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EMA starts review of conditional marketing authorisation application for Skycovion COVID-19 vaccine

EMA's human medicines committee (CHMP) has started a review of a conditional marketing authorisation application for Skycovion, a vaccine for protecting against COVID-19.

The applicant, SK Chemicals GmbH, has submitted data on how well the vaccine triggers the production of antibodies against the original strain of SARS-CoV-2, the virus that causes COVID-19. The company also submitted data on the safety and quality of the vaccine.

After reviewing the data, the CHMP will issue an opinion on whether to grant a conditional marketing authorisation. The European Commission will then make a legally binding decision. EMA will communicate further at the time of CHMP's opinion.

The evaluation of Skycovion is one of the ongoing evaluations of data on COVID-19 vaccines. As the pandemic continues to evolve, it is important that the EU has a wide array of vaccines and treatments to enable Member States to combat the pandemic effectively.

EMA and its scientific committees are committed to ensuring a robust review of all data on COVID-19 vaccines and medicines.

More about the vaccine

Skycovion has small particles known as nanoparticles containing parts of the spike protein found on the surface of SARS-CoV-2.

When a person is given the vaccine, their immune system is expected to identify the nanoparticles containing parts of the spike protein as foreign and produce natural defences — antibodies and T cells — against them. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

The vaccine also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

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