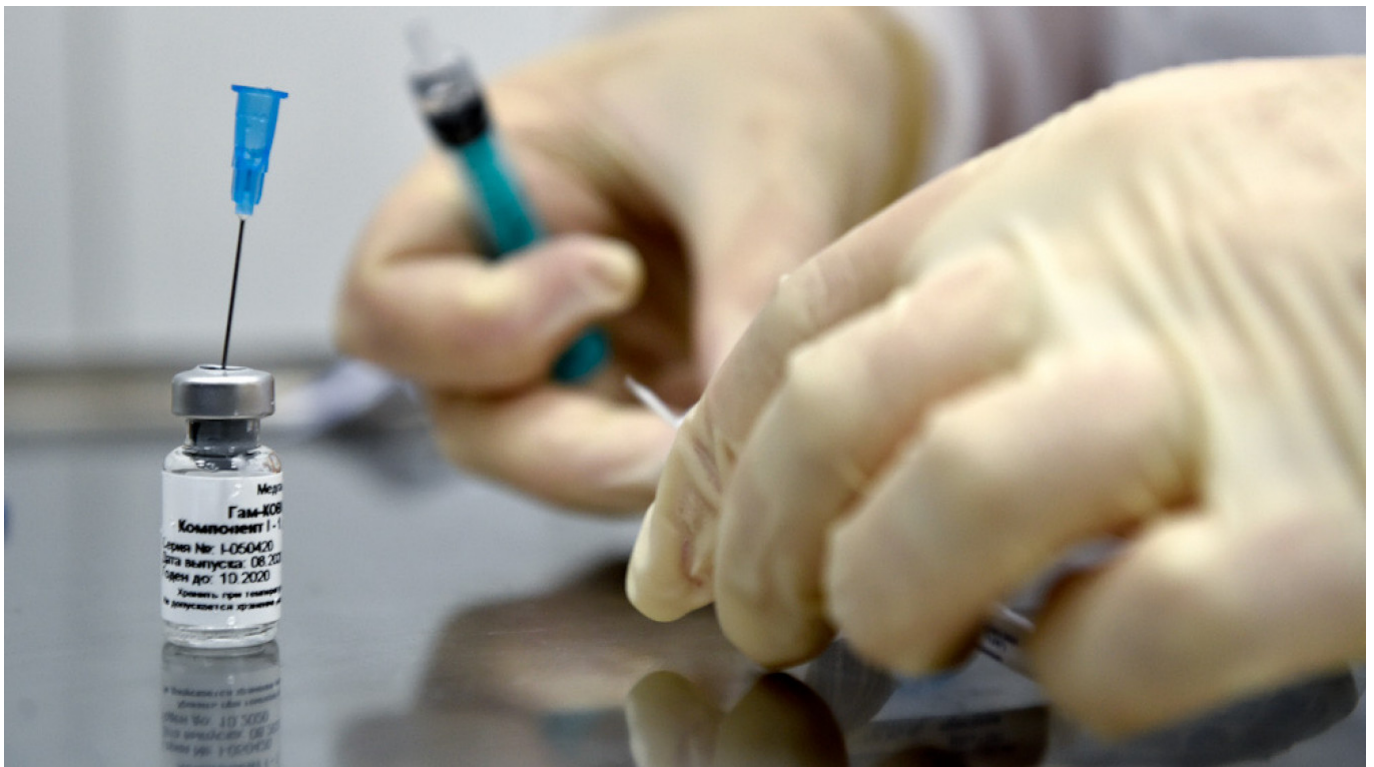


EU Delays Russia's Sputnik V Covid Vaccine Approval – Reuters

June 16, 2021



The EMA launched a rolling review of Sputnik V, which Russia touts as the world's first government-approved vaccine, this spring. **Natalia Kolesnikova / AFP**

The European Union will delay approval of Russia's Sputnik V coronavirus vaccine until later in 2021 because of a missed deadline to submit required data, Reuters [reported](#) Wednesday.

The delay shrinks Sputnik V's prospects as part of the EU's pandemic response.

Russia's Direct Investment Fund, which markets the jab worldwide, said earlier in the day it was confident that the European Medicines Agency (EMA) would approve Sputnik V within two months. The EMA launched a rolling review of Sputnik V, which Russia touts as the world's first government-approved vaccine, this spring.

Related article: [Majority of Europeans Don't Trust Russia's Coronavirus Vaccines – Poll](#)

“Approval of Sputnik will be delayed probably until September, maybe until the end of the

year,” Reuters quoted an unnamed German government official as saying.

The EMA allegedly issued Sputnik V's developer, the Gamaleya Institute, another week to file the required data after it missed the June 10 cut-off date, Reuters cited another unnamed source as saying.

RDIF said meanwhile that “all of the information on the Sputnik V vaccine clinical trials has been provided and GCP (General Clinical Practice) review has been completed with positive feedback from the” EMA.

An EMA inspection team in April [investigated](#) whether Sputnik V's developers violated GCP standards during clinical trials.

Peer-reviewed research showed Sputnik V, which has been approved in around 70 countries including EU members Hungary and Slovakia, to be 91.6% effective.

Back home, officials say around 13% of Russia's population has received Sputnik V or one of the other three homegrown coronavirus vaccines so far as polls show deep-rooted skepticism of Russian-made jabs.

The Kremlin expressed dissatisfaction with vaccination rates this week, saying they “leave much to be desired” but insisting that immunizations should remain voluntary.

Moscow's mayor nonetheless issued a surprise announcement Wednesday to make vaccinations mandatory for 60% of service sector employees in hopes of slowing down a recent surge in cases. Following the announcement, the Kremlin said there are no plans to extend the compulsory vaccination measures nationwide.

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