



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA starts rolling review of remdesivir for COVID-19

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on the use of the investigational antiviral medicine remdesivir for the treatment of coronavirus disease (COVID-19).

The start of the rolling review only means that the evaluation of remdesivir has started and does not imply that its benefits outweigh its risks.

A rolling review is one of the regulatory tools available to the Agency to speed up the assessment of a promising investigational medicine during a public health emergency, such as the ongoing pandemic.

Under normal circumstances, all data supporting a marketing authorisation application must be submitted at the start of the evaluation procedure. In the case of a rolling review, CHMP Rapporteurs are appointed whilst development is still ongoing and the Agency reviews data as they become available.

Several rolling review cycles can be carried out during the evaluation of one product as data continue to emerge, with each cycle lasting around two weeks depending on the amount of data to be assessed. Once the data package is complete, the developer submits a formal marketing authorisation application which is then processed under a shortened timetable.

While the overall review timeline for remdesivir cannot be anticipated at this moment, it is expected that this procedure will allow EMA to complete its assessment significantly earlier compared with a regular evaluation procedure, while still ensuring a robust scientific opinion is reached.

The CHMP's decision to start the rolling review of remdesivir is based on preliminary results from the [ACTT study](#), which suggest a beneficial effect of remdesivir in the treatment of hospitalised patients with mild-to-moderate or severe COVID-19. However, EMA has not yet evaluated the full study and it is too early to draw any conclusions regarding the benefit-risk balance of the medicine.

Any new data that becomes available for evaluation during this rolling review need to be considered in the context of all other existing data. The CHMP will evaluate all data on remdesivir, including evidence from a recently published [study](#) from China and other clinical trials and conclude on the medicine's benefits and risks as soon as possible.

Although remdesivir is not yet authorised in the European Union, it is available to patients through clinical trials and so-called 'compassionate use' programmes through which patients can get access to unauthorised medicines in emergency situations.



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.

Information on compassionate use for remdesivir in the EU is available here:

<https://www.ema.europa.eu/en/news/ema-provides-recommendations-compassionate-use-remdesivir-covid-19>