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EMA provides recommendations on compassionate use of remdesivir for COVID-19

During an extraordinary virtual meeting held on 2 April 2020, EMA's human medicines committee (CHMP) gave recommendations on how the investigational antiviral medicine remdesivir should be used for treating coronavirus disease (COVID-19) in compassionate use programmes in the European Union.

Compassionate use programmes, which are set up at the level of individual EU Member States, are intended to give patients with a life-threatening, long-lasting or seriously disabling disease and no available treatment options, access to treatments that are still under development and that have not yet received a marketing authorisation.

In this case Estonia, Greece, the Netherlands and Romania requested an opinion from the CHMP on the conditions under which early access to remdesivir through compassionate use could be given to patients with COVID-19. In severe cases, COVID-19 can cause pneumonia, severe acute respiratory syndrome, multi-organ failure and death.

"Clinical trials remain the gold standard for the collection of robust data on the safety and effectiveness of investigational medicinal products, but the CHMP acknowledges the need for a harmonised approach to compassionate use in the EU to allow access to remdesivir for patients who are not eligible for inclusion in clinical trials", said Dr Harald Enzmann, the chair of the CHMP. "The CHMP encourages the company to make remdesivir available in a fair and transparent way to those Member States wishing to take part in international clinical trials or treat patients in compassionate use programmes."

Remdesivir has been shown to be active against SARS-CoV-2 and other types of coronavirus (i.e. SARS-CoV and MERS-CoV) in laboratory studies; however, there are currently only limited data on the use of remdesivir in patients with COVID-19.

The aim of the CHMP's recommendations for remdesivir is to ensure a common approach regarding the criteria and conditions of its use prior to authorisation of compassionate use programmes by Member States. The recommendations are for EU Member States that are considering setting up such a programme and their implementation is not mandatory. In addition to describing which patients may benefit from the medicine, the recommendations explain how to use remdesivir and give preliminary information on its safety.

The summary on compassionate use and conditions of use of remdesivir in this setting are available on the Agency's website.

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More about the medicine

Remdesivir is an antiviral medicine which is being investigated for the treatment of COVID-19. Remdesivir is a 'viral RNA polymerase inhibitor' (a medicine that interferes with the production of viral genetic material, preventing the virus from multiplying). It has shown broad *in vitro* activity against different RNA viruses, including SARS-CoV-2 and was originally developed for the treatment of Ebola virus disease.

Remdesivir is being developed by Gilead Sciences Ireland CU and is given by infusion (drip) into a vein.

More about the procedure

National competent authorities can ask EMA for an opinion on how to administer, distribute and use certain medicines for compassionate use under Article 83 of Regulation (EC) No 726/2004.

More information on compassionate use is available on the Agency's website: https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use.