Eva Heims Slobodan Tomic March 11th, 2021

Covid-19 vaccines and the competition between independent and politicised models of regulation

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The regulatory approaches used to approve Covid-19 vaccines vary substantially across different countries. While some states assign responsibility for vaccine approval to independent regulatory agencies, politicians in other states have greater scope to influence decision-making. **Eva Heims** *and* **Slobodan Tomic** *write that the current push to roll out vaccination programmes as quickly as possible is shining a light on competition between these independent and politicised models of regulation.*

A good deal of commentary on the approval and procurement of Covid-19 vaccines has taken a geopolitical lens in which the focus has been on the 'race' between nations, or more broadly, between what can roughly be called the Eastern and Western bloc. Yet one aspect that has been insufficiently explored in this context is the impact of different models of regulation.

Vaccines are generally approved by regulatory agencies, but these institutions do not operate under the same model in all countries. A key dimension on which they differ is whether they are characterised by independent 'technocratic' or by politicised regulatory decision making on vaccine market approval.

The independent model of regulatory decision-making – known as the 'regulatory state' in academic literature – is one in which a regulator, to which legislators have delegated regulatory powers, is structurally separated from the locus of political power, through appointment and staff removal procedures, as well as budgeting models that minimise the role of political authorities.

Regulators which are reputed for their strict standards and detachment from political authorities are, for example, the American Federal Drugs Administration (FDA), as well as a number of other national regulators, many of which are present in the big EU countries or in other 'modern governance frontrunners' within the OECD. At the EU level, this model is epitomised by the European Medicines Agency (EMA), a supranational regulator that issues scientific opinions on whether a given medicinal product is effective and safe enough to enter the EU market.

The politicised model of regulatory decision-making, in contrast, is one in which regulators are under formally established, or informally

practiced political control. Outside the 'Western core', the 'regulatory state' model has recently been diffused across a large number of non-Western countries, primarily in the transitional and developing world. However, in practice, this model does not necessarily ensure non-politicised regulatory decision-making as political authorities can use informal networks and pressures to influence regulators' work.

Such practice is particularly observed among semi-authoritarian states and those experiencing democratic backsliding. Despite the existence of de-jure independent regulators, these countries ought nonetheless to be grouped into the model of politicised regulatory governance. The other group of states that comprise the 'politicised regulation' bloc includes countries where a regulator is formally subsumed to the political locus of power. Examples include China, where the leaders and members of its medicines regulator, the National Medical Products Administration, which has approved the state-sponsored Sinopharm and Sinovac vaccines, are appointed and controlled by the Communist Party, and Russia, where the national regulator is subsumed under the state's Ministry of Health.

Political pressure

As Covid-19 vaccines were being developed by pharmaceutical companies around the world, the local regulators, particularly those most prominent – from the global powers – found themselves under pressure to approve vaccines as quickly as possible. This revived the traditional tension in medicines regulation between the speed of product approval and product safety and efficacy.

In the Western bloc, the vaccine approval procedures unfolded under the technocratic governance model. However, in the context of the pandemic, political pressure on medicines regulators was also

evident. The American FDA was under political pressure in its emergency approval of blood plasma to treat hospitalised Covid-19 patients, to which it seemingly bowed. But following public criticism, the FDA tried to quickly recover from this episode by vowing to act completely independently from political pressure when approving Covid-19 vaccines; later on, it indeed defied heavy pressure from the Trump administration for speedy approval of vaccines.

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In Europe, on the other hand, the EMA has been under fire for the slow vaccine rollout in the EU, and following criticism from political leaders, it started moving its approval dates forward. Thus, even the most independent of regulators are clearly not entirely immune to political pressure. With this stated, the Covid-19 vaccine debate is certainly an outlier when it comes to political leaders publicly lambasting medicines regulators, and set regulatory standards and due procedures were still not compromised. However, instead of publicly praising the advantages of the independent model of regulation, state officials, politicians and public commentators in Western countries focused on criticising differences in the approval procedures between the US, UK and EU, and the alleged slowness of the 'overly

technocratic mode of regulatory approval'.

Safety versus speed

In the non-Western bloc, the lack of independent regulatory policymaking enabled the use of vaccines to build soft power externally, and legitimacy internally, vis-à-vis the population of the countries in question. Thus, in the states which were developing vaccines under state direction – China and Russia – the lack of independent regulatory decision-making enabled quick vaccine approval which was then used to portray the states as being 'ahead of the Western competition'.

This quick approval was criticised in Western circles on grounds of failing to complete the necessary tests and confirm safety standards, but the vaccines were, nonetheless, being promoted among non-Western states, an increasing number of which procured them as it became clear that, for the vaccines approved in systems of the 'regulatory state', primarily in the US and EU (e.g. Pfizer, Moderna and AstraZeneca) there will be a queue and stringent requirements on efficacy and safety data.

Following the purchase and prior to the use of vaccines, a diffusion of 'pro-forma', politically blessed regulatory approvals took place across those states. The UAE's national regulator was the first to approve the Chinese Sinopharm vaccine, and then a series of countries followed suit. Similarly, the Russian Sputnik vaccine has been approved by almost 30 countries so far, mainly outside the EU, and in most, if not all of those countries, the political authorities precluded that the 'vaccine is safe and effective' before the domestic regulator approved it, even before it received the data on the vaccines' efficacy and safety. Hungary was the first EU country to approve the vaccine in

February, and is likely to be joined by Slovakia and the Czech Republic. Meanwhile, the EMA started reviewing the vaccine for EU wide approval in early March.

In this bloc of counties, the procurement of vaccines has been mainly framed as an issue of expediency, and, as anecdotal evidence indicates, public opinion has bought into the 'any vaccine is better than no vaccine' credo. Interestingly, there was little concern in the public debates about following due regulatory procedures, and when such arguments were raised publicly, the authorities would frame the issue as one of 'geopolitical squabbles', putting forward a 'health first, not geopolitics' argument. Thus, political authorities framed the question of following the full domestic regulatory procedures as one of arguably unnecessary 'red tape', whilst at the same time suggesting that the approval in the producer country, and in other third countries which have started using the vaccine, is a guarantee of the quality of the vaccine.

A challenge to the independent regulatory model

The question that arises is whether the above developments could weaken the 'appeal' of the independent regulatory model in the long-run and whether it will provide further ammunition for those lambasting 'technocratic governance'. We suggest that it is still too early for such conclusions. While, so far, it might seem that the model of independent decision-making is coming out of this stage of the pandemic with a 'dented image', the ultimate reputation of the independent, technocratic model of regulation will depend on how things transpire in the rest of the vaccination period.

If, for example, vaccines approved under the non-regulatory state models turn out to be less effective or safe, thus leading to recurring

waves of infection and a slower exit from the pandemic, political trust could be damaged. Interestingly, the countries where anti-vaccine movements have strengthened the most in the last six years feature non-regulatory state models. This might turn the tide in favour of the 'regulatory state' and highlight the importance of due regulatory processes as opposed to 'shortened' politically-blessed regulatory approvals.

However, early and large-scale successes of vaccination programmes in countries following politicised models of vaccine approval may yet turn up the heat on the model of independent, technocratic regulation. In any case, leaders of Western countries may do well to defend the advantages of the model of independent regulation more passionately than they have done to date.

Note: This article gives the views of the authors, not the position of EUROPP – European Politics and Policy or the London School of Economics. Featured image credit: Tom Wolf (CC BY 2.0)

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