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EU to Probe Russian Coronavirus Vaccine Trial Standards – FT

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The EU medicines regulator is reportedly concerned that Sputnik V trials had not been ethically run, a claim the vaccine's developer denied. **Moskva News Agency**

Updated at 6:44 p.m. on April 7 to add statement from Sputnik V's official Twitter account.

The European Union's medicines regulator will investigate whether the developers of Russia's Sputnik V coronavirus vaccine went against global ethical and scientific standards in clinical trials, the Financial Times reported Wednesday.

The European Medicines Agency (EMA) last month launched a rolling review of Sputnik V, which could become the first non-Western Covid-19 jab to be used across the 27-nation bloc if approved. Russia at the time said it expected approval of Sputnik V in the next two months.

Related article: Explainer: Sputnik V's Road to the European Market

According to the FT's unnamed sources familiar with the EMA's approval process, the

European regulator is concerned that Sputnik V trials had not been ethically run. The outlet linked the concerns to Russia's use of soldiers and state employees as trial subjects.

"There was no pressure [on participants] and Sputnik V complied with all clinical practices," Kirill Dmitriyev, CEO of the state-run Russian Direct Investment Fund (RDIF) which funded the jab and markets it abroad, told FT.

Dmitriyev said the EMA inspection is expected to begin next week.

"We are not aware of any concerns from the EMA," he added, accusing the FT's report of "trying to undermine the EMA approval process which is supposed to be unbiased and without discrimination."

The EMA said Sputnik V's approval was contingent on whether the clinical trials met the internationally agreed standards known as Good Clinical Practice, the FT reported.

Sputnik V's official Twitter account later called the FT's report on the EMA investigation "incorrect."

"Sputnik V team is going through a regular rolling review of EMA, in which Good Clinical Practice (GCP) is a part of the standard procedure for all vaccines. Sputnik V specifically invited EMA to conduct a rolling review and is showing full transparency. 59 countries already confirmed Sputnik V compliance with GCP and we expect EMA to do so as well," it tweeted.

"Fake reports by anonymous sources try to undermine the objective nature of EMA review," it added, urging to follow official announcements from the EMA and from the vaccine's developers.

The regulator was expected to send a team to Russia this month to review clinical trial results and evaluate Sputnik V's production process.

However, Dmitriyev told the FT that the EMA inspection had been delayed by a few days in order for Russia to accommodate inspection visits from other countries that had ordered Sputnik V doses first.

French President Emmanuel Macron's office has said the EMA's review of Sputnik V "will be based on the same standards it applies for each vaccine."

Peer-reviewed research published in The Lancet medical journal in February showed Sputnik V to be 91.6% effective.

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