Procurement of COVID-19 vaccines: Exploration from the negotiation and contracting perspective

In December 2019, a novel virus was identified in Wuhan, China.[1] At first, the Western media reported on the news coming from China only in passing. However, the events in Wuhan would soon prove to be not merely of local or regional interest, but would turn out to be of such magnitude so as to rightfully earn their place in the history books. This new virus – a strain of coronavirus – was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2] The disease caused by SARS-CoV-2 has come to be known as Coronavirus disease 2019, or simply as COVID-19.[3]

The initial attempts to contain the virus soon failed, and it spread like wildfire across the globe in 2020. Despite the fact that the observed case-fatality ration of SARS-CoV-2 is relatively low (ranging from Iceland's 0.1%, across France's, Germany's and Austria's 0.4%, to Peru's 4.9%),[4] the low probability reflected in these numbers is most certainly not a true representation of the virus's formidable scale and scope of impact. SARS-CoV-2 can spread at an alarmingly fast rate, and throughout 2020 and 2021, many people with COVID-19 required hospitalisation, often times in intensive care units.[5] In turn, this caused immense pressure on the healthcare systems in general, requiring careful selection in deployment of available resources. The reported death toll at a global level as a result of COVID-19 stands at 6,881,995 as of March 2023,[6] while some have argued that the real death toll is much higher.[7] Estimates go in excess of 30 million people supposedly losing their lives due to COVID-19.[8]

The global response to the pandemic was not uniform. It ranged from strict lockdowns enforced by police curfews to lax approaches that depended on voluntary compliance by the population. Some countries did not even have the capacity to mitigate the impact of the virus and the resulting pandemic.[9] Some of the measures implemented in order to combat the spread of the virus included social distancing, mask mandates, movement restrictions, use of disinfectants, etc. However, what the world was impatiently waiting for was a miraculous solution in the form of a vaccine.

Development of the COVID-19 vaccines

It generally takes anywhere between 10 and 15 years to develop a vaccine.[10] The process involves developing the vaccine itself in the laboratory, conducting clinical trials in order to assess the safety and the efficacy of the vaccine, as well as getting the regulatory approval. Moreover, the additional challenge is to ensure that the manufacturing process is effective so that a sufficient number of vaccines will be produced and then distributed to the population. In the context of COVID-19, it was not an option to wait one decade to get the vaccine. In other words, the vaccine needed to be ready in record time.

The urgency of the situation resulted in a(n) (un)healthy dose of rivalry and competition. Many biotechnology companies, universities and institutes entered the race to produce the COVID-19 vaccine. However, the whole endeavour was not only informed and incentivised by the pressing need to put the global pandemic under control. It also became a matter of national pride.[11] A country in which an effective COVID-19 vaccine would be developed could boast scientific, and ostensibly even cultural and political superiority over others.

The leading players at the initial stages were as follows:

- Pfizer (US pharmaceutical and biotechnology company) and BioNTech (German biotechnology company), which in cooperation developed and manufactured an mRNA *Pfizer–BioNTech COVID-19 vaccine (Comirnaty)*,
- Moderna (US pharmaceutical and biotechnology company), which developed and manufactured an mRNA *Moderna COVID-19 vaccine (Spikevax)*,
- Oxford University (one of the leading global and UK universities) and AstraZeneca (Anglo-Swedish pharmaceutical and biotechnology company), which together developed and manufactured a viral vector *Oxford–AstraZeneca COVID-19 vaccine (Covishield and Vaxzevria),*
- Johnson & Johnson (US multinational), whose subsidiary – Janssen Vaccines – developed a viral vector *Janssen COVID-19 vaccine*,
- Sinopharm (a major Chinese pharmaceutical corporation), which developed and produced an inactivated Sinopharm *BIBP COVID-19 vaccine (BBIBP-CorV)*,
- Sinovac (Chinese biotechnology company), which developed an inactivated *CoronaVac*, and
- Gamaleya Research Institute of Epidemiology and Microbiology (Russian medical-research institute), which developed a viral vector *Sputnik V (Gam-COVID-Vac)*.

Defying a convention that 10–15 years would be needed to develop an effective and safe vaccine, these entities managed to do what many have thought would be a mission impossible – they developed their respective COVID-19 vaccines, ran clinical trials and obtained emergency use authorisations in less than a year.[12] It is important to note, however, that the emergency use authorisations varied country by country since not all vaccines received it in all countries. For example,

Sputnik V, BIBP COVID-19 vaccine and CoronaVac were generally not given emergency use authorisations in Western countries.[13]

Unequal access to COVID-19 vaccines

While the extraordinary nature of scientific achievements that culminated in the COVID-19 vaccines is something that would be practically impossible to dispute, a much darker story can be told regarding the distribution of those vaccines across the globe. Namely, the distribution efforts have not been informed or led by the notion that the whole world is in a joint fight against the virus. Instead, the distribution was marred by political, and above all, protectionist considerations. This, in turn, led to a situation whereby the access to COVID-19 vaccines has been uneven for different countries and populations, with developing, and particularly least developed countries, being especially adversely affected. Wells and Galvani noted in The Lancet that the UN targets for vaccination rates in the low-income countries have particularly been adversely affected:

> The primary barrier is the lack of access to vaccines due to a combination of restricted supply and funding in resource-constrained settings. Several high-income countries secured advanced purchasing agreements with vaccine manufacturers. In the case of the USA, the number of vaccine doses purchased even before production was enough to fully vaccinate its entire population three times over. By contrast, low-income countries were unable to pay the premium prices negotiated by high-income countries, delaying the delivery of vaccines. In Burundi, for example, vaccine rollout was initiated 10 months later than in the USA. [footnotes omitted][14]

Even if one was to brush the ethical considerations aside in terms of equitable access to COVID-19 vaccines, one would still be left with the reality that easily transmittable viruses have no considerations for political divisions or boundaries. To combat the global pandemic effectively, an optimal approach would be to set the political divisions aside, and to prioritise vaccine distribution at a global level in a way that would maximise the global efforts to curb the spread of the virus. However, given the realities of the current world order and the accompanying political, economic and cultural divisions, implementing this approach to combat the pandemic is simply easier said than done.

Negotiation and contracting perspective

Much has been written on the equitable access to COVID-19 vaccines. The discussions have sought not only to inform the efforts in relation to the distribution of COVID-19 vaccines, but also to serve as lessons for combating future pandemics whose occurrence is not a question of 'if', but 'when'. The papers published in this special section seek to make a contribution to the debate primarily from an interdisciplinary perspective, and with special attention to negotiation and contracting. In other words, how can contracting and negotiation practices be optimised so as to bring about a more equitable result in terms of access to the vaccines?

The negotiation and contracting perspective in the procurement of COVID-19 vaccines plays a pivotal role in shaping the global response to the pandemic. The urgency and scale of vaccine development required a unique set of strategies and considerations in the negotiation and contracting processes.

One crucial aspect is the negotiation of agreements between pharmaceutical companies, governments and international organizations. These agreements determine the terms of vaccine production, distribution and access. As observed in the development phase, competition among countries and companies for the vaccine spotlighted the importance of effective negotiation skills. Governments and organizations needed to navigate complex contractual arrangements to secure timely and sufficient vaccine supplies.[15] The contracts between vaccine developers and governments should address not only the volume of doses but also the equitable distribution of vaccines. Negotiators must balance the interests of both parties, ensuring that contractual terms prioritise global health over nationalistic considerations. This is particularly important to prevent hoarding by wealthier nations, ensuring that vaccines are distributed based on need rather than economic power.[16]

Furthermore, the negotiation process should emphasize transparency and information-sharing. Timely and accurate communication between vaccine developers and governments is essential for addressing uncertainties, ensuring the smooth flow of vaccine production, and avoiding unnecessary delays. Clear contractual obligations regarding data sharing, production timelines and regulatory approvals contribute to a more efficient global vaccine distribution system.[17]

Contracting practices also play a vital role in addressing issues of affordability and accessibility. Negotiations should focus on fair pricing models that consider the economic conditions of both developed and developing nations. Incentives for vaccine developers to provide affordable options and technology transfer

agreements can contribute to overcoming financial barriers and promoting broader vaccine accessibility.[18]

In the context of international collaboration, the negotiation of contracts between countries and vaccine manufacturers must reflect a commitment to solidarity. Multilateral agreements and partnerships can facilitate the fair allocation of vaccines based on global health needs.[19] This requires a shift from purely transactional negotiations to agreements that emphasize shared responsibility in combating a global threat. Additionally, the negotiation and contracting perspective should extend beyond the initial vaccine procurement phase. Agreements should include provisions for ongoing collaboration, technology transfer, and capacity-building in vaccine production. This ensures that nations, particularly those with limited resources, can contribute to and benefit from the global effort to combat not only the current pandemic but also future health crises.[20]

In this special issue, taking into consideration all of the above, Maria Carolina Foss and Diogo R. Coutinho, in their paper titled 'Public procurement for innovation: Lessons and challenges of a COVID-19 vaccine contract', explore how the technology and safety risks have been addressed in the COVID-19 vaccines public procurement contracts (signed with AstraZeneca) in Brazil. Among other things, the paper showcases how Brazil's existing innovation legislation was utilised to create and formulate advanced forms of public–private agreements, specifically the technology order agreement. These agreements facilitated the prompt procurement of vaccines during the pandemic, despite the alarming reality that the federal government downplayed the severity of the pandemic and exhibited an unexplained reluctance to actively pursue widespread vaccination efforts in the country.

In their paper titled, 'COVID-19 vaccination procurement and contract management in a South African context', Anita Read, Rob Botha and Khadija Jamaloodien explore the possibilities to enhance future procurement and contract management within the public health sector. More precisely, they look into the lessons learnt from the procurement of COVID-19 vaccines in South Africa in order to put forth suggestions on how to 'strengthen future procurement and contract management in the public health sector'.

Dhanay Cadillo Chandler, Jouko Nuottila and Rosa Maria Ballardini, in their article titled 'Equitable access to COVID-19 vaccine distribution – the case of the Andean Community', identify different factors needed to accomplish cohesive policy strategies in terms of procurement of vaccines and put forth suggestions aimed at fostering fair vaccine distribution in the Andean Community and other regions. Among other things, the authors are skeptical of the approach adopted in the Andean Community, specifically relying more on imports and donations rather than implementing potentially more effective policies. For instance, to enhance the bargaining power of the Andean Community, the authors propose implementing a joint procurement mechanism modelled after the one devised by the European Union.

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Footnotes

1. AL Giwa and Akash Desai, 'Novel Coronavirus COVID-19: An Overview for Emergency Clinicians', *Emergency Medicine Practice* 22, no. 2 Suppl 2 (2020): 2.

2. Li Yang Hsu, Po Ying Chia, and Jeremy FY Lim, 'The Novel Coronavirus (SARS-CoV-2) Pandemic', *Annals, Academy of Medicine, Singapore* 49, no. 3 (2020): 105.

3. Ibid.

4. 'Mortality Analyses', Johns Hopkins University & Medicine: Corona Virus Resource Center, 10 March 2023, https://coronavirus.jhu.edu/data/mortality.

5. Bart G. Pijls et al., 'Temporal Trends of Sex Differences for COVID-19 Infection, Hospitalisation, Severe Disease, Intensive Care Unit (ICU) Admission and Death: A Meta-Analysis of 229 Studies Covering over 10M Patients', *F1000Research* 11 (2022).

6. Mortality Analyses' (n. 4).

7. 'The Pandemic's True Death Toll', *The Economist*, 18 November 2023, https://www.economist.com/graphic-detail/coronavirus-excess-deaths-estimates.

8. Ibid.

9. 'World's Most Vulnerable Countries Lack the Capacity to Respond to a Global Pandemic', United Nations, n.d., https://www.un.org/ohrlls/news/world's-most-vulnerable-countries-lack-capacity-respond-global-pandemic-credit-mfdelyas-alwazir.

10. 'How Vaccines Are Developed and Approved for Use', How Vaccines are Developed and Approved for Use, 30 March 2023, https://www.cdc.gov/vaccines/basics/test-approve.html.

11. Samantha Vanderslott et al., 'Vaccine Nationalism and Internationalism: Perspectives of COVID-19 Vaccine Trial Participants in the United Kingdom', *BMJ Global Health* 6, no. 10 (2021): e006305.

12. 'COVID-19 Medicines', European Medicines Agency, n.d., https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines.

13. Ibid.

14. Chad R Wells and Alison P Galvani, 'The Global Impact of Disproportionate Vaccination Coverage on COVID-19 Mortality', *The Lancet Infectious Diseases* 22, no. 9 (2022): 1254.

15. Zhehan Li, Jiajun Lu, and Jiamin Lv, 'The Inefficient and Unjust Global Distribution of COVID-19 Vaccines: From a Perspective of Critical Global Justice', *Inquiry: A Journal of Medical Care Organization, Provision and Financing* 58 (5 December 2021): 00469580211060992, https://doi.org/10.1177/00469580211060992.

16. Heidi Ledford, 'COVID Vaccine Hoarding Might Have Cost More than a Million Lives', *Nature*, 2 November 2022, https://doi.org/10.1038/d41586-022-03529-3.

17. John A. Muckstadt et al., 'Efficient and Effective Large-Scale Vaccine Distribution', *International Journal of Production Economics* 262 (1 August 2023): 108921, https://doi.org/10.1016/j.ijpe.2023.108921.

18. Carlos E. Carpio et al., 'COVID-19 Vaccine Demand and Financial Incentives', *Applied Health Economics and Health Policy* 19, no. 6 (2021): 871–83, https://doi.org/10.1007/s40258-021-00687-9.

19. Bawa Singh, Jaspal Kaur, and Vijay Kumar Chattu, 'Global Vaccine Inequities and Multilateralism amid COVID-19: Reconnaissance of Global Health Diplomacy as a Panacea?', *Health Promotion Perspectives* 12, no. 4 (31 December 2022): 315–24, https://doi.org/10.34172/hpp.2022.41.

20. Li, Lu, and Lv, 'The Inefficient and Unjust Global Distribution of COVID-19 Vaccines' (n. 15).

Biographies

Boris Praštalo joined Brunel Law School in 2022 as Lecturer in Commercial Law. Before that, he was an Assistant Professor at the International University of Sarajevo (IUS), Faculty of Law (FLW) where he taught an array of courses, including Business Law, Commercial Law, Private International Law, Introduction

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