

## Slovakian Drug Institute Unable to Evaluate Sputnik V 'Due to Lack of Data'

Slovakia, one of Europe's hardest-hit countries by the pandemic, has bought 200,000 doses of the Russian vaccine but has yet to start administering shots.

By Pjotr Sauer

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## Federico Parra / AFP

Slovakia's State Institute for Drug Control has told the country's Health Ministry it has been unable to evaluate the risks and benefits of Russia's Sputnik V vaccine due to a lack of data and inconsistencies in dosages, the watchdog's spokeswoman Magdaléna Jurkemíková told The Moscow Times on Wednesday.

Slovakia, one of Europe's hardest-hit countries by the pandemic, received 200,000 doses of the Russian vaccine on March 1 amid accusations of political maneuvering but has yet to start administering shots.

"On March 30 2021, the State Institute officially sent an evaluation report to the Health Ministry stating that it was not possible to decide on the risk-benefit balance of Sputnik V due to the lack of data from the manufacturer, inconsistencies in dosages and inability to compare batches used in various studies and countries," the institute said in a statement.

The Russian Direct Investment Fund (RDIF), which has financed the development of the vaccine, did not immediately respond to a request to comment. Last month, the RDIF said in a statement that it had been approved after a "comprehensive assessment of the vaccine by experts in Slovakia."

The purchase of Sputnik V pushed Slovakia into a political crisis after coalition partners of ruling Prime Minister Igor Matovic accused him of orchestrating the deal without their approval. Matovic found himself at the center of another scandal after he <u>joked</u> in a radio interview about paying for Sputnik V shipments with Ukrainian territory.

On March 30, Matovic resigned, making Slovakia the first European government to collapse with so-called "vaccine diplomacy" as a catalyst. Slovakia's Health Minister, who has since been replaced, granted the country's original approval for Sputnik V March 1, before the political crisis erupted.

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On Wednesday, Slovakia's Health Minister Vladimir Lengvarsky <u>said</u> during a parliamentary meeting that a <u>decision</u> on whether or not to use Sputnik V will be taken early next week as the Health Ministry is waiting for a final recommendation from the State Institute for Drug Control. A positive response would make Slovakia the second EU country after Hungary to approve Sputnik V.

The delay is another blow to Russia's ambitions to export the Sputnik V vaccine to the EU market. Russian officials have accused the EU of foot-dragging on the approval process for the vaccine, saying its regulators are delaying their review of the drug.

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

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