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Abstract

Russian authorities' decision to grant the Sputnik V vaccine emergency approval in August 2020 sent shock waves across the scientific and policy-making communities. How did Russia acquire the capacity to develop and produce a vaccine against SARS-Cov-2 so quickly? Based on a case study of the institutions and firms involved in the development and production of Sputnik V, I argue that this capacity results from efforts by Russia's national security state to turn a Cold War advantage in the development of biological weapons into a contemporary public health advantage in vaccine and drug development. Since at least the late 2000s, the Russian state has pursued a form of security motivated statecraft aimed at supporting both the growth of handpicked domestically-owned biotechnological firms – with their growth being deemed essential to ensuring the pharmaceutical security of Russia's population and Armed Forces – and the upgrading of state research institutes involved in Russian biodefense – i.e. in defending civilians and military troops against naturally occurring dangerous pathogens or pathogens potentially used in biological weapons. Yet contemporary Russia has also supported those specific firms and research institutes largely because these have had a pre-existing competitive advantage in the science of genetic engineering that they inherited from their involvement in the Soviet Union's enhanced – effectively, the world's most advanced – biological weapons program from the mid-1970s until the early 1990s in direct violation of the 1972 Biological Weapons Convention.

Keywords

Biodefense, biological weapons, biotechnology, COVID-19, national security state, Russia, vaccines.

1. Introduction*

In early August 2020, Russia took almost everyone by surprise as it became the first country in the world to grant a vaccine against COVID-19 – its homegrown "Sputnik V" (Gam-COVID-Vac) – emergency approval (Kremlin.ru, 2020). This move was undoubtedly a publicity stunt. Kirill Dmitriev, the head of the Russian Direct Investment Fund – the sovereign wealth fund that has bankrolled preparations for the mass production of the vaccine and has helped market it around the world – talked about a "Sputnik moment" and argued that "Americans were surprised when they heard Sputnik's beeping. It's the same with this vaccine. Russia will have got there first" (Chance, 2020; see also sputnikvaccine.com, 2021).

Since Sputnik V was approved before large-scale Phase III randomized controlled trials were even carried out, scientists initially expressed their skepticism about its safety and efficacy (Callaway, 2020). The World Health Organization urged Russian authorities not to cut any corners and to go through all the required trials before licensing it for roll-out (AFP, 2020b). Yet, once the results of the Phase III trials were reported in *The Lancet* in early 2021 (Logunov et al. 2021), the vaccine started gaining legitimacy within the scientific community (Jones and Roy 2021; van Tulleken 2021) even if it continued arousing contention both among the public – including among numerous "anti-vaxxers" in Russia (Vlassov, 2021) – and among various governments targeted by Russia's vaccine diplomacy (e.g. Higgins, 2021).

Regardless of the scientific and political controversies that Sputnik V has sparked, there is no doubt that the state research institutes that have developed this vaccine have demonstrated scientific excellence whereas the privately owned biotechnological firms producing it have made some steps towards becoming internationally competitive national champions. That Russia should have such institutions and firms would come as a surprise to many observers of the Russian political economy since a typical focus of social science research on that country has been on the predatory and corrupt practices of its business and state elites (Gans-Morse 2012; Ledeneva 2013; Yakovlev, Sobolev and Kazun 2014; Vasileva, 2018; Åslund 2019) and on whether those practices and the rise of authoritarianism have been facilitated by Russia's vast endowment in gas and oil becoming a "resource curse" (e.g. Ahrend, 2005; Jones Luong and Weithal, 2010; Ross, 2012, p. 229). To be sure, some analysts have documented Russian rulers' attempts to build East-Asian-style "developmental" institutions so as to help increase their country's economic competitiveness (Gel'man 2016; Bluhm and Varga 2020), but pockets of institutional excellence and of economic efficiency are believed to be rare (Freinkman and Yakovlev 2015), leading some to even label Russia as a "failed developmental state" (Szakonyi 2020). Yet, as I will argue, Russia's success in the specific niche of COVID-19 vaccine development and, to a lesser extent, in vaccine production should not be considered puzzling at all.

Why has Russia had the capacity to develop and produce the Sputnik V vaccine so quickly? Key to answering this question is the proposition that states and firms build comparative advantage in different types of economic activities depending on whether they are motivated mainly by economic ambitions or by security considerations (Weiss and Thurbon 2021). Modern vaccine development and production have become increasingly reliant on advances in biotechnology (Josefsberg and Buckland 2012), but biotechnology in general and vaccines in particular have dual-use potential, that is they can have both civilian and military usage (Atlas and Dando, 2006). Driven by economic motivations over the biotech industry's capacity to generate high value added, many governments around the world – including Russia – have tried to build institutional ecosystems that would help support the biotechnology

* I would like to thank Cornel Ban for our rich exchanges on the content of this paper and look forward to continuing our collaboration on the topic. I would also like to thank an anonymous reviewer and the participants of an online workshop on Covid-19 in Central and Eastern Europe – especially, paper discussant Vera Šćepanović – for their comments on earlier drafts of this paper. Last but not least, I am grateful to Dorothee Bohle, Daniele Caramani and Lorenzo Cicchi for their support in getting this version published in the *RSC Working Papers* series.

industry's growth. However, biotech firms typically have no commercial incentives to develop and produce vaccines against rare viruses (Martins et al., 2016, p. 1101).

I argue that the crucial ingredient that has made Russia competitive in the development and production of advanced vaccines is its present and the Soviet Union's past as a "national security state" (NSS) that has striven to achieve military and technological parity with – if not supremacy over – its most serious rivals, particularly the United States (on America as an NSS, see Weiss 2014). Since at least the late 2000s, the Russian state has actively implemented a form of security motivated statecraft to support both the growth of domestically-owned pharmaceutical and biotechnological firms – with domestic pharma and biotech being deemed essential to ensuring the pharmaceutical security of Russia's population and Armed Forces – and the upgrading of state research institutes involved in Russian biodefense – i.e. in defending civilians and military troops against naturally occurring dangerous pathogens or pathogens potentially used in biological weapons. Yet contemporary Russia has also supported specific biotechnological firms and biodefense research institutes because these had inherited precious technical know-how in genetic engineering from their involvement in the Soviet NSS's enhanced – effectively, the world's most advanced – biological weapons program from the mid-1970s until the early 1990s in direct violation of the 1972 Biological Weapons Convention (Leitenberg and Zilinskas, 2012).

I do certainly not claim that Russia's capacity to develop and produce the Sputnik V vaccine directly stems from the Soviet bioweapons (BW) program, but I show that the state research institutes that have developed the vaccine and the facilities upon which the largest Russian producers of Sputnik V were built were all directly or indirectly involved in that program and, at the very least, in Soviet biodefense. All of these institutions and firms have continued relying on the science base of Soviet biowarfare and biodefense. While that science base could have faded into oblivion with the Soviet Union's collapse in 1991 and with Russia's crises throughout the 1990s, it has been maintained and subsequently renewed and converted for public health purposes through security motivated statecraft targeting these former Soviet state research institutions and emerging Russian biotech firms in the 2010s. Once the COVID-19 pandemic broke out, the Russian state was able rapidly to mobilize research institutes and firms with decades of experience in areas of science with direct relevance for vaccine development and production.

Understanding the sources of comparative advantage and of national trajectories of economic development lies at the heart of political economy. It has long been recognized that those sources are to be found not only in countries' resource endowments, but also in their institutions (Porter, 1990; North, 1991; Hall and Soskice, 2001). Although many scholars have paid attention to the role of "autonomous" state interests and state actors in shaping national institutional environments (Evans et al., 1985; Doner et al., 2005; Block, 2008; Schmidt, 2009), most political economists have considered the economic sphere – with economic interests and ideas being mediated by political parties and interest groups in the political sphere – as the most influential source of institutional design and change (e.g. Gourevitch, 1986; Sokoloff and Engerman, 2000; Hall and Thelen, 2009; Frye, 2010; Beramendi et al., 2015). This focus on the economic sphere certainly became dominant with the end of the Cold War and the triumph of the liberal international order. Yet, in the years following the global financial crisis of 2008, state interests – particularly those stemming from states' security[1] concerns and countries' unequal position in the international order – started regaining attention even though the focus has mainly been on the case of the American hegemon (Weiss, 2014; Mazzucato, 2015; Oatley 2015; LeBaron et al. 2021; Schwartz, 2021; Weiss and Thurbon, 2021). This paper directly contributes to this growing literature on the security-economy nexus by enlarging its geographical scope and by showing how superpower rivalry has also shaped technological upgrading in post-Soviet Russia.

[1] Interestingly, there has also been a resurgence of interest in the links between security concerns and the rise of welfare states, including healthcare systems (Obinger and Petersen 2015).

In the next section, I further develop the paper's argument. I then provide evidence for it through a case study of the origins of Sputnik V. It should be noted that, due to the potential political sensitivity of some of the issues[2] discussed in the paper, I have not sought to conduct any interviews and only rely on – surprisingly rich – published and/or publicly available information on the institutions and firms described in the paper. This means that I cannot really open the "black box of causality" and that the empirical strategy I use is closer to the congruence method than it is to process tracing (George and Bennett, 2005; Beach and Pedersen, 2016). The last section concludes and situates Russia's pathway towards COVID-19 vaccine development and production in a comparative perspective.

2. Developmental states and national security states

While political scientists have recently started exploring the politics of vaccination policies (Ansell and Lindvall, 2020: Chapter 8), they have largely ignored the political economy of vaccine development and production. By contrast, there is a rich literature on the rise of the biotechnology industry, which now plays a crucial role in developing vaccines. States and their developmental institutions have been actively involved in promoting this sector whose product – particularly drug and vaccine – development process is characterized by inherent uncertainty (Wong, 2011).

Governments have created various types of developmental arrangements that have effectively tried to address the "three challenges" characterizing biotechnology: "first, accessing a science base that generates new knowledge and intellectual property; second, obtaining early funding for the timely development of a viable product; and third, navigating commercial and regulatory demands in taking the product to market" (Gilding et al, 2020). One typical policy instrument that potentially provides a – partial – solution to all three challenges is the creation of incubators and technology/science parks around universities or other types of research institutions. Such parks not only facilitate the diffusion of scientific knowledge and the creation of university spin-offs, but they also typically establish an administrative infrastructure that offers support to entrepreneurial researchers in, for example, finding seed funding for the commercialization of their research findings or in designing business plans and accessing management consultancy services to help them take their product to market (e.g. Casper, 2000; Chiaroni and Chiesa, 2006; Zhang, Cooke and Wu, 2011). Another widely used strategy to address the second challenge identified above has been to get states involved in venture capital either through direct state provision of venture capital funds or, increasingly, through the creation (state-owned) funds of (privately owned) venture capital funds (Klingler-Vidra 2018).

State support for biotechnology has also been shown to have been a key success factor in the rise of the national biotech industry that is widely considered as the leading one in the world, namely American biotech (Block, 2008, pp. 176-178; Mazzucato, 2015, chapter 3). A key role here has been played by the National Institutes of Health (NIH), a medical research agency of the Department of Health and Human Services (DHHS), that has not only massively funded – public and private – research on genetic engineering, but has also lobbied policymakers to eliminate any regulatory barriers that might prevent scientists from pursuing research in this area (Ibid.). Although Block's and Mazzucato's analyses would suggest that the US's developmentalism in the biotech area has been driven by public health concerns, Linda Weiss (2014) – who characterizes the US as a "national security state" pursuing perpetual innovation for military preparedness instead of using Block's concept of a "hidden developmental state" or Mazzucato's notion of the "entrepreneurial state" – has suggested that a more important driver has been security considerations.

Weiss argues that "health is a quintessentially dual-use agency, with one foot in the civilian sector and the other firmly planted in the NSS" (Ibid, p. 25). She indicates that, after the Second World War, the NIH partly inherited the charge of defending the health of US service personnel and of defense

[2] For example, note that "it has been made a crime for anyone in present-day Russia to divulge information about the former offensive BW program" (Leitenberg and Zilinskas, 2012, p. xii).

against biological and chemical weapons. During much of the post-war period, cooperation between the U.S. Department of Defense (DoD) and the NIH in those areas was institutionalized in a Chemical-Biological Coordination Center of the National Research Council (Ibid.). Furthermore, Weiss argues that, following President Nixon's decision to phase out the US's bioweapons program and the ratification of the Biological Weapons Convention (BWC) of 1972, "the federal government deployed the conversion process to kick-start a commercial dual-use biotechnology industry, transferring to the private sector a good deal of the technology that had been locked up in government labs" (Ibid., p. 35). Weiss mentions the example of the conversion in 1972 of some of the Army's former biological warfare facilities in Fort Detrick, Frederick, Maryland – where the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the main institution for America's military biodefense, continues to be located – into a laboratory of the NIH-run National Cancer Institute (Ibid.).

There are further examples of such connections between the military and the US biotechnological industry. The state of Maryland has a strong biotechnology cluster concentrated in-between Frederick and Washington, DC with many of its firms being actively engaged in providing services to military research institutions (Feldman and Francis, 2003). Military laboratories – particularly the Walter Reed Army Institute of Research, the DoD's largest biomedical facility – have also been a major source of entrepreneurs in the Maryland cluster (Feldman, 2001). After 9/11 and the 2001 "anthrax letters" bioterrorist attack, the US government created new programs such as Project Bioshield that was coordinated by the newly created Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (Lentzos, 2006; Weiss, 2014, p. 49). Spending on biodefense research increased 20-fold over the five years following the attacks (Reppy, 2008, p. 802). Remarkably, the DHHS, the NIH, BARDA, the DoD – including its Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and the Defense Advanced Research Projects Agency (DARPA) – have all been mobilized to support the development of COVID-19 vaccines as part of "Operation Warp Speed" (Slaoui and Hepburn, 2020).

The US emerged as an NSS during the post-war period because of its rivalry with the Soviet Union. "The Cold War was not simply an arms race but a science and technology race, as both the United States and the Soviet Union concentrated their resources to gain a technological edge over and impose technological surprise on each other" (Weiss, 2014, p. 37). Although Weiss does not explicitly label the Soviet Union itself as an NSS, I believe that it is fair to do so. To be sure, the USSR's command economy proved to be much less efficient than American capitalism, but – as emphasized by Weiss herself – much of it was organized around a perceived need to ensure military and technological supremacy over the US. So was Soviet science, which, from the 1920s, was reorganized in order to meet "a specific obligation: the strengthening of the industrial and military power of the Soviet Union" (Graham, 1975, p. 324). Soviet science was overwhelmingly organized around a system of research institutes attached to the Soviet Academy of Sciences or to specific ministries with a focus on "big technology" relevant to the military (Graham, 1992). More than two thirds of overall research and development (R&D) expenditure "went into military research; the defense industry was the major client of many, if not most, academy institutes" (Mayntz, 1998, p. 788). That specific system caused huge embarrassment in America when it managed to launch Sputnik into space in 1957 (Weiss, 2014, pp. 31-34). Perhaps the last technological surprise it caused was when, from the late 1980s, the West found out about the fact that the USSR had continued pursuing an upgraded offensive biological warfare program throughout the 1970s and the 1980s despite it ratifying the 1972 BWC.

The substantive focus and organizational structure of the Soviet biowarfare program have been documented in much detail by defectors of the program (Alibek, 1999), other former participants (Domaradskii, 2003) and researchers (e.g. Leitenberg and Zilinskas, 2012; Rimmington, 2003; 2019). An essential characteristic of the program was that it relied both on a military component and on a civilian one. Both components were coordinated by the Fifteenth Directorate of the Ministry of Defense (MOD). MOD facilities based in the cities of Kirov, Sverdlovsk (now Yekaterinburg) and Zagorsk (now Sergiyev Posad) constituted the core of the program. Remarkably, a civilian *Ferment* program involved

a very extensive network of research institutes, production plants and storage facilities controlled by the All-Union Science Production Association "Biopreparat", which was itself placed under the authority of the Main Administration of Microbiological Industry (*Glavmikrobioprom*). Institutes from the USSR Academies of Sciences and Medical Sciences were also involved in Ferment (Leitenberg and Zilinskas, 2012, p. 8). So was the Ministry of Health which "gave institutions outside of the military permission to work with pathogens" (Ibid., p. 72). In addition, the Ministry of Health coordinated a so-called "Program 5" biodefense program (Ibid., Chapter 5). Finally, the Ministry of Agriculture ran an *Ekologiya* program "to produce biological weapons directed against animals and plants" (Ibid., p. 9).

The whole Soviet BW program is estimated to have involved between 40,000 and 65,000 "scientists, engineers, technicians, and infrastructure support personnel" (Ibid., p. 700) and is believed to have given the USSR a "research and development advantage … on any foreign opponents" (Lilja, Roffey and Westerdahl, 1999 cited in Rimmington, 2003, p. 5). The program was officially phased out from 1992 following trilateral negotiations between the United Kingdom, the United States and Russia with Western countries providing financial assistance to help former civilian BW facilities convert to peacefully directed pursuits (Leitenberg and Zilinskas, 2012, chapters 22 and 23). Yet Russian authorities' refusal to allow foreign visitors in former military BW facilities has led some countries – particularly the US – to suspect that those facilities might still be pursuing offensive-directed activities (Rimmington, 2003).

Economic geographers have shown that regional patterns of innovation in contemporary Russia are still influenced by Soviet policies since endowment with Soviet-founded "science cities" remains a strong predictor of current patenting (Crescenzi and Jaax, 2017). I argue that, in the case of COVID-19 vaccines, Russia's capacity to develop and produce such vaccines has not only been influenced by its contemporary security motivated statecraft targeting biotech firms (see Zvonareva, 2020, chapter 4) and biodefense institutions, but is also still largely the legacy of those firms' and institutions' involvement in the Soviet BW program. With their focus on the genetic engineering of dangerous viruses or bacteria, biowarfare programs lead to the accumulation of a highly specific science base that cannot be easily reproduced. Russia not only inherited such a science base from the Soviet Union, but, with its renewed ambition to exert a leading role on the global stage, it has sought to rebuild some of its capacities as a "national security state", particularly in biodefense and biotechnology with direct applications to public health challenges.

Reliance on the traditional tools of economically motivated industrial policies for biotech described above would have been insufficient for the rapid development of vaccines against rare viruses because it would lead to the creation of firms that lack the commercial incentives to invest in R&D needed for such endeavors. As has been suggested by a team of USAMRIID and NIH virologists from Fort Detrick, "development of vaccines for protection against infection with rare or exotic pathogens typically falls into the spheres of public health and/or biodefense. Such development does not, however, often pique the interest from the pharmaceutical industry. With little financial incentive to justify a private company's investment into vaccines that only few people would actually need, candidate vaccines for rare diseases often languish at the research bench stage, regardless of the strength of the preclinical studies assessing them" (Martins et al., 2016, p. 1101). Given Russia's comparatively low expenditure on healthcare and low gross expenditure on R&D (see Appendix A.1), it is highly unlikely that strong capabilities for the development of vaccines against rare or exotic pathogens could emerge from Russia's sphere of public health. However, in Russia's NSS, a historically well-developed and recently revamped sphere of biodefense has ensured exceptional readiness for such development, including in the case of SARS-CoV-2 .

I now move on to the empirical evidence.

3. Developing the Sputnik V vaccine

In the summer of 2020, Kirill Dmitriev, the head of the Russian Direct Investment Fund – the sovereign wealth fund that has bankrolled research on the Sputnik V vaccine and has helped market it around the world –, appeared in numerous English-speaking media in order to defend the vaccine's credibility after Russian authorities' controversial decision to authorize it before Phase III trials. In several interviews, Dmitriev insisted on the fact that Sputnik's human adenoviral vector technology – based on adenovirus type 26 (Ad26) for the first shot and adenovirus type 5 (Ad5) for the second one – had been "proven safe over the last few decades" and that "for example, the US military gives all of its conscripts human adenovirus vaccines since 1971. So, it is very different from the mRNA and the monkey adenovirus approaches that are new" (Bloomberg, 2020: 0:20-0:40; see also CNBC International TV 2020a: 3:36-4:25; 2020b: 2:15-3:00).

The US Army had indeed started vaccinating its trainees against adenovirus types 4 and 7 in the early 1970s – and, after a 12-year gap, reintroduced such vaccines in 2011 – because acute respiratory disease caused by these viruses had been a leading cause of hospitalization in U.S. Army personnel (Top, 1975; Radin et al. 2014). Adenovirus *vectors* started being massively researched from the 1980s because they offered a promising system for gene therapy and vaccine development (e.g. Graham and Prevec, 1992; Kozarsky and Wilson, 1993). Their potential as platform technologies for vaccines against biowarfare or bioterror pathogens such as anthrax, plague and Ebola had also been recognized for a long time (Boyer et al. 2005). Yet, by early 2020, the only adenovirus-based vaccine to have ever been granted marketing authorization in the OECD – more precisely in the European Union – was the Zabdeno-Mvabea Ebola vaccine whose adenovirus-based Zabdeno (Ad26.ZEBOV) component had been developed by Janssen Pharmaceutical Companies of Johnson & Johnson (J&J, 2020). In 2017, China had also approved an Ad5-based vaccine for Ebola – developed by Chinese biotech firm, CanSino Biologics -, but only for emergency use and national stockpiling (Cross, 2020).

Why did Kirill Dmitriev mention the US Army's work on adenovirus vaccines during his interviews on Sputnik V? And why did he, for example, never mention the direct involvement of the Russian Armed Forces in developing the vaccine? Given the controversies surrounding Sputnik V, it seems plausible that, by putting the spotlight on the former, he was hoping to avoid being interrogated by journalists on the latter – in which, surprisingly, he succeeded. While the emphasis in the mass media has been on the role played by the Gamaleya National Center of Epidemiology and Microbiology of the Russian Ministry of Health (MOH) in developing the vaccine, one of the co-authors of the papers on Sputnik V published in *The Lancet* and one of the people listed as one of the leaders of the "Sputnik V Team" on the vaccine's official website is Sergei Borisevich, the head of the 48th Central Scientific Institute of the Russian Ministry of Defense (MOD; Logunov et al. 2020; Logunov et al. 2021; see appendix A.2.). Researchers at that Institute conducted pre-clinical trials on monkeys and hamsters and clinical (Phases I and II) trials on several dozens of volunteers among military personnel including medical staff from the Main Military Clinical Burdenko Hospital in Moscow (Logunov et al. 2020, p. 889; TASS, 2020a).

In *Krasnaya Zvezda* (Red Star) – the official newspaper of the Russian Armed Forces, Borisevich said:

> It would be impossible to even start designing a vaccine without studying the biological properties of the pathogen COVID-19 and without characterizing the vaccine strain. But the 48th Central Research Institute has already worked out the methodology for the quantitative assessment of the pathogen and has developed a laboratory model that allows reproducing the course of SARS-CoV in order to assess the protective efficacy of drugs. Patents for these inventions belong to the Institute. (…) In this regard, the experience of 2003 – when our employees were actively involved in the fight against SARS – helped us significantly to reduce research time. I note that it was in the 48th Central Research Institute that, for the first time in Russia, the causative agent of SARS was isolated and modern diagnostic test systems for its determination were developed. (…) For almost 80 years of its existence, the Institute has issued dozens of vaccines – including against

> plague, anthrax and smallpox – to the state, which were actively used in the past and continue to be used in the present (Alekseev, 2020).

Based in the city of Kirov since 1941, the 48th Institute used to be known as the Red Army's Scientific-Research Institute of Epidemiology and Hygiene and is notorious for having been the "hub" of the Soviet biological weapons (BW) program (Rimmington, 2019, p. 176; Leitenberg and Zilinskas, 2012). A Trilateral Agreement signed between Russia, the United States and the United Kingdom in 1992 prescribed that the three signatories would be able to hold visits of their BW-related facilities, but Russian authorities have ever since refused to give foreigners access to the Kirov Institute and to two other military facilities – located in Yekaterinburg and in Sergiyev Posad – that have been closely associated with it thereby arousing suspicion that Russia may have maintained an offensive BW program (Trakimavičius, 2018). After the poisoning of opposition figure Alexei Navalny with the Novichok nerve agent – in violation of the Chemical Weapons Convention – in August 2020, these three specific facilities were blacklisted by the US Department of Commerce (Bureau of Industry and Security, 2020) before being sanctioned by the US Department of State (Department of State, 2021). Kremlin spokesman Dmitry Peskov berated the sanctions as "absolute nonsense" (TASS, 2020b).

In another interview in Krasnaya Zvezda, the director of the Gamaleya Institute, Alexander Gintsburg, explained that:

> Together with the Ministry of Defense of the Russian Federation, primarily with the 48th Central Research Institute, we managed to pass virtually all research and preclinical tests in record time. This became possible because, before that, we had developed several vaccines and drugs [among others against Ebola – see Dolzhikova et al., 2017] that were registered in the Russian Federation. (…) Scientific cooperation of our institute with medical organizations of the Russian Federation's Ministry of Defense began a long time ago – not only when I became the director of the Gamaleya Institute, which, by the way, was 24 years ago. I inherited this cooperation. (…) I am very grateful to the Defense Department… for their very fruitful and high-quality work. (…) I would like to note that not once in the long history of our scientific contacts have we had to double-check or alter something. Hopefully, colleagues are giving the same feedback on the results of the interim studies that we are passing on to them. This allows you to achieve the desired result in a very limited, strictly regulated time frame (Biryulin, 2020).

The Gamaleya Institute is a public health institution, but, in the Soviet Union, the Institute was also the hub of the so-called "Problem 5" program aimed at protecting the population against highly dangerous or exotic pathogens, including those used in biological weapons possessed by foreign countries (Leitenberg and Zilinskas, 2012, Chapter 5; see also Zilinskas, 2006). The program "had entire closed institutes dedicated to it, as well as laboratories within the Biopreparat institutes and otherwise open institutes" (Leitenberg and Zilinskas, 2012, p. 146). In principle, Problem 5 was a biodefense program, but it is believed to have contributed to the Soviet offensive BW program, for example by handling and supplying virulent pathogens to *Biopreparat* and MOD biological facilities "that were subsequently developed for military purposes" (Ibid., p. 151). The program was run by a commission that was headquartered at the Gamaleya Institute. "The organizational structure of Problem 5 was straightforward. The MOD decided what work needed to be done under Problem 5 and issued the required task orders to the MOH's 2nd Directorate, which forwarded them to the Problem 5 Commission [at Gamaleya]" (Ibid, p. 144). Regardless of the exact nature of Problem 5, Gamaleya's central position in it means that the Institute was a direct consumer and producer of state-of-the-art research in genetic engineering that, given its central importance in the Soviet Union's world-leading BW program (Leitenberg and Zilinskas, 2012, Chapters 2 and 7-9), must have also been central for civilian biodefense.

In explaining the success factors of the exceptionally rapid development of Sputnik V, Gamaleya researchers have been emphasizing the importance of the science base of the Soviet Union. On the state-owned television's news service Vesti, Gamaleya's deputy director, Denis Logunov said: "Epidemics

do not happen often. But you must be ready all the time for this. You must have technologies, specialists of a certain level. Nothing could have been done without people and without the school that was founded in the Soviet Union" (Erofeyeva, 2021). Anatoly Altstein, chief researcher at the Institute, said: "already in the 70s-80s, work has begun on the genetic engineering of adenoviruses at the Institute of Virology, under the leadership of Professor Tikhonenko" (Ibid.). Logunov added: "The founding father of all this technology in Russia is Boris S. Naroditsky. This is my teacher. He began his work in the late 70s of the last century" (Ibid.). Naroditsky himself stressed: "This is the strength of the Gamaleya Institute. Here, the continuity of generations is preserved. This is something that was very lost in the 90s in many institutions. (…) This is an essential component" (Ibid.). Alexander Gintsburg also emphasized that "one of [his] main achievements as director… is that four generations of employees are now working at the Gamaleya Institute, and they are actively working – 90-year-old employees - Zuev, Kostyukov, Ershov, Lvov – and 25-year-olds. The platform began to be created 20, or even 25 years ago" (Vesti, 2021).

Of course, the science base of the Institute and other institutions involved in epidemiological research and in biodefense had to be cultivated and renewed in recent decades. One important state initiative was a 1999 federal target program called "Protection against pathogens" one of whose main objectives was the "restoration and development of the scientific, material and technical potential of research organizations of biotechnological profile, including through the reconstruction, the technological and technical re-equipment of the experimental-production and production base" (Russian Government, 1999; see also Leitenberg and Zilinskas, p. 661 and p. 673). Among other things, the program allocated funds to the "technical re-equipment of the experimental production" of the Gamaleya Institute and to the "reconstruction and technical re-equipment" of facilities in Kirov, Yekaterinburg and Sergiev Posad (Ibid.).

At Gamaleya, research on adenovirus vectors was effectively relaunched in the 2010s with the outbreak of epidemies of Ebola and MERS. As explained by Alexander Gintsburg, "when it was necessary to create a new technology against those pathogens against which there were no vaccine preparations 10 years ago, we evaluated this [adenovirus-vector] technology, and Denis Y. Logunov and his employees began to actively use this technology to create … a vaccine against the pathogen Ebola and against another coronavirus, the MERS coronavirus" (Vesti, 2021).

Noteworthy here was the collaboration between Gamaleya and the MOD's 48th Central Scientific Institute to develop the – partly Ad5-vector-based – *GamEvac-Combi* vaccine against Ebola which, like Sputnik V, was authorized by Russia in late 2015 for emergency use after Phase I and II clinical trials (see section 1 of Appendix A.3; see also affiliations of authors of Dolzhikova et al. 2017 in Appendix A.4). Phase III trials were conducted over two thousand volunteers in Guinea between 2017-2019 (Africaguinee.com, 2019), but the vaccine has not received full approval from a public health body to date. Those Phase III trials provide a striking example of how Russia's renewed security-motivated statecraft has relied on military-civilian collaboration: Indeed, they were conducted at a "Centre for Microbiological Research and Treatment of Epidemiological Diseases" that had been built in 2015 by the Russian aluminium company Rusal – for $10 million – in the city of Kindia where Rusal has been managing one of the world's largest bauxite mines since 2002. Before the centre was built, Rusal had already been "actively involved in deploying a mobile 200-bed hospital for the Ministry of Defense of the Russian Federation, which was donated to the Republic of Guinea in accordance with a decision by the President of Russia" (Rusal.ru, 2015). French newspaper *Le Monde* cited a Guinean health ministry official anonymously as saying that only Russians had access to the new centre's laboratories, that they could "do what they want" and that there was no doubt that the researchers were from the Russian military (Freudenthal and Hecketsweiler, 2019).

In sum, it is highly improbable that Russia would have been able to develop Sputnik V so fast had it not directly inherited from the Soviet Union's advanced biowarfare-related research and had it not upgraded that research after its own reassertion on the global stage in the 2000s. As put by Gamaleya's Boris Naroditsky, "eight months is very fast. But there is an explanation. We have been accumulating

experience over the past 35 years. In 2015, we registered an Ebola vaccine where we used an adenoviral vector as a component. That is, we went all the way on Ebola. We already had experience" (Erofeyeva, 2021).

4. Producing the Sputnik V vaccine

Not only were the Gamaleya Institute and the 48th Central Scientific Institute able to develop the Sputnik V vaccine in record time, but, apart from Gamaleya itself, six Russian pharmaceutical and biotechnological firms – Binnopharm, Biocad, Generium, Lekko, R-Pharm and Pharmstandard – have been involved in producing it (Rogoża and Wiśniewska, 2021). To be sure, those firms have majorly struggled to scale up production. Although the Russian Direct Investment Fund (RDIF) and Gamaleya had signed agreements committing them to produce several hundreds of millions of vaccines for foreign countries, Russian firms had only turned somewhat more than 30 million vaccines (i.e. based on the two components of Sputnik V) out by mid-May 2021, which paled in comparison with the hundreds of millions of doses being manufactured each month by their Western counterparts (Nikolskaya and Ivanova, 2021). The firms had not produced high-tech viral vector vaccines on a massive scale before the COVID-19 pandemic and had to repurpose their existing facilities to that end once Sputnik V had been developed.

The founder and chief executive officer of Biocad, Dmitry Morozov, explained that "vaccines are not our core competence. We make more complex drugs for the treatment of cancer, autoimmune diseases" and that "nobody was ready. One of the key problems is that Russia still has practically no own production of pharmaceutical substances, without which it is impossible to create any drugs at all, including vaccines. Most companies import raw materials. We warned many times that this issue needed to be addressed, but nothing was done. (…) When the pandemic began, Russia immediately lost these supplies, as foreign companies focused on providing raw materials primarily to their own countries" (Kotova, 2021).

From that point of view, agreements negotiated by RDIF with Indian and Chinese companies to mass-produce Sputnik V abroad were essential for Russia to be able to honour its commitments towards foreign governments (RDIF, 2021; Wu and Litvinova, 2021). In Russia itself, President Vladimir Putin and government officials held regular meetings with biotech and pharma firms to discuss efforts at increasing the manufacturing capacity of COVID-19 vaccines (e.g. Kremlin.ru, 2021). As part of those efforts, RDIF also funded the construction of new production facilities for the manufacturing of some of the active pharmaceutical ingredients needed for the production of biotech vaccines (RDIF, 2020).

Yet, in comparison with the almost total lack of involvement of EU-based CEE biotechnological firms in the production of COVID-19 vaccines, the capacity of Russia's hitherto largely unknown biotech firms to produce adenoviral vector-based vaccines is still remarkable. How did these firms acquire this technological capacity? The explanation lies in Russian biotech entrepreneurs' readiness to tap not only into state support provided as part of Russia's more recent "economically motivated statecraft", but also into the science base of the USSR's bioweapons program. We illustrate this argument through an analysis of the rise of the two largest Russian producers of the Sputnik V vaccine.

Among the six firms producing Sputnik V, Generium is the "biggest producer" while Biocad is considered as "the only other major producer" (Nikolskaya and Ivanova, 2021). Together with Lekko and Pharmstandard, these two firms are effectively controlled by Viktor Kharitonin, an "oligarch" who appears in the Forbes Billionaires List (Forbes.com, 2021). Generium – which describes itself as the leader in Russia's market for "orphan" drugs (Generium.ru, 2021) – was established in 2009 as a joint venture between Lekko and Pharmstandard. Biocad was founded by banker Dmitry Morozov in 2001. Kharitonin and his associates acquired a controlling stake in it in 2014.

Generium and Biocad both benefited from strong state support as part of "Pharma 2020". This import-substitution program was launched in 2009 by the Ministry of Trade and Industry (MTI) under

the aegis of President Dmitry Medvedev (Zvonareva, 2020, chapter 4). Its aim was to reduce Russia's dependence on pharmaceutical products – generics and more advanced drugs and vaccines – developed by foreign pharmaceutical companies from 80% of all drugs sold in Russia to 50% by 2020 (Ibid.). Pharma 2020 was also clearly presented as an initiative designed to strengthen national security for example by securing supply of domestically produced drugs – particularly those against rare diseases – to the Russian population and the defense sector (Zvonareva, 2020, pp. 111-112). The program was defined in close consultation with the Russian pharma industry. Biocad's Morozov described himself as "one of [its] authors" (Biocad.ru, 2015). From the beginning of the program, Generium and Biocad were at the center of two "priority" projects out of five such projects presented by the MTI (Finmarket, 2009). The Generium project was to result in the creation of a high-tech research center in biotechnology. Biocad was to develop "a full cycle of production of drugs based on monoclonal antibodies… [which] are highly effective in the treatment of the most common cancers" (Ibid.). Both companies were to benefit from sped-up registration procedures for drugs.

Generium's original infrastructure was financed by Lekko and Pharmstandard, but it has been allocated land for that infrastructure by the Vladimir Region (Ria Novosti, 2011). It has also benefited from a preferential loan from the MTI-controlled Industrial Development Fund to further develop its facilities (IDF, 2018). Originally based in the outskirts of Moscow, Biocad moved its headquarters to St Petersburg in the early 2010s. In doing so, it saw Russia's development bank Vnesheconombank finance a large part of its new complex on the "Noydorf" territory of the St. Petersburg special economic zone that has set the establishment of a cluster in medical technologies and pharmaceuticals as one of its priority areas (pharmvestnik.ru, 2012). Like Generium, Biocad benefited from a preferential loan from the Industrial Development Fund to expand that new site (IDA, 2016). In addition, Biocad became a resident of the Zelenograd-based (Moscow) "Technopolis" special economic zone that also has medtech and life science as a priority area. The firm was allocated a site there and built a new plant on it as a condition of a 2017 contract signed with the Moscow Department of Health under which Biocad became Moscow's sole supplier of anticancer drugs in 2021-2027 (Kotova, 2017).

While directly benefiting from the Russian Federation's new developmentalism in the 2010s, both Generium and Biocad have their beginnings in specific entrepreneurs' decision to use former *Biopreparat* closed facilities and their staff as the foundation for establishing their firms and their R&D centres.

Generium is located in the Volginsky "settlement" (*posyolok*) about 100 kilometres east of Moscow. This is also where Lekko is located. Before Kharitonin's Pharmstandard supported the Generium project financially by setting up a joint venture, it is Lekko that had been planning a project to establish a 60 million euro "Genetic Engineering Center" for the development and production of new generation medicines (Novecon, 2007). CNN has reported that Generium is located on a site where "decades ago, Soviet scientists researched biological weapons", but did not provide further details (Ullah and Chance, 2021). While very little information can be found on this specific site, American bioweapons expert claim that facilities in Volginsky participated in "an organized BW program of the Ministry of Agriculture, codenamed 'Ekologiya'" with the aim to develop "anti-animal and anti-plant weaponry" based, among others, on anthrax (Kuhn and Leitenberg, 2016, p. 95; see also Leitenberg and Zilinskas, 2012, Table 6.1, p. 161; Vogel 2000: Table 1, p. 4).

Lekko's official company website reports that the company "began its activity in 1993 on the basis of one of the production buildings of the Pokrovsky plant of biological preparations with the production of probiotics." The Pokrov plant – which belonged to the Ministry of Agriculture – is also listed as former BW facility (Leitenberg and Zilinskas, 2012, Table 6.1, p. 161). So is the former "All-Union Scientific Research Institute of Veterinary Virology and Microbiology", which "was directly subordinate to the Main Directorate of Research and Experimental Production Institutions of the USSR Ministry of Agriculture" (Ficvim.ru, 2021a) That Institute – which is based in Volginsky – is now called the "Federal Research Center for Virology and Microbiology" (FICVIM) and is managed by the Russian Academy of Sciences. Its main task is to develop "means and methods of defence [particularly vaccines

and diagnostic kits] against emerging, exotic and zoonotic infectious diseases of livestock" (Ficvim.ru, 2021b). Authorships of the Institute's recent scientific publications show that FICVIM and Generium researchers collaborate with each other (e.g. Vassarays et al., 2021).

At the time the Generium centre was built, the company's deputy director-general, Vitaly Pantyushenko, argued that "there was a very intelligent environment in Volginsky from the beginning", but the company saw itself as contributing to the village's "renaissance" because "today, the research and production 'cluster' in Volginsky, which includes several enterprises at once, mainly related to pharmaceuticals, has almost completely used the human potential that is available in the village. (…) Over the past twenty years, the village has lost many professionals, but there are good prospects for their return. It is the emergence of a powerful scientific component that will bring a new breath, because specialists who have already arrived and will still come to work at Generium will organically merge into this environment" (Generium.ru, 2011). During a visit to Generium, President Medvedev emphasized that "it is most important that, on the basis that had existed there, a fundamentally new high-technology center has emerged, which both conducts research and commercializes the results" (TASS, 2012).

The history of the Biocad company and of the R&D centre that allowed it to develop new products has been much better documented. Having worked as a banker in the 1990s, Dmitry Morozov decided in 1999 to set up a start-up that would be the first one to develop and produce genetically engineered pharmaceutical products in Russia (Naumov, Petrovskaya and Puffer, 2008). Morozov first set up a distribution company that manufactured biotech generics, but, as he learnt in 2000 from a Biopreparat manager that one of its research institutes – based in the village of Lyubuchany near Moscow - was going bankrupt, Morozov bought a very large part of it – including laboratories, equipment and scientific staff – and transformed into his company's R&D centre under the designation of the "Centre for Immunological Engineering" (Ibid, pp. 14-17). The Biopreparat institute in question was the "Institute of Engineering Immunology" (IEI) that was created in 1979 (Leitenberg and Zilinskas, 2012, pp. 261-274) and whose main objectives were "to assess the immune response of animals to pathogens of BW interest, to discover immune system weaknesses that could be exploited by new BW agents, to overcome immune responses induced by current vaccines, and to develop vaccines to protect Biopreparat scientific workers from the pathogens on which they worked" (Leitenberg and Zilinskas, 2012, pp. 261-274).

Morozov bought the center because he was intent on tapping into the science base of the Soviet Union's biowarfare program. As he explained to the authors of a case study on his firm:

> "I realized that not all of the scientists were gone and that we had research accomplishments at the world level. It is an exaggeration to say that there are many, but still there are some. Russia had invested more than a billion dollars in biotechnology. It was an opportunity for me to enter the market, and I realized it would be difficult to start from scratch. At the same time, it would not be easy to get high-quality results quickly. The research projects were incomplete, and few products had gone through pre-clinical and clinical testing or had technical documentation for mass production. If we did not bring these ideas to the market, they would just keep gathering dust on the shelves" (Naumov, Petrovskaya and Puffer, 2008, p. 15).

In an official history of Biocad, Valentina Mogutnova, a lead manager-consultant who had worked at the IEI in the 1980s, said that "the structure was closed and worked for defense" (Stogov, 2018, p. 24) and added that "we did not create weapons. On the contrary, the challenge was to develop remedies" (Ibid., p. 25). Yet Roman Ivanov, the company's vice-president of development and research, had a somewhat more equivocal interpretation of the IEI's transformation – and, more broadly, of that of the Soviet Union's biowarfare program – in the 1990s:

> "In the USSR, the scientific base was one of the strongest in the world. But after 1991, the situation changed dramatically. The decisive role in this was played by an international structure called the ISTC (International Science and Technology Center). The countries – the USA, Great Britain, Japan, Canada and several others – that considered themselves the victors in the cold war created that centre. They allocated funds to destroy the technologies associated with the

> production of weapons of mass destruction [in fact, programs such as the ISTC tried to help transform facilities involved in such military programs into civilian – e.g. research or commercial – facilities so as to avoid a migration of scientists involved in these programs towards rogue states – see Brumfiel, 2003; Leitenberg and Zilinskas, 2012, chapter 23] throughout the territory of the former USSR. The task was ambitious: to dispose of nuclear, bacteriological, chemical – any – Russian weapons. Well, let us say they were not allowed to do that with nuclear weapons at that time, but everything else was cleaned up very much. As I understand it, the country's leadership in the nineties believed that there would be no more wars, and there was no longer money to maintain military production. So, let the partners dispose of it, if they so desire" (Stogov, 2018, p. 27).

No matter the type of activity in which the Volginsky-based facilities and the IEI had to engaged in the USSR's "national security state", there is little doubt that it is because they directly built on the science developed in those facilities that Generium and Biocad became potential "national champions" worthy of being supported by Russian's developmental institutions in the 2010s and eventually becoming capable of producing COVID-19 vaccines on an emergency basis.

5. Conclusion

In this paper, I have investigated the institutional underpinnings of Russia's success in rapidly developing and producing an adenoviral vector vaccine against COVID-19 after the pandemic broke out. I have argued that Russia's state research institutions involved in biodefense and, to a lesser extent, a number of Russian-owned biotechnological firms have had a pre-existing comparative advantage in this particular niche not only because of contemporary security motivated statecraft that has been supporting them, but also because of the legacies of the Soviet Union's own security motivated statecraft in the area of biowarfare. Based on a detailed analysis of published material from newspapers, televisions, official company publications and academic literature, I have, firstly, documented some of the institutional support that these entities have received from the Russian state over the past decade or so. Secondly, I have shown that the research institutions in charge of developing Sputnik V and the leading producers of that vaccine were all relatively active participants in the Soviet bioweapons program and that the leaders of many of those institutions and firms still claim that the Soviet research apparatus in genetic engineering had given them an edge in their current R&D.

Surprisingly, these entities' pedigree had been almost entirely overlooked in the international media – and in other commentary – despite their giving Sputnik V extensive coverage. However, some media had picked up on the fact that a second Russian-made COVID-19 vaccine, the peptide-based EpiVacCorona – that was also approved by Russian authorities ahead of Phase III trials –, was developed by Novosibirsk-based "VECTOR, the famed State Research Center of Virology and Biotechnology that once studied bioweapons and now is one of two global repositories of the eradicated smallpox virus" (Dobrovidova, 2021; see also AFP, 2020a; Rudnitsky, 2020; on Vector's role in the Soviet BW program, see Leitenberg and Zilinskas, 2012, chapter 8; see also Brumfiel, 2003).

Despite the controversies its decisions to give early authorizations to COVID-19 vaccines generated, Russia's NSS has undoubtedly managed to put its hitherto largely unknown pharmaceutical and biotechnological industries on the map during the pandemic. Given its long-time support for other high-tech areas such as nanotechnology or the defense industry (Connolly, 2013; Bukkvoll, Malmlöf and Makienko, 2017; Connolly and Sendstad, 2018), it is not impossible that Russia will see new national champions emerge in the coming years.

In the area of vaccine development and production, reliance on strong military-civilian collaboration is certainly not a sine qua non for achieving success: For example, both the Oxford-AstraZeneca (AZD1222) and the Pfizer-BioNTech (BNT162b2) vaccines seem to have been mainly supported – beyond the private sector itself – by civilian state funding. However, Russia has definitely not been the

only country to have relied on military-civilian collaboration in this area. Strikingly, such collaboration has been clearly instrumental in COVID-19 vaccine development in China and the United States, which suggests that the security link in this specific area of biotechnology is most likely strongest in countries aspiring to be superpowers.

Before Chinese authorities approved other vaccines for sale, China's Central Military Commission already approved a first – the adenoviral (Ad5) vector-based CanSino – vaccine for emergency use by the military as early as June 2021 (Liu and Woo, 2020). Like in Russia, this vaccine was approved before Phase III were conducted. As the *Financial Times* reported, "key to CanSino's vaccine development research is [Major General] Chen Wei, head of the Academy of Military Medical Sciences and one of China's leading epidemiologists (…) Dr Chen does not have an official role at CanSino but has previously worked with the company to develop an Ebola vaccine that was manufactured and stored by the Chinese state. Although it was never widely distributed, the vaccine was given to Chinese peacekeeping troops in the Democratic Republic of Congo" (Shepherd and Xueqiao, 2020; see also Lewis, 2020). *FT* journalists added that China did "not have monopoly on medical-military collaboration" and that it had partly taken inspiration from the US's Defense Advanced Research Projects Agency (DARPA) that was working "on a variety of Covid-19 diagnostics and vaccines to help military personnel as well as the wider population. The US Department of Defense, along with the Department of Health and Human Services, is also working with Johnson & Johnson [J&J] on the large-scale manufacturing and delivery of its Covid-19 vaccine candidate" (Shepherd and Xueqiao, 2020).

The scientists in charge of developing J&J's adenoviral vector-based (Ad26.COV2.S) did indeed report, among other sources of support, that "Janssen Pharmaceuticals [J&J's arm in charge of developing the vaccine] and the US Army have a cooperative research agreement (Cooperative Research and Development Agreement, CRADA)" (Sadoff et al., 2020). Moderna's mRNA-based vaccine technology has also been reported to have been largely funded by DARPA (Mancini, 2020; Crow, 2021; Dolgin, 2021, p. 190). This kind of collaboration in the US case should certainly not come as a surprise given some of the conventional wisdom in the literature on the American "national security state" (Weiss, 2014) and the explicit involvement of defense institutions in Operation Warp Speed (Slaoui and Hepburn, 2020). Yet, now that the largest pandemic in a century has also constituted a "big reveal" on the importance of vaccinology (McNamara and Newman, 2020), future social science research might be needed to better understand success factors in vaccine development and, in particular, cross-national similarities and differences in civilian-military collaboration in that area.

One example of a significant difference between the US and its Chinese and Russian rivals is the strong exterritorial reach of military-medical partnerships established by America's NSS. J&J's Janssen Pharmaceuticals is in reality based in Belgium and in the Netherlands. Janssen's unit in charge of vaccines used to be known as Crucell N.V. until it was acquired by Janssen in 2011. Crucell N.V. was established as a spin-off of Leiden University in the Netherlands and had already been collaborating with American institutions such as the NIH, the U.S. Army Research Institute of Infectious Diseases (USAMRIID) or the Walter Reed Army Institute of Research on adenoviral vector-based vaccines against Ebola, Malaria and other pathogens since the early 2000s (Crucell N.V., 2003; 2005; Boddie, 2015). Another foreign firm with strong ties to America's NSS has been German biotech firm CureVac whose mRNA technology platform – which has been used to develop a vaccine against COVID-19 – received significant funding from DARPA from 2012 (CureVac, 2020; Dolgin, 2021, p. 190). Russia is definitely not alone in institutionalizing military-civilian collaborations in biotechnology.

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Appendix A.1: Countries with domestically developed vaccines - some comparative elements

	Domestically developed vaccines approved by domestic authorities (October 2021)	Current health expenditure as % of GDP (2018)	Gross expenditure on R&D as % of GDP	Military expenditure as % of GDP
China	Ad5-nCoV; BBIBP-Corv (Vero Cells); CoronaVac; Inactivate (vero Cells); ZF2001	5.4	2.1	1.7
Cuba	CIGB-66	11.2	0.5	2.9
Germany	BNT162b2	11.4	3.1	1.2
India	Covaxin, ZyCoV-D	3.5	0.7	2.4
Iran	COVIran Barekat	8.7	0.83	2.5
Kazakhstan	QazVac	2.9	0.12	0.9
Russian Federation	EpiVacCorona; KoviVac; Sputnik Light; Sputnik V	5.3	1.0	3.7
Taiwan	MVC-COV1901	n.a.	1.7	n.a.
United Kingdom	AZD1222	10.0	1.7	1.9
United States of America	Ad26COV2.S; BNT162b2; mRNA-1273	16.9	2.8	3.3
Source:	*McGill COVID-19 Vaccine Tracker*	*WTO*	*UIS.UNESCO*	*SIPRI*

Appendix A.2: The Sputnik V Team as listed on the official Sputnik V website

Source: https://sputnikvaccine.com/about-us/ [Retrieved on 17 May 2021]

Alexander Gintsburg, Doctor of Biology, Member of the Russian Academy of Sciences

Denis Logunov, Doctor of Biology, Corresponding Member of the Russian Academy of Sciences

Boris Naroditsky, Doctor of Biology, Professor

Sergei Borisevich, Director, FGBU Central Research Institute No. 48 of the Russian Ministry of Defense, Doctor of Biology, Candidate of Medicine, Professor

Andrei Botikov

Darya Grousova

Alina Dzharullayeva

Inna Dolzhikova, PhD

Darya Yegorova, PhD

Ilyas Yesmagambetov, PhD

Olga Zubkova, PhD

Tatyana Ozharovskaya

Olga Popova

Aleksandr Semikhin, PhD

Yelizaveta Tokarskaya, PhD

Amir Tukhvatulin, PhD

Dmitry Shcheblyakov, PhD

Dmitry Shcherbinin, PhD

Appendix A.3. "Previous Vaccines" page of the official Sputnik V website

Source: https://sputnikvaccine.com/about-us/previous-vaccines/ [Retrieved on 18 May, 2021]

PREVIOUS VACCINES

Since the 1980s, the Gamaleya Center led the effort to develop a technological platform using adenoviruses, found in human adenoids and normally transmitting the common cold.

The Gamaleya Center successfully developed and registered in 2015 two vector-based vaccines against Ebola fever using the adenovirus vector platform. The vaccines have been officially approved for use by the Russian Health Ministry. About 2,000 people in Guinea received injections of Gamaleya vaccines in 2017-18. Gamaleya Research Center received an international patent for Ebola vaccine.

References and links for registration certificates, international patents and scientific publications about vaccines developed by the Gamaleya center

1. Gamaleya EBOLA vaccine

Clinical trial:

An Open Study of the Safety and Pharmacokinetics of a Medicinal Product for Emergency Prevention of Ebola (03-AT-2017) https://clinicaltrials.gov/ct2/show/NCT03428347

International Multicenter Study of the Immunogenicity of Medicinal Product GamEvac-Combi https://clinicaltrials.gov/ct2/show/NCT03072030

International patents:

International patent WO2016130047A1 Immunobiological drug and method for using same for inducing specific.immunity.against.the.Ebola.virus
https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016130047

Russian Health Ministry registration certificates:

GamEvac-Combi.is.a.multivalent.vector-based.Ebola.vaccine
https://grls.rosminzdrav.ru/Grls_View_v2.aspx?routingGuid=a52736b8-b1ac-408c-a2c1-3fb82c941267&t

GamEvac-Lyo.is.a.multivalent.vector-based.Ebola.vaccine
https://grls.rosminzdrav.ru/Grls_View_v2.aspx?routingGuid=a52736b8-b1ac-408c-a2c1-3fb82c941200&t

GamEvac.is.a.vector-based.Ebola.vaccine
https://grls.rosminzdrav.ru/Grls_View_v2.aspx?routingGuid=3974b1cc-27ed-4032-94ec-8c897f2421d3&t

Scientific publications:

Dolzhikova IV, Zubkova OV, Tukhvatulin AI, et al. Safety and immunogenicity of GamEvac-Combi, a heterologous VSV- and Ad5-vectored Ebola vaccine: An open phase I/II trial in healthy adults in Russia. Hum Vaccin Immunother. 2017 https://doi.org/10.1080/21645515.2016.1238535

Dolzhikova IV, Tokarskaya EA, Dzharullaeva AS, et al. Virus-Vectored Ebola Vaccines. Acta Naturae. 2017. https://doi.org/10.32607/20758251-2017-9-3-4-11

Useful links:

Extract from Global Advisory Committee on Vaccine Safety meeting on 5-6 June 2019, published in the World Health Organization Weekly Epidemiological Record of 12 July 2019 https://www.who.int/vaccine_safety/committee/topics/ebola/Jul_2019/en/

Russian Foreign Ministry press release on the post-registration clinical trials of the Russian Ebola vaccine Gam Evac Combi in Guinea. https://www.mid.ru/en/main_en/-/asset_publisher/G51iJnfMMNKX/content/id/2838077

Russia and Rusal complete Ebola vaccinations in Guinea. Pharmaceutical Technology. https://www.pharmaceutical-technology.com/news/rusal-ebola-vaccinations-in-guinea/

2. Gamaleya MERS vaccine

Clinical trial:

Study.of.Safety.and.Immunogenicity.of.BVRS-GamVac
https://clinicaltrials.gov/ct2/show/NCT04130594

Study.of.Safety.and.Immunogenicity.of.BVRS-GamVac-Combi
https://clinicaltrials.gov/ct2/show/NCT04128059

Scientific publications:

Ozharovskaia TA, Zubkova OV, Dolzhikova IV, et al. Immunogenicity of Different Forms of Middle East Respiratory Syndrome S Glycoprotein. Acta Naturae. 2019;11(1):38-47. https://doi.org/10.32607/20758251-2019-11-1-38-47

3. Gamaleya influenza vaccine

Clinical trial:

A Double-blind Randomized Placebo-controlled Study Study of the Safety, Reactogenicity and Immunogenicity of the GamFluVac https://clinicaltrials.gov/ct2/show/NCT04034290

The Study of the Safety, Reactogenicity and Immunogenicity of the GamFluVac https://clinicaltrials.gov/ct2/show/NCT03651544

Scientific publications:

Tutykhina I, Esmagambetov I, Bagaev A, et al. Vaccination potential of B and T epitope-enriched NP and M2 against Influenza A viruses from different clades and hosts. Published 2018 Jan 29. https://doi.org/10.1371/journal.pone.0191574

Tutykhina IL, Logunov DY, Shcherbinin DN, et al. Development of adenoviral vector-based mucosal vaccine against influenza. 2011. J Mol Med (Berl). https://doi.org/10.1007/s00109-010-0696-0

International patents:

Patent WO2013129961A1 Recombinant trivalent vaccine against human influenza. https://patentimages.storage.googleapis.com/b9/98/3c/5f0d7be2283729/EP2839840A1.pdf

4. General publications on adenoviral vector-based vaccines

Future Prospects for the Development of Cost-Effective Adenovirus Vaccines. By Cyrielle Fougeroux and Peter J. Holst https://doi.org/10.3390/ijms18040686

Repurposing Adenoviruses as Vectors for Vaccines. https://thenativeantigencompany.com/repurposing-adenoviruses-as-vectors-for-vaccines/

Burmistrova DA, Tillib SV, Shcheblyakov DV, et al. Genetic Passive Immunization with Adenoviral Vector Expressing Chimeric Nanobody-Fc Molecules as Therapy for Genital Infection Caused by Mycoplasma hominis. PLoS One. 2016 https://doi.org/10.1371/journal.pone.0150958

Shcherbinin DN, Esmagambetov IB, Noskov AN, et al. Protective Immune Response against Bacillus anthracis Induced by Intranasal Introduction of a Recombinant Adenovirus Expressing the Protective Antigen Fused to the Fc-fragment of IgG2a. Acta Naturae. 2014 https://doi.org/10.32607/20758251-2014-6-1-76-84

Tutykhina IL, Sedova ES, Gribova IY, et al. Passive immunization with a recombinant adenovirus expressing an HA (H5)-specific single-domain antibody protects mice from lethal influenza infection. Antiviral Res. 2013;97(3):318-328. https://doi.org/10.1016/j.antiviral.2012.12.021

Naroditsky BS, Zavizion BA, Karamov EV, Tikhonenko TI. Analysis of the genome of type 7 simian adenovirus.using.restrictases.Nucleic.Acids.Res.1978;5(3):999-1011.
https://doi.org/10.1093/nar/5.3.999

Appendix A.4: Affiliations of authors of Dolzhikova et al. 2017 paper on Phase 1/2 trials of GamEvac-Combi vaccine against Ebola

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- D. A. Egorova
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