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EMA starts evaluating use of Veklury in COVID-19 patients not requiring supplemental oxygen

EMA has started evaluating an application to extend the use of Veklury to include treating adults with COVID-19 who do not require supplemental oxygen.

Veklury is currently authorised for use in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at the start of treatment).

EMA's human medicines committee (CHMP) will assess data submitted by the applicant (Gilead Sciences) and recommend whether or not the extension of indication should be authorised. The CHMP's opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

EMA will communicate on the outcome of the evaluation, which is expected before the summer.

Veklury was first authorised in the EU in July 2020. The active substance, remdesivir, is a viral RNA polymerase inhibitor which interferes with the production of viral RNA (genetic material), preventing SARS-CoV-2 virus from multiplying inside cells. More information about the medicine is available on EMA's website.

