Agora briefing : The UK's relationship with the Sputnik vaccine

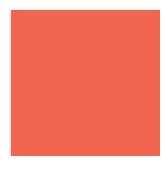


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Executive summary

The development of a successful vaccine was of central concern to governments around the world from the moment the coronavirus crisis began. When Russia's Gamaleya Institute announced that their Sputnik V vaccine was ready for use in August 2020 - to great shock and derision – the Russian government made clear its intention that Sputnik would be a "vaccine for all mankind". Yet, as the UK and her Western allies built their vaccine portfolios, Sputnik remained conspicuous by its absence. While information operations and wider geopolitical considerations were undoubtedly at play, this paper sets out the data and efficacy concerns that were central to explaining the lack of Western interest in the Sputnik jab.

N.B. Much of the insight in this paper was informed by conversations with several of the British public servants who worked on the UK's vaccine strategy, including those tasked with countering associated Russian information operations. The author also received invaluable guidance from several analysts of vaccine diplomacy. With limited exceptions, contributions were provided on condition of anonymity. We am grateful to all those who gave their time and expertise.

Introduction

Political leaders placed significant stock in the successful development of a vaccine virtually from the outbreak of the pandemic. Of course, there were serious doubts as to the pace at which any vaccine could be delivered. The official World Health Organisation (WHO) estimation was an 18 month process. By mid-2020, both USA President Donald Trump and UK Prime Minister Boris Johnson were predicting their countries would have an operational vaccine by the end of the year.

Russia's Gamaleya Institute announced in August 2020 that their Sputnik V vaccine was ready. The associated Russian authorities claimed Sputnik would become the "first registered COVID-19 vaccine on the market" and would be "a vaccine for all mankind" [1][2]. As 2021 turned to 2022, these lofty ambitions were yet to be realised, and the Sputnik vaccine never achieved the public health and geopolitical advancements that the Russian government had intended. This was reflected in the limited interest the UK and its Western allies showed in adding the Sputnik vaccine to their rapidly burgeoning vaccine portfolios.

A lack of enthusiasm in the West?

Sputnik undoubtedly helped Russia consolidate its status within traditional spheres of influence [3]. Beyond this, the UK, its allies, and much of the rest of the international community has remained sceptical. To explain this reality, it is important to note that allegations of corruption and incompetence remain rife throughout the production process and subsequent supply chains [4]. Criticism must also be levelled at Russia for their use of offensive information operations against competing vaccine development projects [5][6]. Most importantly though — and the focus of this paper — the UK and her allies simply did not have access to genuinely credible efficacy data for the Sputnik vaccine in the crucial stages of their portfolio development.

Czech President Miloš Zeman remarked that "in a war [...] you need to do whatever you can to make it stop. [Buying Sputnik doesn't mean] losing independence [...] it's a business deal, for God's sake" [7]. Channelling a similar sentiment to President Zeman, when Johnson appointed Dame Kate Bingham to chair the UK's Vaccine Taskforce early in the pandemic, his instructions to her were simple: "just stop people from dying" [8]. Given this barely-concealed desperation that infused much of the UK's, and, more generally, the West's, initial response, it is notable that there seems to have been limited engagement with the possibility of adding the Sputnik vaccine to the speculative vaccine portfolios. This absence is made more conspicuous by the wider approach to preemptive procurement. In the UK, building the vaccine portfolio included acquiring hundreds of millions of doses of a range of vaccines — from Oxford/AstraZeneca to Pfizer, Moderna, and Janssen — well before concrete efficacy results were returned. Yet one official with knowledge of the UK process dispelled the possibility that geopolitical game-playing was occurring at this stage, noting that those involved in the UK procurement process were completely clear that they would not rule out the Sputnik vaccine; 'if it works, we'll take it'.

In fact, such was the spirit of cooperation in pursuit of solutions to the pandemic, Russia's Gamaleya Institute actually cooperated with AstraZeneca in December 2020 on a limited trial to explore the possibility that the two vaccines could combine in a two-dose regime to trigger a more effective immune response. As journalists noted, these collaborative conversations highlighted "the pressure to develop an effective shot" [9].

So, when considering why Western countries were not among those signing contracts to receive – and in some cases develop – the Sputnik vaccine, it is helpful to consider the view of Dame Kate and the specifics of vaccine technology. To inform this paper, Bingham noted that "[the UK] didn't look at Sputnik in any detail as it is an ad5 - not attractive – and ad26, which is the same as Janssen. So we were already covered with the adeno formats from companies where we could do detailed due diligence" [10]. That is, Sputnik was not the type of vaccine the UK either wanted or needed. While it is clearly possible to speculate on whether or not the UK Government would have been willing to enter into a commercial deal for Sputnik, it simply never got that far.

The complicated story of Sputnik's efficacy data

Of course, just being similar in technology to the Janssen vaccine did not preclude UK interest in Sputnik on its own. The key fact was that Janssen and the wider portfolio of Western vaccines simply offered more transparent, straightforward routes to data-driven efficacy assessments.

In August 2020, just five months into the pandemic, the Gamaleya Institute announced that the Sputnik vaccine was ready. This announcement was conspicuously early. The Institute – a laboratory with no track record of engaging with any major independent regulator – reported that the vaccine had 92% effectiveness, while Putin himself confirmed the vaccine had gone through all necessary trials [11]. While early peer-reviewed data did appear in world-renowned medical journal *The Lancet* in September 2020, the fact this data was based on very low trial numbers – two non-randomised, open label studies, each of 38 people – did little to dispel Western scepticism [12].

The response was almost immediate. Prof Enrico Bucci, representing an Italian research integrity company, pointed out apparently identical and repeating data points. Over 50 scientists published an open letter in the *The Lancet* demanding more data [13]. Gamaleya called the data discrepancies coincidences.

By February 2021, after a period in which scepticism persisted and interest waned, *The Lancet* published peer-reviewed data that suggested Sputnik was 91.6% effective at preventing symptomatic COVID-19 in adults, based on 15,000 trialists [14]. The London School of Hygiene and Tropical Medicine's Prof Polly Roy noted that "the outcome reported here is clear", while Prof John Moore, of Weill Cornell Medicine, New York, agreed that Sputnik "looks to be a very effective vaccine" [15]. By April 2021, Gamaleya was reporting 97.6% effectiveness at preventing infection, based on the unpublished data of 3.8m vaccine recipients across Russia [16].

But the problems persisted. Immediately following The Lancet's publication in February 2021, Prof Bucci flagged a series of errors in the data — for example, hundreds of people whose data was included at day 20 of the study but not at day 10 — that while minor in isolation were significant in their totality for such a major study [17].

Significant debates followed regarding *The Lancet*'s role in providing validity to the Sputnik vaccine despite the ongoing concerns of large sections of the scientific community. While Sputnik's website was championing "efficacy and safety results [that] are validated by internationally peer-reviewed data published in *The Lancet*", and millions of doses of the vaccine were being rolled out across the world to countries without their own independent or well-resourced regulators, the journal was having to defend itself, noting its reviewers do not have access to the "raw data related to research studies" [18].

In April 2021, Gamaleya was rejecting suggestions that the vaccine may be prone to similar risks of blood clots or thrombosis as the AstraZeneca vaccine with which it shared technology. Gamaleya provided no data to support this assertion [19]. The picture was similar in their response to questions regarding the vaccine's efficacy in the face of new variants, an issue that clearly retains relevance today.

Indeed, much of this process was playing out without the Gamaleya Institute having made an application to any major regulator, while the Institute was the only major vaccine developer not to release its full trial protocol. The European Medicines Agency (EMA) only began reviewing Sputnik data in early March 2021, and both the EMA and WHO were still trying to access sufficient data to make their approval decisions by the end of that year.

Conclusion

Combining the complicated data story with Dame Kate Bingham's reflections suggests Western resistance to the Sputnik vaccine, while likely exacerbated by concerns regarding information operations and geopolitical implications, was rooted in the vaccine's development and the availability, or lack thereof, of adequate data. In an interview given in February 2021, Dame Kate reiterated the strategy: "look at the science, look at data, and then decide what the risks are" [20]. She went as far as to say "geography didn't matter. I was only interested in securing the best vaccines" [21]. While she was taking this approach, "getting comprehensive information [regarding Sputnik was] difficult" given the "many unknowns" [22]. In understanding this reality, the limitations on Russian ambitions and the likelihood of Western interest are patently clear.

In February 2021, Dame Kate was still speaking about the possibility that UK experts might "see the data [that] says it's effective and safe", at a time when the UK had amassed a portfolio of hundreds of millions of doses of which Bingham and her team had made robust empirical assessments [23]. In fact, as late as October 2021, it was being reported that the EMA was "unlikely to decide whether to approve Russia's Sputnik V coronavirus vaccine until at least the first quarter of 2022 because some data needed for the review is still missing" [24]. Despite the continued assertions from the Russian Direct Investment Fund that the vaccine has superior efficacy to similar vaccines on the market, the fact the WHO approval process similarly continued to stall lends further weight to these apparent data and process problems.

There is nothing to suggest these shortcomings were borne from nefarious motivations, but they have undoubtedly undermined the Russian effort. Given the UK, the US, and the EU decided early on to hold major regulatory approval as a necessary condition for use — for example for those seeking to travel — these delays clearly impacted Russia's ability to compete in large sections of the global market, not least in the UK.

About the author

Alex Urwin is a current graduate student at Columbia University, where he is studying for a politics Master's and focusing on the UK and its place in the world. Before arriving at Columbia, Alex was a civil servant in the Prime Minister's Office and a Philosophy, Politics, and Economics undergraduate at Oxford.

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