

Don't let safety fall by the wayside in the rush to find a vaccine

- Peter Drahos

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The oseltamivir fiasco of H5N1 shows what happens if companies and patents are allowed to prevail over public health. Picture: Shutterstock

In 2003, the World Health Organization believed that [H5N1](#), a strain of avian influenza virus, was a pandemic in waiting. There was no vaccine, but the WHO recommended the stockpiling and use of [oseltamivir](#) - sold under the brand name Tamiflu - as a treatment.

The company behind oseltamivir funded research into the drug, and much of that research [failed to highlight](#) the likelihood of "serious adverse events, especially neuropsychiatric events" associated with taking the drug. The WHO, in recommending its stockpiling, relied on compromised and incomplete research on the drug because of the urgency of the moment. These lessons must not be forgotten by states in the current pandemic.

[This story](#) shows how difficult it is to meet urgent and global demand for a pandemic treatment that is under patent, especially when the patent owner does not share manufacturing knowledge with others. The pharmaceutical company behind oseltamivir claimed that the fermentation process for the making of shikimic acid, the starting ingredient, was too complex for other firms to handle.

They even warned there was a high risk of [it exploding](#). The truth of this turned out to be questionable, and other manufacturers eventually reverse-engineered the process without blowing themselves up. A chemist at Harvard University, Elias Corey, found a way to synthesise the active ingredient, [bypassing](#) the need for the shikimic acid altogether.

The lesson from this, quite simply, is that if leaders want speed in manufacturing a vaccine, they are better off trusting open science, and not secrecy. Secrecy will delay the rapid scaling up of manufacturing to meet global demand.

In this case, the fact that only one company was producing the drug caused a global shortage of oseltamivir. Faced with this shortage, countries scrambled to look after themselves, and the ones with the biggest sticks and pockets did the best in terms of stockpiles - a hugely inequitable outcome.

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The United States, for example, threatened the company with a compulsory licence and insisted that it ramp up production of oseltamivir. The poorest and highest-risk countries though, like Laos and Vietnam, ended up with little or no stockpile. They had to rely on donations from other countries. Donation is a [fragile basis](#) on which to run public health.

If policymakers are to avoid the power plays of [vaccine nationalism](#), all states funding vaccine development must oblige manufacturers to share vaccine knowledge. This is key to making the vaccine a global public good. States have the leverage to insist on knowledge transfer because they are meeting the upfront costs of vaccine development, and the oseltamivir fiasco of H5N1 shows what happens if big pharmaceutical companies are allowed to harness secrecy and patents are allowed to prevail over public health.

The oseltamivir story has much to teach policymakers. The clinical trial evidence for the benefits of oseltamivir included a reduction in risk of secondary complications from influenza, as well as reducing the risk of person-to-person transmission, but this evidence came from a small number of trials funded by the manufacturer.

Beginning in 2009, a Cochrane review team took almost four years to [assemble](#) around 150,000 pages of clinical trial data on the drug, most of which had never been made public. Cochrane reviews are systematic and transparent reviews by independent researchers of all the scientific evidence on a given problem, and the analysis showed evidence of potential harm from oseltamivir such as nausea, vomiting and psychiatric events that were not reported publicly.

In all, an independent review did not support previous claims of efficacy, and [concluded](#) that governments had paid billions of dollars to stockpile a treatment that was probably "no more effective than aspirin".

The lesson here is clear. Every single piece of scientifically relevant evidence to the production and testing of any vaccine should be made public and easily accessible for independent scrutiny.

Unfortunately, shortcomings in drug-testing are too widespread, and pharmaceuticals are an industry that cannot be blindly trusted. Indeed, criminologists have shown that data manipulation and fraud are major problems in the pharmaceutical industry.

Importantly, vaccines developed by universities like Oxford University will not be manufactured by those universities, so public availability of all data, in both development and manufacturing, should be a non-negotiable issue for governments committing tax dollars to any pharmaceutical vaccine manufacturer. Nothing less than the future of vaccines is at stake.

At the moment, regulators and companies are caught up in a corner-cutting race to release a vaccine. With more than 165 vaccines in various stages of development, the release of more than one vaccine is almost certain.

In this environment, governments should be paying attention to Cochrane's other recommendation: focus on safety and effectiveness. The Cochrane team recommended meta-reviews of many important pharmaceuticals, reviews that would be independent of regulators and pharmaceutical manufacturers.

Wishful or incomplete interpretations of data among regulators is very much a danger in the race to a COVID-19 vaccine. Setting up an independent process of review for a COVID-19 vaccine that runs in parallel with the work of pharmaceutical regulators is critical, and trusting in regulators and drug companies alone would be a fatal mistake.

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