National compassionate use programme

Dear 5.1.2e

The Centre for Infectious Disease Control of the Dutch National Institute for Public Health and the Environment (RIVM) requests the CHMP, in light of a need to initiate a compassionate use programme at a national level and an interest to have a harmonised approach at the EU level, to adopt an Opinion in accordance with Article 83(4) of Regulation (EC) No 726/2004.

In the Netherlands we have participated in the initial named-patient program of Gilead to obtain remdesivir for severe COVID-19 in the last 3 weeks. The RIVM collaborated with Gilead, because of a ministerial exemption for the RIVM to import non-registered antiviral medication, which allowed transport to the Netherlands and administration of this substance to patients in hospitals when physicians deemed administration potentially beneficial considering the severity of disease.

The MEB and RIVM wish to participate in the continuation of a compassionate use program of remdesivir at a national level as soon as possible.

This concerns the following:
Active substance: remdesivir
Pharmaceutical form and strength: The solution formulation of remdesivir is supplied as a sterile, preservative-free, clear, colorless to yellow, aqueous-based concentrated solution containing 5 mg/mL remdesivir to be diluted into infusion fluids prior to IV administration. It is supplied as a sterile product in a single-use, clear glass vial with sufficient volume to allow withdrawal of 20 mL (100 mg remdesivir). In addition to the active ingredient, the solution formulation of remdesivir contains the following inactive ingredients: water for injection, sulfobutylether β-cyclodextrin sodium (SBECD), and hydrochloric acid and/or sodium hydroxide.
The manufacturer/sponsor/applicant: Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404
The target population ('indication'): SARS-CoV2 Infection
The start date of the programme : to be decided

Yours sincerely

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5.1.2e (RIVM)

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(MEB)