

EU regulators start review of China's Sinovac vaccine

4 May 2021, by Mike Corder



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The European Union's drug regulator announced Tuesday that it has started a rolling review of China's Sinovac coronavirus vaccine to assess its effectiveness and safety, a first step toward possible approval for use in the 27-nation bloc.

The European Medicines Agency said Tuesday that its decision to start the review is based on preliminary results from [laboratory studies](#) and [clinical studies](#).

"These studies suggest that the [vaccine](#) triggers the production of antibodies" that fight the coronavirus "and may help protect against the disease," the agency said in a statement.

The EMA, which so far has approved four [coronavirus](#) vaccines, added that no application seeking marketing authorization for the Sinovac vaccine has been submitted yet.

The agency said its experts will "evaluate data as they become available to decide if the benefits outweigh the risks" of the vaccine. The rolling review will continue until "enough evidence is

available for a formal marketing authorization application," the EMA said, adding that it could not predict timelines.

The announcement from the Amsterdam-based agency came a day after a top World Health Organization official said the WHO is set to decide this week whether to approve two Chinese COVID-19 vaccines for emergency use.

Such approval would mark the first time that a Chinese vaccine had been granted a so-called emergency use listing from the U.N. health agency, and would trigger a broader rollout of Chinese vaccines that are already being used in some countries beyond China.

Mariangela Simao, assistant director-general for access to medicines, vaccines and pharmaceuticals, says some "final arrangements" remain to be made before the crucial word from a WHO technical advisory group comes on the Sinopharm and Sinovac vaccines.

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APA citation: EU regulators start review of China's Sinovac vaccine (2021, May 4) retrieved 3 June 2022 from <https://medicalxpress.com/news/2021-05-eu-china-sinovac-vaccine.html>

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