

Russia in the global 'vaccine race'

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During the second wave of the COVID-19 pandemic, Moscow has stepped up its activities in the global 'vaccine race' against SARS-CoV-2. So far Russia has registered two vaccines, which was announced by President Vladimir Putin himself. The presentation of Sputnik V, which the Russian government has branded as the 'world's first vaccine', caused controversy from the very start, for both medical (as the clinical trial procedure was not completed) and ethical reasons (forcing 'volunteers' to take part in the tests). Foreign specialists, alongside the Russian medical community and the Russian public, have expressed scepticism about the insufficiently tested preparation. Despite this, the government is planning to carry out a mass campaign of public vaccination using Sputnik V and export this vaccine, mainly to developing countries.

Since the start of the pandemic, Moscow has viewed the vaccine's registration as an important instrument of its foreign policy and of Russia's soft power which will illustrate its ambition and determination to win the 'vaccine race' with the West. Alongside the element of prestige, the launch of the vaccine is also of major financial significance due to the high profits expected from its sale. For the global economy, the vaccine's launch is an opportunity to reduce the losses triggered by the pandemic. Russia is mainly focusing on emerging markets, although Sputnik V will face strong competition there from Chinese-made vaccines.

Russian vaccines: 'the first in the world'

The second wave of the COVID-19 pandemic building up in most countries has increased the pressure on governments and research institutes to develop an effective vaccine against SARS-CoV-2 as quickly as possible. In Russia, the second wave of the pandemic started in September 2020. Over the next month the number of infected individuals tripled, and by the end of October more than 17,000 cases were being diagnosed daily. At that time, the

number of deaths doubled and reached nearly 300 daily (a total of nearly 25,000 Russians have died of COVID-19). In order to curb the spread of the disease, the government has launched measures to restore restrictions for selected groups of citizens (mainly seniors), although for the time being these restrictions have not been introduced on a large scale.

Moreover, laboratories have joined the fight against the virus. On 11 August 2020, President



Putin announced that Russia was the first country to have registered a vaccine against SARS-CoV-2. It was developed by the Gamaleya National Centre of Epidemiology and Microbiology, which is supervised by the Ministry of Health, in cooperation with the Central Scientific Research Institute of the Russian Ministry of Defence. The preparation, referred to as Gam-COVID-Vac and given the trade name Sputnik V, is a vector-based vaccine in which a vector virus delivers the genetic instructions for SARS-CoV-2 antigens directly into patients' cells, instructs them to make SARS-CoV-2 protein, and stimulates an immune response. The body then produces antibodies in response to the replication of these proteins.¹ At the time of registration, the vaccine had only completed two phases of clinical trials. The 38 participants in both trials were volunteer subjects aged 18–60 (this was not a placebo-controlled trial). In addition, the vaccine is being introduced into general circulation on only a temporary basis (until 1 January 2021). At present, phase III of the clinical trial is ongoing; it is expected to cover 40,000 volunteers aged 18 and older. Once it is finished, the preparation should obtain full registration in December 2020.

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At present, around fifteen other vaccines are at a similar stage of development worldwide. Up to eight of them have been approved to take part in a phase-III clinical trial before the Russian vaccine: five vaccines developed by Western pharmaceutical companies and three by Chinese ones. For comparison, the European company AstraZeneca, in collaboration with the University of Oxford, carried out the vaccine's phase-I and -II clinical trials with the participation of nearly 1100 subjects, whereas the Chinese company CanSino Biologics included more than 700 subjects in

its phase-I and -II trials.² Due to the fast spread of the pandemic, all pharmaceutical companies have reduced the duration of these two phases to around six months (instead of the usual two to four years).

Although the testing process has not yet been completed, public distribution of Sputnik V was launched in Russia as early as 8 September. Before obtaining full registration, the preparation will probably be made available to representatives of high-risk professions (including medical staff and teachers), and a mass vaccination campaign is to be launched next year.

Sputnik V is one of several vaccines against SARS-CoV-2 currently being developed in Russia. On 14 October 2020, the EpiVacCorona was registered (like Sputnik V) ahead of its phase III clinical trial. EpiVacCorona was developed by the Vector laboratory based in Novosibirsk, which is supervised by the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (*Rospotrebnadzor*). Back in the Soviet era, Vector was involved in research on biological weapons under the cover of a civilian scientific and technical institute.³ EpiVacCorona is a synthetic peptide-base vaccine; it does not cause the virus to replicate within the human body, which makes it a safer option for immunocompromised people. This vaccine is to be marketed domestically as of 1 January 2021. Both the Russian vaccines were developed in record time because they were based on a body of research which the two institutes had previously carried out, mainly concerning a vaccine against Ebola.

Although other research institutions are working on similar preparations, these two laboratories had in fact been privileged as they enjoyed financial and political support from various groups in the Russian elite. At the same time, they were engaged in fierce competition; they hindered

¹ For more details on the vaccine see sputnikvaccine.com/about-vaccine.

² A. Rivas, P. Loftus, A. Cervantes, 'Covid-19 Vaccines: What's Coming and When?', *The Wall Street Journal*, 25 September 2020, www.wsj.com.

³ Д. Туровский, «Другого способа лечения нет и сейчас», *Meduza*, 31 October 2014, www.meduza.io.

each other's research by blocking access to the information regarding patients they had access to. This competition reflected the rivalry between their 'patrons'. The two vaccines also competed in terms of their advertising campaign: Sputnik V was promoted by representatives of the Russian elites linked to the defence ministry and the Kremlin: defence minister Sergei Shoigu, Moscow's mayor Sergei Sobianin and President Putin's daughter reported they had been vaccinated with Sputnik, while EpiVacCorona was promoted by the head of *Rospotrebnadzor* Anna Popova and deputy prime minister Tatyana Golikova, who said they had taken this vaccine.

Sputnik V: medical and ethical dilemmas

From the beginning, the process of testing and marketing the vaccine sparked numerous doubts and major medical and ethical controversies. Following President Putin's announcement regarding Sputnik V's registration and the publication by the vaccine's developers in the *Lancet*, representatives of medical and scientific communities (mainly foreign) expressed their criticism regarding the research methodology used and the results obtained by the vaccine's development team. They highlighted numerous information gaps, the very small group of subjects in the clinical trials, the statistical irregularities in the results presented, and the insufficient analysis of possible side-effects. Their doubts were not dispelled by the subsequent explanations submitted by the preparation's creators,⁴ and Sputnik V has frequently been referred to in the Western press as an "under-tested vaccine".⁵ In addition, its credibility has been undermined by the dubious reputation of Russian laboratories and by doubts regarding their previous achievements (the Ebola vaccines they developed have not been put into general use).

⁴ 'Российские разработчики вакцины против коронавируса наконец-то подробно ответили на критику западных ученых. Разбираем, чьи аргументы убедительнее', *Meduza*, 23 September 2020, www.meduza.io.

⁵ J. Twigg, 'Vladimir Putin Has a Vaccine, and He's Rushing to Share It', *The New York Times*, 13 October 2020, www.nytimes.com.

Many controversies as regards the ethical aspect of the vaccine's development have also emerged; for example, employees of public institutions who were subordinate to the vaccine's developers were pressurised to take part in the trials of Sputnik V. The vaccine was administered to employees of institutions supervised by the health ministry (including the Gamaleya Centre which developed the vaccine; its employees were given Sputnik V when it was still at its pre-clinical stage), the defence ministry, the Moscow healthcare department and some municipal companies. In some instances, the 'volunteers' forced to take part in this procedure complained that the tests performed ahead of their inoculation showed that their body had already produced antibodies to SARS-CoV-2, which disqualified them from participating in the study.⁶ In some cases, their employers promised to pay them gratuities for taking part,⁷ while others threatened to strip them of their bonuses or even to dismiss them.⁸

” President Putin personally announced the registration of Sputnik V which in Russia is referred to as 'the first in the world'.

Distrust of Sputnik V has also been expressed by the Russian medical community, who will be first in line for the vaccination programme (the government claims that participation in this programme will be voluntary). In a poll conducted in August 2020,⁹ a mere 24% of physicians said that they would be willing to have themselves vaccinated

⁶ See 'Спецкор «Медузы» Светлана Рейтер стала добровольцем на испытаниях вакцины от коронавируса «Спутник V». Мы попросили ее записывать свои ощущения — день за днем', *Meduza*, 29 September 2020, www.meduza.io.

⁷ For taking part in the study the volunteers received a remuneration of US\$1500 and were offered an insurance policy enabling them to receive US\$4000 in case of health complications and US\$26,000 in case of their death.

⁸ Е. Фохт, '«Некоторые первый раз слышат, куда пришли». Кто и зачем испытывает на себе российскую вакцину от коронавируса', *BBC News Русская служба*, 6 October 2020, www.bbc.com/russian.

⁹ The poll was conducted on a sample of 3040 individuals via a popular application used by medical professionals known as 'Doctor's Guide', used by around half of all physicians in Russia (580,000 individuals). For more, see 'Прививка от COVID-19: аргументы медиков за и против скорой вакцинации', *BusinessFM*, 14 August 2020, www.bfm.ru.

with Sputnik, whereas 52% were apprehensive about taking an under-tested, hastily developed vaccine. This scepticism about the preparation is shared by the Russian public, which has always been distrustful of Russian-made pharmaceuticals and preferred Western-made ones. A poll conducted in September by the pro-Kremlin United Russia party showed that 73% of respondents did not intend to have themselves vaccinated with Sputnik.¹⁰ A poll conducted by the Levada Centre back in August 2020 revealed that 54% of the individuals surveyed did not intend to take Sputnik V.¹¹ The vaccine was found to evoke mainly negative feelings in the respondents, including 'distrust' and 'doubts' (both were indicated by 20% of those questioned).

The Russian vaccine: *cui bono*?

In Russia, the fight against the coronavirus is mainly being financed from public funds. Anton Siluanov, Russia's finance minister, has estimated that the total extra budgetary spending on health care and sanitary & epidemiological activities in 2020 stands at more than US\$2.5 billion. It is difficult to estimate how much has been spent on vaccine development because each phase of the research has been financed separately. In addition, alongside direct subsidies from the state budget, the laboratories receive support from other public institutions, in particular the Russian Direct Investment Fund (RDIF). Pharmaceutical companies are also investing in the mass production process. However, estimates show that Russian spending on vaccine research (around US\$100 million) was much lower than the amounts spent by Russia's foreign competitors. The largest sum (more than US\$10 billion) has been spent by the government of the United States to this end; it includes US\$1.2 billion invested in research carried out by the pharmaceutical company AstraZeneca in collaboration with the University of

Oxford (in exchange Washington has pledged to buy around 300 million doses of the vaccine if its efficacy is confirmed).

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In Russia, the biggest support from the state budget was offered to two state-controlled laboratories: in 2020 the Gamaleya Centre received a subsidy worth around US\$25 million,¹² while the Vector Centre received a sum of around US\$20 million.¹³ The RDIF¹⁴ has become the principal investor in preparations for the mass production of Sputnik V and its promotion abroad; it has earmarked around US\$50 million for that purpose. According to government announcements, 800,000 doses of the vaccine are to be manufactured in November, around 1.5 million in December, and in spring 2021 the production volume is to reach around 15 million doses monthly. Initially, manufacturing will be carried out by three Russian pharmaceutical companies with which the RDIF has signed the relevant contracts. These companies are a privately-owned company, R-Farm (which has also signed an agreement with AstraZeneca to produce the British coronavirus vaccine); Binnofarm, which is a component of the Alium pharmaceutical holding (it is owned by the state-controlled VTB bank, the privately-owned AFK Sistema company, and foreign investors linked to the RDIF); and the privately-owned company Biocad, which is both the Vector Centre's partner in developing the vaccine and its planned manufacturer. For comparison,

¹⁰ The survey was conducted in party offices on a sample of 20,000 individuals. See 'Более 70% россиян не хотят делать прививку от коронавируса, показал опрос', РИА Новости, 5 October 2020, www.ria.ru.

¹¹ 'Новость о создании вакцины от коронавируса у 46% россиян вызвала негативные эмоции', Левада-Центр, 28 August 2020, www.levada.ru.

¹² Н. Телегина, 'Первая российская вакцина от коронавируса обошлась федеральному бюджету в 1,8 млрд рублей', Открытые медиа, 26 August 2020, www.openmedia.io.

¹³ А. Стогней, К. Аренина, '«Обогнать весь мир политической волей и решительностью». Как Россия делает вакцину от коронавируса', The Bell, 16 June 2020, www.thebell.io.

¹⁴ A state-controlled investment fund, established in 2011, which invests in Russian companies in partnership with foreign businesses. It manages capital worth US\$10 billion and is an important instrument of Russia's international economic cooperation; for example, it holds a stake in several pharmaceutical companies.

Russian companies produce around 50 million doses of flu vaccine annually.

The Gamaleya Centre has also received support from Sberbank, Russia's biggest bank. This bank established the *Immunotekhnologii* company to provide organisational, technological and manufacturing support for the production of Sputnik V (the sum of US\$40 million will be invested in these activities). Moscow's municipal authorities have joined the financing of phase III of the clinical trials. The investors can be practically certain of a return on their investment: the Kremlin is planning to have around 70 million citizens (50% of Russia's population) vaccinated, which will mainly be financed from the state budget. Each dose of Sputnik V is expected to cost around US\$10.

It should be noted that the main beneficiaries of these state expenditures, both on fighting the pandemic in Russia and developing the vaccines against SARS-CoV-2, are state-controlled institutions and companies which have close ties to the ruling elite. The Rostekh state corporation, managed by President Putin's confidant Sergei Chemezov, brings together companies operating mainly in the defence sector, and it has become the main supplier of ventilators, protective suits and thermometers, as well as flu vaccines (it holds a 70% share in this market¹⁵). Deliveries of coronavirus tests under public procurement (so far, more than 50 million tests, mainly Russian-made, have been performed) have largely been provided by private businesses with links to the ruling elite, including Deputy Prime Minister Golikova and President Putin's crony Arkady Rotenberg.¹⁶

Moreover, the government is using the fight against the coronavirus to strengthen state capitalism. This involves relying on public institutions and increasing the involvement of the defence sector (e.g. Rostekh) in meeting the growing demand for

medical equipment and pharmaceuticals. However, and most importantly, the Kremlin's focus on self-sufficiency and its reliance on domestic production (even if it is unable to fully replace imported goods) is strengthening the process of import substitution in the pharmaceutical and the medical equipment sector, which has been ongoing since 2009. Until recently, it was progressing at a rather slow pace: in 2019 the share of Russian-made drugs on the Russian pharmaceutical market in terms of value was only just over 30% (compared to 25% in 2014), and the share of Russian-made equipment on the medical equipment and materials market was a mere 23%.¹⁷

Vaccine diplomacy: Sputnik V as an instrument of Russia's soft power

Russia sees the current pandemic as another chapter of its rivalry with the West, as well as an opportunity to strengthen its position on the international stage. It has incorporated the issues related to the fight against COVID-19, including developing the vaccine against SARS-CoV-2, into its set of diplomatic tools. Moscow has also made it a point of honour to make sure it registers a vaccine first. The Kremlin has consistently referred to Sputnik V as the world's first coronavirus vaccine, even though the testing process is still unfinished (several foreign-made vaccines are at a more advanced stage of clinical trials). Sputnik V's registration was accompanied by a high-profile propaganda campaign involving President Putin himself. Russian media and politicians compared this event to the launch of the first satellite, Sputnik 1 (hence the name of the vaccine), back in 1957 and stressed that once again Russia has outpaced the United States.¹⁸ The fight against the pandemic, in particular Russia's 'coronavirus philanthropy', has become an

¹⁵ 'Как госмонополия «Нацимбио» заработала на вакцинах и кто от этого выиграл', Transparency International Russia, 16 October 2017, www.transparency.org.ru.

¹⁶ М. Плюснина, 'Брат чиновника из АП, бизнесмен из окружения Голиковой и вездесущие Ротенберги', *Znak*, 27 April 2020, www.znak.com.

¹⁷ А. Левинский, 'Время дженериков: к чему привело импортозамещение в медицине и фармацевтике', *Forbes*, 8 September 2020, www.forbes.ru.

¹⁸ In an interview for CNN, the RDIF's director Kirill Dmitriev said: "It's a Sputnik moment. Americans were surprised when they heard Sputnik's beeping. It's the same with this vaccine. Russia will have got there first". See M. Chance, 'Russia says foreign inquiries about its potential fast-track Covid-19 vaccine are pouring in. But questions abound', CNN, 30 July 2020, www.edition.cnn.com.

important instrument of its soft power. As part of its humanitarian aid, the Kremlin has provided one million SARS-CoV-2 tests, mainly to the CIS countries; dispatched military medical personnel to Italy; and sent medical equipment including ventilators to the US. During his recent address to the UN General Assembly, President Putin offered to make the vaccine available to employees of the United Nations free of charge.

” The research into the Russian vaccine is being jointly funded by numerous public institutions, and the costs borne by Russia have proved much lower than the expenditures incurred by its foreign competitors.

Participation in the global ‘vaccine rivalry’ is associated not only with prestige, but most importantly with tangible profits. The RDIF has estimated the initial demand for the vaccine at 3–5 billion doses, worth around US\$75 billion. The Fund is hoping that Russia will be able to supply around 1 billion doses by the end of 2021. Alongside the domestic market and the CIS region, the Russian government is mainly promoting Sputnik V in developing countries, especially those highly affected by the pandemic. Moscow is concentrating on bilateral agreements, which could enable it to tighten its relationships with these countries and to sell them the potential vaccine at an attractive price. This is why the Kremlin has decided not to join the multilateral solidarity initiative known as COVAX, promoted by the WHO and numerous non-governmental organisations (it has been joined by more than 170 states, although the US decided to opt out). The goal of COVAX is to raise funds to finance the purchase of at least 2 billion doses of a COVID-19 vaccine by the end of 2021 and to distribute them equally to all countries in the world, particularly the poorest ones which cannot afford to buy them out of their own budgets.

The RDIF is conducting talks with at least 20 states, and has already reached an agreement with several of them regarding the vaccine’s clinical trials and supply. The first batches of the vaccine to be tested in phase-III trials have now been delivered to Belarus. Other countries expecting to receive batches of Sputnik V include Uzbekistan (35 million doses in total) and Kazakhstan (2 million doses). The Fund has also announced agreements with Mexico (32 million doses in total), India (100 million doses), Egypt (25 million doses), Brazil’s State of Bahia (50 million doses) and Nepal (25 million doses).¹⁹ It has also launched talks with Saudi Arabia, the United Arab Emirates, Iran and the Philippines. The export of Sputnik V will be possible once its safety and efficacy are proven and it has been approved for sale in the target countries.

It should be noted that Russia will mainly be competing for emerging markets with China. In an attempt to attract customers, Moscow has declared that in order to increase the vaccine’s availability it is ready to share its technology and use the support from the RDIF to launch the vaccine’s production abroad, including in India, Brazil and South Korea. What makes Sputnik V less attractive is the fact that, like the majority of vaccines at the most advanced testing stage, it requires the administration of two doses (at a three-week interval), whereas the vaccine produced by the Chinese company CanSino Biologics can be administered in a single dose (this variant is preferred by the WHO). It will also be difficult to sell Sputnik V in the West due to the distrust of the Russian preparation and the strong competition on the part of multinational pharmaceutical companies. Developed countries are already signing agreements for the delivery of potential SARS-CoV-2 vaccines with reputable Western companies.

¹⁹ ‘РФПИ договорился о поставках 25 млн доз вакцины «Спутник V» в Непал’, TACC, 29 September 2020, www.tass.ru.