



WHAT WENT WRONG WITH RUSSIA'S SPUTNIK V VACCINE ROLLOUT

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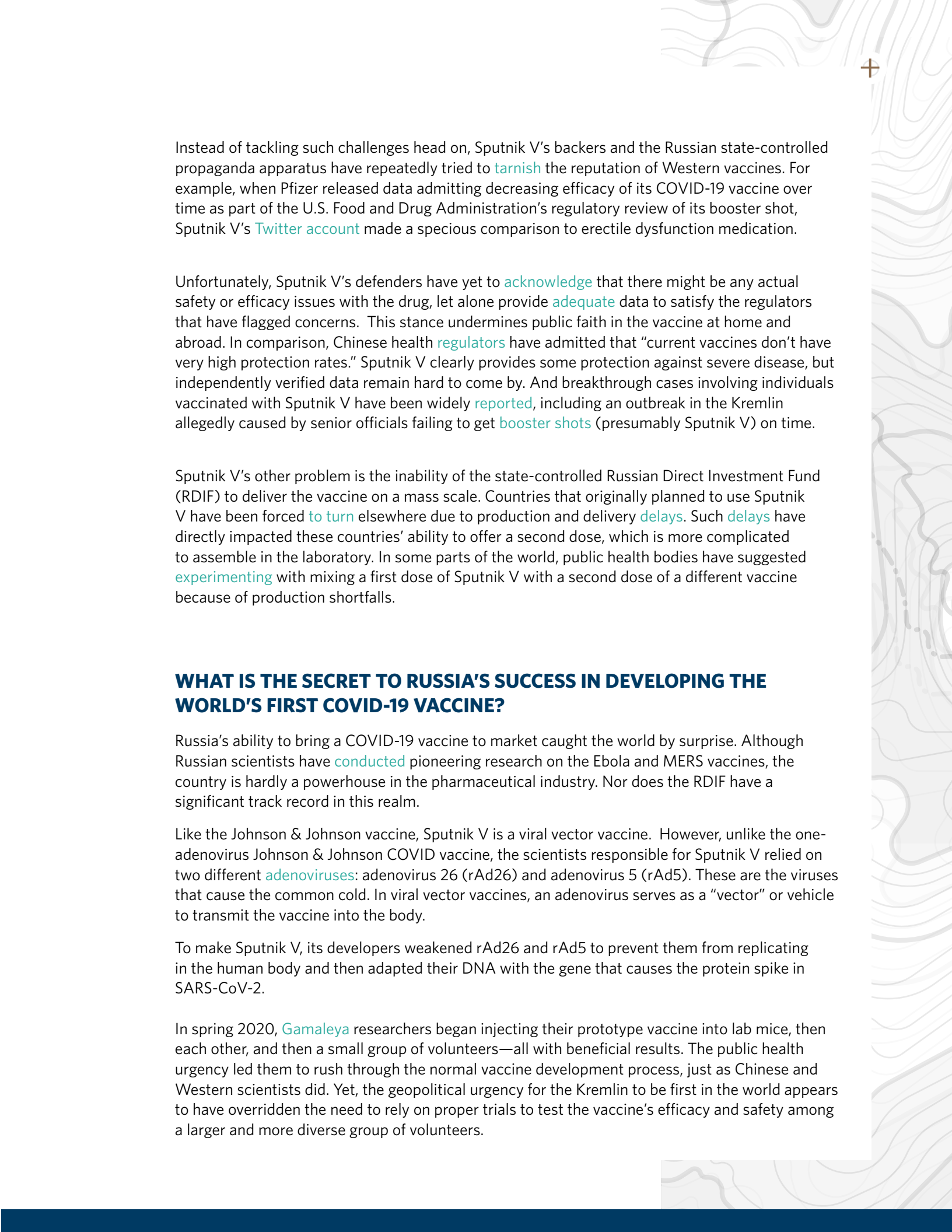
In August 2020, Russia was the [first country](#) to announce the development of a COVID-19 vaccine. Since then, a relentless publicity blitz has promoted the attributes of the Sputnik V vaccine. However, Sputnik V has [struggled](#) to gain mass acceptance inside Russia, let alone in other countries where it is marketed as an [alternative](#) to vaccines developed by Western and Chinese pharmaceutical firms. Hovering over the vaccine's commercial prospects are lingering questions about its safety and efficacy—as well as Moscow's ability to deliver promised numbers of doses and navigate complicated global supply chains.

HOW HAS SPUTNIK V'S ROLLOUT GONE?

The developers of Sputnik V at Moscow's Gamaleya Institute have been slow to share scientific data with international regulators and researchers for reasons that remain unclear. This has fed doubts about the [91–97 percent](#) efficacy they have claimed at various times. The decision [to rush](#) Sputnik V to the market before the completion of broad-based Stage III trials also damaged the vaccine's image inside Russia and overseas—while complicating prospects for emergency-use authorization by key international regulatory bodies, including the [World Health Organization](#), the [European Medicines Agency](#), and the [South African Health Products Regulatory Authority](#).

Inside Russia, vaccine hesitancy is a bigger challenge, and average [Russians](#) have proven to be especially skeptical of Sputnik V. Even President Vladimir Putin [hesitated](#) to take it, waiting for roughly seven months to be [jabbed](#). Russia's low vaccination rate is on par with much poorer countries. Only about [36 percent](#) of Russians have been fully vaccinated as of November 18, according to the Johns Hopkins University Coronavirus Resource Center vaccine database. This likely has [contributed](#) to the country's deadly [COVID-19](#) waves in 2021.

Western and Chinese COVID-19 vaccines that are being marketed globally have also faced a barrage of questions over safety and efficacy from regulators and citizens alike. Sputnik V's Western competitors generally are far more transparent with regulators. In fact, the most stringent international regulators have complex approval processes that mandate transparency; require applicants to hand over detailed data on efficacy, safety, and production capabilities; and request additional data as part of scientific and regulatory reviews. Delays in approving new drugs are common across the globe, but Sputnik V's Western competitors have a better [track record](#) of [navigating](#) these [processes](#).



Instead of tackling such challenges head on, Sputnik V's backers and the Russian state-controlled propaganda apparatus have repeatedly tried to [tarnish](#) the reputation of Western vaccines. For example, when Pfizer released data admitting decreasing efficacy of its COVID-19 vaccine over time as part of the U.S. Food and Drug Administration's regulatory review of its booster shot, Sputnik V's [Twitter account](#) made a specious comparison to erectile dysfunction medication.

Unfortunately, Sputnik V's defenders have yet to [acknowledge](#) that there might be any actual safety or efficacy issues with the drug, let alone provide [adequate](#) data to satisfy the regulators that have flagged concerns. This stance undermines public faith in the vaccine at home and abroad. In comparison, Chinese health [regulators](#) have admitted that "current vaccines don't have very high protection rates." Sputnik V clearly provides some protection against severe disease, but independently verified data remain hard to come by. And breakthrough cases involving individuals vaccinated with Sputnik V have been widely [reported](#), including an outbreak in the Kremlin allegedly caused by senior officials failing to get [booster shots](#) (presumably Sputnik V) on time.

Sputnik V's other problem is the inability of the state-controlled Russian Direct Investment Fund (RDIF) to deliver the vaccine on a mass scale. Countries that originally planned to use Sputnik V have been forced to [turn](#) elsewhere due to production and delivery [delays](#). Such [delays](#) have directly impacted these countries' ability to offer a second dose, which is more complicated to assemble in the laboratory. In some parts of the world, public health bodies have suggested [experimenting](#) with mixing a first dose of Sputnik V with a second dose of a different vaccine because of production shortfalls.

WHAT IS THE SECRET TO RUSSIA'S SUCCESS IN DEVELOPING THE WORLD'S FIRST COVID-19 VACCINE?

Russia's ability to bring a COVID-19 vaccine to market caught the world by surprise. Although Russian scientists have [conducted](#) pioneering research on the Ebola and MERS vaccines, the country is hardly a powerhouse in the pharmaceutical industry. Nor does the RDIF have a significant track record in this realm.

Like the Johnson & Johnson vaccine, Sputnik V is a viral vector vaccine. However, unlike the one-adenovirus Johnson & Johnson COVID vaccine, the scientists responsible for Sputnik V relied on two different [adenoviruses](#): adenovirus 26 (rAd26) and adenovirus 5 (rAd5). These are the viruses that cause the common cold. In viral vector vaccines, an adenovirus serves as a "vector" or vehicle to transmit the vaccine into the body.

To make Sputnik V, its developers weakened rAd26 and rAd5 to prevent them from replicating in the human body and then adapted their DNA with the gene that causes the protein spike in SARS-CoV-2.

In spring 2020, [Gamaleya](#) researchers began injecting their prototype vaccine into lab mice, then each other, and then a small group of volunteers—all with beneficial results. The public health urgency led them to rush through the normal vaccine development process, just as Chinese and Western scientists did. Yet, the geopolitical urgency for the Kremlin to be first in the world appears to have overridden the need to rely on proper trials to test the vaccine's efficacy and safety among a larger and more diverse group of volunteers.



IS SPUTNIK V HAVING AN ACTUAL IMPACT IN CURBING VIRUS SPREAD?

Sputnik V is a key part of many countries' vaccination plans, particularly in the Global South and parts of the former Soviet Union. Yet, in their rush to market, its developers overestimated Russian manufacturing capacity and the ability to reserve space in global supply chains. The RDIF's efforts to outsource production to other countries have been [stymied](#) at times by supply chain issues, technology sharing and regulatory delays, and limited local capacity.

The RDIF purportedly [eyed](#) Algeria, Egypt, Morocco, and [possibly](#) Nigeria as potential production or distribution [hubs](#) for Africa, but only Algeria and Egypt have concrete production plans. Nigeria has a limited domestic pharmaceutical industry and is not known as a vaccine producer, which raises questions about how knowledgeable Russian planners are about the countries in which they hope to operate. [Factories](#) in [Argentina](#) and [Brazil](#) have experienced [long delays in starting production](#), compounding supply problems in Latin America. There are more successful overseas production sites in [India](#), [Serbia](#), and [South Korea](#). Nonetheless, overall production shortfalls have [prevented](#) the RDIF and its regional distributors from meeting their delivery commitments. Scrutiny of these delays led to renewed efforts in summer 2021 to jumpstart Sputnik V production at home and abroad to [resolve](#) delivery shortfalls.

The decision to use two different adenoviruses (rAd26 in the first dose and rAd5 in the second) further [complicates](#) production. Russia has had greater shortfalls producing [rAd5](#) for the second dose, meaning recipients in several countries have experienced long waits for the [follow-up shot](#). Recognizing it had a problem, RDIF rolled out "Sputnik Light" in May 2021 with a purported [79.4 percent](#) efficacy rate. Yet, Sputnik Light is essentially just the first dose of Sputnik V without the harder-to-produce second. It is not the Russian version of the one-shot Johnson & Johnson, just the first [half](#) of Sputnik V. Since its rollout in Russia, the RDIF has claimed that Sputnik Light's efficacy may be as high as 93 percent, based on small-sample studies from [Argentina](#), [Libya](#), and [Paraguay](#).

IF SPUTNIK IS NOT AS SUCCESSFUL AS CLAIMED, WHY HAS THERE BEEN SO MUCH HYPE AND CONCERN ABOUT IT?

Sputnik V has its own social media presence—on [Facebook](#), [Instagram](#), and [Twitter](#). The RDIF's public relations machine highlights virtually every [delivery](#) of the drug across the world, no matter how [small](#) or [delayed](#). Press releases note that the drug is "[registered](#)" in over seventy countries.

Russian state media do not, though, report the fact that many of the countries that have registered it are not using it, either because Russia cannot deliver, because it is more expensive, or due to new safety concerns or the lack of [local](#) demand. They have also avoided addressing delivery shortfalls and the growing [anger](#) toward Russia in places that once embraced Sputnik V. One distributor in [India](#), for example, imported 3 million vials of Sputnik V but has administered less than 950,000 doses so far, and some private clinics have canceled orders. Yet, the country still has plans to produce 850 million more vaccines per year. Sputnik V costs nearly 50 percent more than the

AstraZeneca vaccine on the Indian private market and must be stored at [-18 degrees Celsius](#) (-0.4 degrees Fahrenheit), making it less economic and more cumbersome to use in a country like India.

Sputnik V has also run into regulatory hurdles. The World Health Organization in September 2021 [stopped](#) its emergency review over insufficient data and quality control issues at a Russian factory. According to press [reports](#), formal approval is not expected before the first quarter of 2022 at the earliest. South Africa thus far has refused emergency-use authorization, citing multiple safety and data transparency concerns. South African regulators have also raised concerns that the formula used in the vaccine's second dose may not be safe for use in a population with high [HIV](#) positivity rates, as noted in its October 18 [press release](#) announcing its decision to defer approval of the Russian vaccine. This announcement caused neighboring [Namibia](#) to stop using the vaccine. [Brazil](#) had similar safety and quality control concerns. It eventually approved Sputnik V only for use among [healthy adults](#) and with several stringent [conditions](#).

The vaccine is [not approved](#) for use in Canada, China, the European Union, Japan, South Korea, South Africa, or the United States. That compounds Sputnik V's authorization review in multiple countries that see these jurisdictions as credible regulators and look to them for guidance in evaluating new drugs.



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