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EU Regulators Complete Special Ethics Probe Into Sputnik V Clinical Trials – EMA

The results of the EMA probe into the ethics of Sputnik V's clinical trials will only be published after all stages are complete.

By Pjotr Sauer

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Darko Vojinovic / AP / TASS

The European Medicines Agency (EMA) has completed a special investigation into how Russia conducted clinical trials for its Sputnik V vaccine as part of the jab's application for approval in the EU.

The regulator told The Moscow Times on Thursday that an EMA inspection team currently in Moscow had conducted a Good Clinical Practices (GCP) inspection — a review that checks the "international ethical and scientific quality standard for designing, recording and reporting [clinical] trials."

"In the context of the evaluation of the Sputnik V vaccine, European inspectors have carried out Good Clinical Practice (GCP) inspections in Russia and Good Manufacturing Practice (GMP) inspections are planned to take place in May," the EMA told The Moscow Times in an emailed statement.

Both stages need to be passed before the EMA will approve the jab. The results of the EMA probe into the ethics and conduct of Sputnik V's clinical trials will only be published after both stages are complete.

Sputnik V's developers previously dismissed a Financial Times report that the EMA was set to conduct the special investigation as "incorrect," saying that the GCP inspection was part of the "standard procedure."

EMA Executive Director Emer Cooke said the inspection was an additional part of Sputnik V's application procedure, but was still part of the regulator's "normal process."

However none of the four vaccines currently approved for use in the EU — the Pfizer, AstraZeneca, Moderna and Johnson & Johnson jabs — were subject to such an investigation by the EMA, according to approval documents posted on the EMA's website.

Inspections "may be triggered by issues arising during the assessment of the [clinical trial] dossier or by other information such as previous inspection experience," the EMA states on its website.

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Early-stage trials into Sputnik V's safety were conducted on military personnel. Reuters news agency reported that some who took part in the trials were pressured into doing so — a possible breach of ethical standards governing the conduct of clinical trials. The Russian Direct Investment Fund (RDIF) denied that forced participants were used during the SputnikV trials. RDIF did not respond to a request to comment from The Moscow Times.

Moscow was dealt a blow to its vaccine diplomacy efforts this week when Brazil's medical authorities followed Slovakia's in turning down Sputnik V after their own lab inspections revealed the vaccine contained a live version of a common cold-causing virus — a defect which could be a safety issue for recipients with low immunity.

Gaining approval in the EU would be a big victory for Sputnik V, which has so far been approved in 59 countries around the world. German officials have said they are in talks with Russia to buy 30 million doses of Sputnik V once it is approved by the EMA, while Austria has also said it will order the vaccine once approved.

Earlier this month, Alexander Gintsburg, the director of the Gamaleya Institute where Sputnik V was developed, slammed the EU for deliberately delaying approval, out of "fear" that Sputnik V would "end up outcompeting the products that the European bureaucracy is promoting at home."

In the statement to The Moscow Times, the EMA said that it was "not in a position to comment on possible timelines for an authorisation of the Sputnik V Covid-19 vaccine before

a marketing authorization application has been submitted to the agency."

Approval by the EMA could also be necessary for recognizing vaccinated Russians as part of a future EU vaccine passport scheme currently under consideration.

Jake Cordell contributed reporting.