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Russia Presses on With Coronavirus Vaccine Registration Despite Safety Concerns

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The Health Ministry is set to register Russia's first coronavirus vaccine Wednesday. **Andrei Nikerichev / Moskva News Agency**

Russia will move forward with registering its potential coronavirus vaccine, its state health watchdog said, defying calls to put off the process until the vaccine's trials are complete.

President Vladimir Putin on Tuesday announced that the vaccine was registered, with mass production expected to start in September and mass vaccination in October. On Monday, the Association of Clinical Trials Organizations (ACTO) industry body that represents organizations conducting multinational clinical trials in Russia had urged for more tests before its registration.

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“ACTO is obviously jumping to conclusions without knowing the results,” Valentina Kosenko, deputy chief of the health watchdog Roszdravnadzor, told the RBC news website Tuesday.

“Several hundred volunteers were vaccinated with this vaccine and there were no serious adverse reactions,” Kosenko was quoted as saying.

Russia’s state-run Gamaleya research institute launched Phase III trials for its Covid-19 vaccine last week. Kosenko said the trials will involve thousands of volunteers.

Sergei Glagolev, the head of Roszdravnadzor’s quality control department, told RBC that laboratory confirmation of the vaccine will be conducted after registration and during final trials.

“It’s acceptable to register the drug during the early stages of clinical studies. Similar schemes exist in the EU and the U.S.,” Glagolev was quoted as saying.

“During pandemics, countries have resorted to allowing drugs in the absence of normal randomized trials; that’s not the case with Gamaleya’s vaccine. In our case, we’re talking about early admission to the market under strictly controlled conditions.”

Gamaleya's vaccine is a so-called viral vector vaccine, meaning it employs another virus to carry the DNA encoding the necessary immune response into cells. It is based on the adenovirus, the common cold.

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