

## **The rush to find a coronavirus vaccine must not trump safety**

*di Thomas Cueni*

We all want a coronavirus vaccine. But no matter how urgently action is needed, it is imperative that the highest standards of quality, safety and efficacy are upheld.

Russia's decision to approve mass use of its "Sputnik 5" vaccine after just two months of human trials is deeply troubling. Efforts by other countries to push through their own candidates at breakneck speed are also problematic.

We must prioritise thorough validation of the results of pre-clinical and clinical trials by independent expert bodies. There is no place for political favour or national one-upmanship. Only the most rigorous application of science and openness in the regulatory process can ensure that everyone, starting with healthcare workers, has confidence in Covid-19 vaccines once they have been properly approved.

To bolster public confidence, leading vaccine manufacturers are rallying to support regulators. The Covid-19 Vaccine Maker Pledge launched yesterday commits to only submit such vaccines for approval after demonstrating safety and efficiency through a Phase 3 clinical study.

Now industry needs governments to follow up. That is where US food and drug commissioner Stephen Hahn comes in. As head of one of the world's leading medicines agencies, he can play a key role in setting the bar so people can trust the quality, safety and efficacy of a new vaccine. But he told the Financial Times he is willing to bypass the normal approval procedure. Vaccine manufacturers need the Food and Drug Administration to provide clear regulatory guidance and set clear criteria for the authorisation or approval of a Covid jab.

FDA leadership is paramount as it can shine a light on the right approach. It should provide a strong counterweight to what is happening in Russia and other countries where the speed to rush through a vaccine seems more an effort to gain a competitive edge than a focus on health. So far, from these other countries, there is little transparency on results of pre-clinical or clinical trials, let alone due process for potential users of the vaccines. It is shocking when a country makes it a patriotic duty for healthcare workers and teachers to agree to being inoculated with a new vaccine without asking questions.

Heidi Larson, who leads the Vaccine Confidence Project, a global surveillance programme on vaccine trust, said she feared Russia's rush could further dent public trust. Fast is good for politicians, but from the public perspective, too fast can be unsafe.

Of course, everybody is keen to develop a safe and effective Covid-19 vaccine as fast as possible, and manufacturers are moving at unprecedented speed. But we also have to move as slowly

as needed to make sure no corners are cut. People should not get a Covid-19 vaccine until national regulatory agencies have approved them, on the basis of solid validation of the vaccines' quality, safety and effectiveness.

Nothing is more important to the companies I represent than the health and safety of those receiving a vaccine. That hasn't changed in this pandemic.

However much it costs — and it might hurt financially to slow down the testing and production of a new vaccine — manufacturers have an ethical duty towards patients and society. They must fully commit to transparency about clinical trials whether the results are good or bad. Regulators need to be allowed to do their work as fast as science and good practice allow and at the appropriate pace needed to ensure delivery of safe and effective vaccines.

People will only trust new vaccines if they believe they have been approved by independent regulators based on pure science. Undermining that trust would further fuel anti-vaccine movements, which are already disrupting immunisation programmes and endanger all of us.