



## Editorial

## Advancing COVID-19 vaccines – avoiding different regulatory standards for different vaccines and need for open and transparent data sharing



### Introduction

The erratic ways by which the global scientific R&D, pharma and technology community conducted themselves during epidemics such as SARS-CoV-1, Ebola virus, MERS-CoV and others, the lack of co-operation and missed opportunities for filling important knowledge gaps and having an enhancing and multiplier effect, led to the establishment of the WHO R&D Blueprint and global strategy and preparedness plan (WHO, 2020a). The Blueprint leverages the successes and addresses the gaps in order for the world to be prepared for the next pandemic(s). Previous attempts to develop a vaccine against two lethal coronaviruses, SARS-CoV-1 and MERS-CoV, generated knowledge about their structure, function and pathogenesis (Prompetchara et al., 2020; Dhama et al., 2020), although several vaccine candidates for SARS-CoV-1 and MERS-CoV failed in early-stage clinical trials, and none were advanced to licensing. However, the experience accelerated rapid development of several technological platforms which are now being used for development of COVID-19 vaccines. The explosive global spread of COVID-19 pandemic has generated international consensus in principle, between the WHO, vaccine developers, governments, funders, donors and industry, with agreement on the need to develop an effective COVID vaccine and plans for fair and equitable rollout to all countries (Lurie et al., 2020). Important concerns during these discussions have been expressed by developing countries that only developed countries will have priority access to any new COVID 19 vaccine.

### COVID-19 vaccine- race to be the first and Sputnik-V

Researchers and vaccine developers around the world have raced to develop a COVID-19 vaccine and over 170 candidate vaccines are now being followed by the World Health Organization (WHO, 2020b). By August 1st 2020, there were 47 vaccine candidates undergoing evaluation, 25 in phase 1, 17 in phase 2, and 6 in phase 3 trials, although none had been approved for general use. The western media has focussed on COVID-19 vaccines being developed by selected western countries (UK, USA, Germany, Italy), and China. Thus the announcement by the Russian authorities on August 10th, 2020 of the approval of a vaccine against SARS-CoV-2 (Science, 2020) for human use came as a major surprise to other vaccine developers. No licenced vaccine exists

based on an adenovirus construct but much work using these constructs has been done and human adenovirus infections only generally cause common colds in immunocompetent persons. The Russia vaccine, named Sputnik-V is based on a human adenovirus carrier inserted with genetic sequences from the SARS-CoV-2. It has been developed by the Gamaleya Research Institute of Epidemiology and Microbiology in Moscow, and will first be administered to vulnerable groups, including medical staff and the elderly. A phase III efficacy trial involving more than 2000 people will begin shortly in Russia, the Middle East, Brazil, and Mexico (Russia Ministry of Health, 2020). Immediately after the announcement of Sputnik-V, several countries were very eager to purchase stocks of the Sputnik-V vaccine. In an article in the Washington Post 11th August 2020 (Washington Post, 2020) a spokesman for the Russian government was quoted to have said that Russia had received preliminary orders for more than 1 billion doses of the vaccine from 20 countries and Russia is preparing manufacture of more than 500 million doses of the vaccine per year in five countries.

### Regulatory standards - concerns and obtaining clarity

In addition, following the announcement there were concerns raised by western researchers that the vaccine may not have been through adequate phase 3 trial evaluation (Callaway, 2020), which is regarded as gold standard practice for approval by the Federal Drug Administration, FDA (U.S.A.), European Medicines Agency, EMA (E.U.) and WHO. Approval of the vaccine before phase three trial data become available and shared, may appear to the critics that this was a political decision. It has been suggested that the Russian regulatory authorities may not be following the same standards and procedure as the FDA and EMA in their rush to be first to roll out a COVID-19 vaccine. The underlying assumption that COVID-19 vaccines being developed in western countries are following the standard protocols leading upto phase 3 trial evidence, before final approval for widespread use, requires further clarification. Before countries start using the Sputnik-V vaccine, or other vaccines developed in western countries, and elsewhere, it is important that phase 2 and 3 trial data, especially immunogenicity and adverse events, leading up to the approval by the regulatory authorities, are made available publicly.

## Towards data sharing, transparency and openness

Data on all the 147 new COVID-19 vaccines under development need to be shared internationally in a transparent and open manner. If any effective SARS-CoV-2 vaccine is going to stop the pandemic we need to generate public trust in the vaccine to obtain a high acceptance rates. It is well documented that that vaccines which show promise in phase 1 and 2 trials, are found to be ineffective in phase 3 trials (Tameris et al., 2013). There have also been vaccines which have been withdrawn from the market after initial approval and widespread use (Staat et al., 2006). Thus, all pre-approval data must be available to the public, and post-approval, post-marketing, surveillance also must be open and transparent. There is an urgent need to avoid competition to the level where competition leads to division into two groups of countries – those that sign up for the Sputnik-V and those who will wait for a FDA or EMA approved vaccine. Whilst an FDA or EMA approved vaccine may provide re-assurance to western countries of a more rigorous process with immunogenicity and safety data, the vaccine will command a higher price. Approval processes for COVID-19 vaccines need to be clearly defined. The first condition that must be part of the Sputnik-V and other vaccines' approval process by regulatory agencies and WHO, should be free access to, and careful review of all pre-clinical, phase 1, phase 2/3 trial raw data. The second condition must be that proper surveillance is in place in countries using any new COVID-19 vaccine so that immunogenic effects and adverse reactions are documented as a surrogate, and vaccines undergo proper phase 3 trial evaluations. Third, defining which populations are at highest risk of developing COVID-19, will be important for identifying specific populations for priority immunization, whilst stocks of vaccines are made available for everyone.

## Conclusions

The COVID-19 vaccine developers need to carefully follow standard developmental and evaluation pathways of safety, immunogenicity, protective immunity, duration of vaccination protection, easy delivery systems, practical dosing regimens, stability, cold chain, rapid manufacturing for scaling upto billions of doses, emergency use authorization before formal licensing, and widespread dissemination of the licensed vaccine (WHO, 2020b, WHO 2020). The rush to roll out a new COVID-19 vaccine should not become another “cold war” like situation where there open transparent data sharing and effective communications are lacking. Being the first to develop and roll out COVID-19 vaccines may seem important, but instead, unity of purpose on open and transparent data sharing must be achieved, and everyone's focus should be on what's best for all of humanity.

## Author declarations

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