

IAP Communiqué on the Development and Distribution of Vaccines against COVID-19

The COVID-19 pandemic continues to spread in most countries around the globe, resulting in significant morbidity and mortality, as well as economic challenges to individuals and nations alike. This global pandemic of a serious, highly transmissible disease poses an ongoing threat for all. COVID-19 anywhere in the world presents risk of COVID-19 everywhere. While public health tools such as physical distancing, wearing of masks and proper hygiene, along with testing and tracing, have been shown to help control the spread, it is widely recognized that **vaccines will be essential to our ability to control the current pandemic, protect against likely future outbreaks of COVID-19 and allow populations to return to their daily lives.**

For these reasons, there has been a rapid and massive mobilization of the scientific research and development community to try to develop vaccines against this disease. Working across sectors, billions of dollars are being invested in vaccine research, which is being carried out at an unprecedented rate.

According to the WHO, as of 3 September 2020^I, there are 34 candidate vaccines in clinical evaluation and an additional 142 in preclinical evaluation. As of now, there are no officially approved COVID-19 vaccines available anywhere in the world. In the United States, a major vaccine development effort is underway, Operation Warp Speed, which is racing to move vaccines forward at unprecedented speed, targeting late autumn 2020 as a goal^{II}. Anti-COVID-19 vaccines in both China and Russia have been given the go-ahead outside of standard clinical trials using non-traditional regulatory pathways: on 25 June 2020, China's CanSino Biologics Inc. announced the 'military specially-needed drug approval' by China's Central Military Commission^{III} and on 11 August 2020, the Russian President, Vladimir Putin, announced the approval of a vaccine developed by the Gamaleya Institute in Moscow^{IV}.

We commend the researchers and sponsors undertaking this vital work, as well as the collaborations that have developed between countries, between public and private sectors, and between private companies^V. **However, while we re-affirm that vaccines are the safest and most effective long-term solution to the COVID-19 crisis, we wish to raise some concerns about their development, evaluation and eventual availability and distribution:**

1. Despite the requirement for accelerated progress – no corners should be cut in assessing the safety and efficacy of any candidate vaccine. Vaccine research and development is a challenging, complex process.

While there is a pressing need to accelerate this process to the greatest degree possible, there are also grave dangers if corners are cut. There is much we still do not know about the SARS-CoV-2 virus and the human immune response to infection. We need to proceed at a pace that enables the necessary scientific understanding and assessment to unfold. Valuable innovations in clinical trial design may enable enhanced speed, along with substantial new investments in early scale-up and manufacturing, even before there is certainty about which vaccines will prove safe and effective for use. However, the phases of clinical vaccine trials^{VI} must go forward with appropriate scientific rigour and the deliberate steps needed to demonstrate safety and efficacy. We note, for example, that the Russian vaccine mentioned above will apparently be rolled out without pre-licensure or pre-registration Phase III trials. This haste to proceed to regulatory approval without adequate safety testing may yet backfire as unexpected side effects may emerge that would not only affect the health of recipients, but also cause a backlash against the vaccine – as well as vaccines in general.

2. Concerted efforts must be made to tackle the misinformation espoused by the vocal anti-vaccine lobbies that are active in many countries. Confidence and trust in tried-and-tested vaccines are already being compromised by the anti-vaxx movement. Even the slightest of safety doubts raised against a new COVID-19 vaccine would play into the hands of such anti-vaxxers, putting the world at risk of prolonging the COVID-19 pandemic and potentially further undermining confidence in the vaccine enterprise overall. Trusted scientific voices such as academies of science and medicine must play their part in engaging the public, while governments and social media giants must play pro-active roles in taking action against individuals and groups that spread misinformation.

^I <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

^{II} <https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazene-ca-covid-19-vaccine-to-be-available-beginning-in-october.html#:~:text=Responding%20to%20President%20Trump's%20call,called%20AZD1222%2C%20with%20the%20first>

^{III} <https://www1.hkexnews.hk/listedco/listconews/seh/2020/06/29/2020062900123.pdf>

^{IV} <http://www.cansinotech.com/html/1/1179/180/409.html>

^V <https://www.bbc.com/news/world-europe-53735718>

^{VI} <https://www.biocentury.com/article/304928>

^{VI} For example, Phase I trials typically involve 20-100 healthy subjects and are used to test for any adverse reaction to the prototype vaccine; Phase II trials involve 100-300 subjects and an analysis of their immune responses; Phase III trials typically involve up to 3,000 patients with monitoring of immune responses, protection against infection, and any potential adverse reactions within this larger cohort.

3. As no country is safe from COVID-19 unless all countries are safe, **it is imperative that that any successful vaccine must be made available on the basis of equity, ethics and public health needs** – including to the world’s most vulnerable, impoverished and disenfranchised people. So-called ‘vaccine nationalism’, or the buying-up in advance of stocks of future vaccines exclusively for national use must be discouraged and access to the vaccine by countries and individuals should be based on need and not on ability to pay^{VII}. For this reason, IAP is participating in the Sustainable Health Equity Movement^{VIII}, and we applaud The Lancet COVID-19 Commission, developed to help speed up global, equitable, and lasting solutions to the pandemic^{IX}. 3. More significantly, we re-affirm our support for the approach of the WHO, which has published international

guidelines for COVID-19 vaccine production^X. Also of importance to note is the COVAX Vaccine Facility, the vaccine arm of the ACT Accelerator, which represents a ground-breaking global collaboration to accelerate the development, production and equitable access to vaccines, as well as the COVAX Advance Market Commitment (AMC)^{XI}. This effort is co-led by GAVI, CEPI and WHO^{XII}, but requires the support and investment of many nations. We urge nations to join this innovative and potentially far-reaching initiative.

Finally, we laud the rapid research advances and unprecedented collaboration of the scientific community, while also expressing the hope that such commitment will continue and be applied across other critical areas of science and un-met medical and public health needs.

VII e.g. https://www.sciencemag.org/news/2020/07/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly?utm_campaign=news_weekly_2020-07-31&et rid=40184457&et_cid=3430879
 VIII <https://www.sustainablehealthequity.org/>
 IX [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(20\)31494-X.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31494-X.pdf)

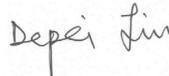
X https://www.who.int/biologicals/Standardization_Covid-19/en/
 XI <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>
 XII GAVI, the Vaccine Alliance (www.gavi.org) and the Coalition for Epidemic Preparedness Innovations (CEPI, www.cepi.net).

Signed by the members of the Steering Committee of the InterAcademy Partnership, September 2020

**Volker ter Meulen,
IAP President**



**Depei Liu,
IAP President
and co-chair, IAP-Health**



**Margaret Hamburg,
co-chair, IAP-Health**



**Krishan Lal,
co-chair, IAP-Science**



**Cherry Murray,
co-chair, IAP-Science**



**Richard Catlow,
co-chair, IAP-Policy**



**Masresha Fetene,
co-chair, IAP-Policy**



Acknowledgements

Drafted by Peter McGrath and Teresa Stoepler. IAP thanks Patrice Debré, Yonina Eldar, Atiya Mosam, and Gagandeep Kang of the IAP COVID-19 Expert Group as well as Robin Fears for their review of this Communiqué.

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