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## **Perspectives in the Study of the Political Economy of COVID-19 Vaccine Regulation**

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Short running title: COVID-19 Vaccine Regulation

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## RESEARCH FORUM

### Perspectives in the Study of the Political Economy of COVID-19 Vaccine Regulation

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Vaccines against SARS-CoV-2 continue to be developed at an astonishingly quick speed and the early ones, like Pfizer and Moderna, have been shown to be more effective than many public health scientists had dared to hope. As COVID-19 vaccine research continues to progress, the world's eyes are turning towards medicines regulators. COVID-19 vaccines need to be authorized for use in each country in which the pharmaceutical industry intends to commercialize its product. This results in a patchwork of regulations that can influence the speed at which products are launched and the standards that govern them. In this research forum article, we discuss several key questions about COVID-19 vaccine regulations that should shape research on the next stage of the pandemic response. We call for a research agenda that looks

into the political economy of pharmaceutical regulation, particularly from a comparative perspective, including Global South countries.

Key words: Pharmaceutical Regulation, COVID-19, Comparative Politics, Political Economy.

In December 2020, the image of a 90-year-old woman receiving the first COVID-19 vaccine shot as part of the United Kingdom's national immunization campaign made the news worldwide. The beginning of vaccination has been a remarkable moment for the COVID-19 pandemic response, and research toward discovering vaccines for COVID-19 continues to rapidly progress. Thus, attention is increasingly turning to the challenges of managing vaccine approval during a period of public health crisis (Nature, 2020). COVID-19 vaccines will need to be authorized for use in each country in which the industry intends to commercialize its product, a patchwork of regulation that can influence the speed at which products are launched and the standards that govern them. For instance, the UK was the first country to authorize a novel technology for immunization, the Pfizer/Biontech's nucleoside-modified RNA (mRNA) vaccine (Reynolds, Halasz, Pleitgen, & Isaac, 2020), followed by the US (BBC, 2020a). In Latin America, countries are authorizing mRNA vaccines at different stages. In December, Chile, Mexico, and Costa Rica approved the Pfizer vaccine, but Brazil did not (BBC, 2020b). India, Russia, and China granted emergency use of their state-sponsored domestic candidate vaccines based on relatively sparse data (BBC, 2021; Burki, 2020; Taylor, 2020), a decision later followed by Indonesia, Argentina, Hungary, and Arab nations that also granted emergency use for some of these products (Cyranoski, 2020).

A great deal of uncertainty exists around every stage of COVID vaccine development and dissemination, from research and formulation through clinical trials, and all stages of regulatory approval (Subbaro, 2020). Key questions include: what guidance are governments providing to industry regarding the streamlined formulation of vaccines, and how does this relate to guidance from the World Health Organization (WHO)? What is the approval process for potential vaccines and how and why does the process differ by country? What factors determine countries' regulatory capacity? To what extent are governments preventing potentially harmful, non-approved 'vaccines' from entering the market and addressing misinformation? How governments go about regulating COVID-19 vaccines (and sharing the knowledge of how to regulate

vaccines), assessing risk-benefit in the context of uncertainty about clinical trials and the length of immunization are questions that should shape the research on the next stage of COVID-19 pandemic response.

A crucial aspect of regulating COVID-19 vaccines is determining and evaluating their efficacy, i.e., the percentage reduction in risk of disease among vaccinated persons relative to unvaccinated persons, which is measured during controlled clinical trials. To guide vaccine developers and regulators, the WHO has established a target product profile for COVID-19 vaccines specifying minimum characteristics, including 50% efficacy (World Health Organization, 2020).

National regulatory authorities are sovereign when defining their marketing approval standards. Despite the various efforts to harmonize pharmaceutical regulation, COVID-19 has exposed the fragmentation of different approval processes worldwide (Nature, 2020; Simpson, Chakrabarti, Robinson, Chirgwin, & Lumpkin, 2020). For instance, the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have signaled that they would be willing to approve vaccines that diminished severity of illness instead of fully protecting against infection (Torreele, 2020). The consequences of approving a suboptimal vaccine could worsen the Covid-19 pandemic as it could interfere with the evaluation of other vaccines; the control group in clinical trials would include individuals previously vaccinated rather than those who only received a placebo. Moreover, people might relax their compliance with non-pharmaceutical interventions or become more hesitant to receive the vaccine (Krause et al., 2020; Singh & Upshur, 2020). There is still great uncertainty about the length of immunization and whether the vaccines will prevent individuals from transmitting the virus (Subbaro, 2020).

When regulating COVID-19 vaccines, the different regulatory capacity levels among countries could create very different political economies of product regulation. A small group of countries in the Global North—including the US, UK, Canada, EU countries, and Japan—are classified as mature (or stringent) regulatory authorities (Khadem Broojerdi et al., 2020).<sup>1</sup> They

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<sup>1</sup> There are different efforts to classify and explain NRAs maturity level, including the WHO Global Benchmarking Tool (Khadem Broojerdi et al., 2020), the National Academies of Sciences, Engineering, and Medicine (National Academies of Sciences Engineering and Medicine, 2019), and the WHO “List of Stringent Regulatory Authorities (SRAs)” <https://www.who.int/medicines/regulation/sras/en/> (accessed Dec 1<sup>st</sup>, 2020).

are founders of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), a network of regulatory agencies and drug producers that discuss regulatory convergence in the pharmaceutical sector. The next tier includes countries with some regulatory capacity that are not a part of the ICH (or have only recently joined), such as Brazil, Russia, China, Chile, and Argentina. These are known as moderately well-resourced regulators. Finally, lower-income countries have little to no regulatory capacity.

Most studies on the political economy of regulating pharmaceuticals are focused on the U.S. and European context (Carpenter, 2010; Maor, 2011; Schweitzer & Lu, 2018; Vogel, 2012), with few comparative initiatives. We still know very little about the mechanics of pharmaceutical regulation in comparative perspective. Such an agenda might interest academics of social science and health policy. For sociologists, public administration scholars, and political scientists, COVID-19 vaccine regulation is an opportunity to explore the learning capabilities, trust, and structure of states concerning industries, epistemic communities, and societal interests. For health policy researchers and practitioners, drug and vaccine regulation are important functions of the state functions that are gaining importance within the context of strengthening health systems (Preston, Valdez, & Bond, 2012), globalization (Vogel, 2012), and that are intensely important in moments of crisis (e.g., HIV/AIDS and Ebola) (Carpenter, 2004; Wolf et al., 2020).

We propose three avenues for research on the political economy of COVID-19 vaccine regulation in comparative perspective: Regulating risk in the Global North, the politics of regulatory reliance, and the process of requesting approval.

*Regulating risk in the Global North.* Regulatory agencies in countries such as the US, Europe, and Japan have historically developed capacity in regulating pharmaceuticals. Drug regulation is an evolving process by nature. As the pharmaceutical industry innovates from original products to generics, from synthetic drugs to biologicals, from biologicals to biosimilars, the regulator also needs to adapt (National Academies of Sciences Engineering and Medicine, 2019). Regulatory agencies in the Global North are at the forefront of regulatory science. For instance, in the past decade, one of the key discussions between these regulatory bodies concerns accelerated pathways for new drug approval (Breckenridge & Liberti, 2018; Gyawali & Kesselheim, 2018). In the case of AIDS, the alarm bells rung highlighted the harmful effects of

slow drug approval, which resonated in regulatory policies to fast-track certain products (Carpenter, 2004; Vogel, 2012). Drug regulation is becoming more convergent across the Atlantic (Vogel, 2012).

Nevertheless, during the critical moment where convergence was most necessary (Nature, 2020), agencies in the US, UK, and Europe adopted decisions at different moments and standards (Boseley, 2020). Why is that? A key avenue for investigation is how different governments get their scientific advice (and whether they have to listen to it) (Freedman, 2020). For instance, the UK has a Vaccine Taskforce (VTF) with a purpose of expediting research to produce a coronavirus vaccine – including authority to co-ordinate with regulators to facilitate trials (Bingham, 2021). According to the VTF report, the advice was to focus on vaccines that, among others, had the potential to secure rapid regulatory approval (Department for Business Energy & Industrial Strategy, 2020). The Taskforce included AstraZeneca, the Wellcome Trust, John Bell of Oxford University, and was chaired by a managing partner of a life sciences venture capital firm. However, the lack of transparency about the VTF raised concerns about conflicts of interest among the UK government’s Covid-19 advisers (Thacker, 2020).

In addition, in the context of COVID-19, where some governments practice “vaccine nationalism” by following their own interests instead of adopting a coordinated global response, attention is required to the influences of geopolitical disputes (Bremmer, 2020) and right-wing populist interventions (Fischer, 2020) in the regulatory process. The previous US president publicly pressured his own FDA to approve a vaccine quickly so he could reap political gains at a particular point of the electoral cycle (LeBlanc, 2020). In the UK, many have expressed concerns about the speed with which the British regulator approved the Pfizer/BioNTech vaccine (Boseley, 2020; Manskar, 2020).

On other side of the argument, how do we bring a global health approach to vaccine regulation? Cooperation among well-resourced regulatory authorities has been discussed by the FDA (National Academies of Sciences Engineering and Medicine, 2019), but there are many challenges due to institutional legacies, technical, and financial resources, and areas of expertise. At the center of the problem is lack of trust (Benish & Levi-Faur, 2020). Collaboration during crisis management will require trusting relationships between actors of regulatory regimes. There is an increasing interest in the study of trust relationships within regulatory regimes; for instance,

the Trust in Governance and Regulation in Europe (TiGRE),<sup>2</sup> a European Union Horizon 2020 initiative that bring together leading scholars in the field of regulation and are well-equipped to investigate these questions.

*The politics of regulatory reliance.* Most concepts of pharmaceutical regulation emerged from European and American cases and are yet to be tested against the context of the Global South. Low- and middle-income countries (LMIC) have different capacities and competences in drug regulation. Agencies (or Ministry of Health departments) responsible for pharmaceutical regulation were built as stand-alone systems, with little conversation among countries. The need to quickly approve COVID-19 vaccine has illuminated differences in drug regulation in these countries. For instance, Pfizer complained that the regulatory requirement for emergency use in Brazil included information that would take too long to gather, such as information on clinical trials conducted in the country (Jeantet & Savarese, 2021). Therefore, obtaining a permanent license through a rolling review application would be easier for the company. On the other hand, Costa Rica, Chile, and Mexico quickly authorized emergency use of Pfizer's vaccine.

Efforts to harmonize pharmaceutical regulation have been made (e.g., Pan American Network for Drug Regulatory Harmonization and the African Medicines Regulatory Harmonization)(Silva & Tagiari, 2016), but countries are still far from a coherent regulatory process. In the case of emergency, LMIC can rely on what other stringent regulators are doing or the guidelines of international harmonization networks such as the WHO or the ICH (National Academies of Sciences Engineering and Medicine, 2019). A regulatory reliance pathway, a form of mutual recognition, means that a regulatory authority accepts the decision of another authority or considers the work products of another regulator to inform its decision-making.

Significantly, many countries did not have accelerated drug approval protocols or emergency-use norms and adopted a regulatory reliance pathway to speed up the process. The case of Brazil is emblematic in this sense, as regulators constantly declared that most of the norm adjustments adopted during the pandemic emulated the FDA norms. There are several avenues for investigating COVID-19 vaccine regulation in LMICs: how are regulatory reliance pathways implemented and translated to local rules? How do countries choose reference agencies, and why

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<sup>2</sup> "TiGRE for better Trust in Governance and Regulation in Europe". <https://www.tigre-project.eu> (accessed Jan 26, 2020)

do they choose them? For instance, although Brazil approved legislation including the US, Canada, EU, China, and Japan as reference agencies, the National Health Surveillance Agency (ANVISA) questioned the transparency of the Chinese process and requested more information than the FDA for approving emergency use, which Pfizer criticized (ANVISA, 2020). Low-income countries with nascent or under-resourced regulatory agencies can use the WHO Emergency Use Listing Procedure as guidance for vaccine approval (World Health Organization, 2020). However, the extent and manner in which they do so warrants further investigation. When do countries decide to rely on international guidelines or go about creating their own rules? Why? International guidelines are implemented and become local rules depending on domestic politics (Shadlen, 2017; Weyland, 2007). Therefore, we must consider different political, professional, and industry actors, their interests, and institutions to understand how LMIC countries approach risk assessment of COVID-19 vaccines.

*The process of requesting approval.* A crucial characteristic of pharmaceutical regulation is that manufacturers must start the process. Governments cannot deliberately approve vaccines and drugs without the request of their developers. At this stage, regulators rely on data, published studies, and clinical trials submitted by the company responsible for developing the product. One question we should be asking is why manufacturers request authorization in some countries and not others. This was the case with Sinovac, which was granted emergency authorization in China but did not submit such a request to other agencies worldwide (until late 2020); similarly, Pfizer requested emergency use first in the UK, followed by the US, Europe, and then some countries in Latin America, but not others. Is the process of requesting approval related to corporate strategy such as conditioned to Advanced Purchase Agreements? Or endogenous to national regulation (e.g., requirements by the local regulators can create incentives – or discourage – developers from requesting market authorization)?

Therefore, there is an important avenue for the sociology of organizations or management science to explore negotiation processes inside the firm (including industries, biotech, and research labs). The construction of economic rationality within the firm can shed light on the strategic choices made by firms regarding where and how to commercialize scarce vaccines, as well as decisions about where and how to outsource production through technology transfer. With global demand for vaccines, some leading pharmaceutical companies working on a COVID-19 vaccine are engaging in technology transfer to achieve a worldwide production scale.



However, technology transfer faces enormous political and regulatory challenges (O'Sullivan, Rutten, & Schatz, 2020).

Scholars interested in the processes that occur inside the firm might face challenges when conducting empirical research given the sensitive (and at times confidential) nature of these decisions. However, the business-government lobbying literature contains the methodological tools necessary to conduct research on such topics. For instance, elite interviewing can be used to gain access to information that is not easily available and gain an “insider’s perspective” on the issue examined (Dexter, 2006; Woll, 2008, 2019). And although firms might not disclose secret information about their corporate procedures, some market strategies are observable (e.g., where pharmaceutical industries submitted market applications). Other methodological avenues might include mathematical models that provide a deductive, formal interpretation of firm behavior. See, for instance, Carpenter's (2004a) study on the regulatory approval of pharmaceuticals in the US.

## **Conclusion**

Almost three decades ago, David Baron, a distinguished professor of political economy from Stanford, wrote that “regulation in pharmaceuticals is more potential than actual (...) it has the potential to encompass both economic regulation (the control of prices) and social regulation (the availability of pharmaceuticals and the direction of research and development)” (Baron, 1993, p. 46). In 2021, the study of pharmaceutical regulation still lacks a sufficiently well-developed comparative perspective and a serious look into the Global South. Social regulation of pharmaceuticals is more important than ever. Baron noted that pharmaceuticals can be studied (and we echo this for COVID-19 vaccines) using normative theory (e.g., regulation of vaccines under incomplete information about clinical trials, particularly for the state-sponsored candidate vaccines such as Sputnik V, Coronavac, and Covaxin), positive theory (e.g., political action by politicians or activists to streamline the vaccine approval process), political economy theory (e.g., stringent vaccine regulation as a function of interests and the associated political action), and even the sociology of organizations (e.g., why firms seek regulatory approval in some countries and not others).

In this Research Forum article, we highlighted some hypotheses and potential explanations, such as scientific advice, the study of trust relationships within regulatory regimes,

and regulatory diffusion and adaptation. Other avenues might include a careful look into capture theory or corporate bias—when the aim of regulations shifts from ensuring safety and efficacy to speeding up drug approval to promote the interests of the pharmaceutical industry (or politicians) (Davis & Abraham, 2013). Such reasoning is particularly important in the context of the Global South, where drug regulation tends to be incipient or deemed functional but not stringent. How does the capture phenomenon play out in independent regulatory agencies (which are supposedly more autonomous from the executive) or departments that are subordinate to the minister of health (and thus more directly under the executive)? Recent studies on preventing regulatory capture provide the analytical and methodological tools required to explore these questions (Carpenter & Moss, 2013).

Regulating Covid-19 vaccines is also an opportunity to revisit studies on regulating health risks, such as Vogel's (2012) "The politics of precaution," which investigates risk regulation in the US and Europe. Vogel analyzes the transatlantic differences in risk assessment in the face of scientific uncertainty, which has become highly contentious.<sup>3</sup> The variation can be explained according to the in strength and scope of public pressure for more protective regulations, the preferences of government officials, and the criteria by which governments assess and manage risk. This literature can provide important insights into the government's pivotal role as a manager of the risks of Covid-19 vaccines, particularly from a comparative perspective: democratic versus authoritarian governments or incipient versus institutionalized drug regulation agencies. Finally, we call attention to the importance of comparative, qualitative studies as they allow an inductive approach that is necessary to explore understudied areas.

Understanding the pharmaceutical regulation of COVID-19 vaccines will be a challenge for all disciplines involved. It will require interdisciplinary inquiry, combining research in politics, economics, and health policy. A better understanding of COVID-19 political economy could eventually allow policy makers and practitioners to navigate political challenges that arise

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<sup>3</sup> Vogel investigates how the EU and US approach the precautionary principle. Although there is no consensus on the precise formulation of the precautionary principle, it is a philosophical principle applied to the decision-making process in the context of scientific uncertainty (European Parliamentary Research Service, 2015). Risk can be measured by methods such as cost-benefit analysis and risk trade-off analysis. However, there is also a lack of consensus on what constitutes the best measure of risk. Hence, the precautionary principle is a major focus of transatlantic tension in environmental forums (Vogel, 2012).

when regulating COVID-19 vaccines, which in turn could promote more global health equity in who will get the vaccines and at what speed.

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