World Health Organization

COVAX Statement on New Variants of SARS-CoV-2

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The emergence of variants of SARS-CoV-2, the virus that causes COVID-19, serve as a powerful reminder that viruses by their very nature mutate, and that the scientific response may need to adapt if they are to remain effective against them.

In light of recent news stories regarding the preliminary data on minimal effectiveness of the AstraZeneca/Oxford vaccine at preventing mild to moderate COVID-19 disease caused by the viral variant B.1.351, it is important to note that primary analysis of data from Phase III trials has so far shown – in the context of viral settings without this variant – that the AstraZeneca/Oxford vaccine offers protection against severe disease, hospitalisation and death. This means it is vitally important now to determine the vaccine's effectiveness when it comes to preventing more severe illness caused by the B.1.351 variant.

Additional studies will also allow us to confirm the optimal vaccination schedule and its impact on vaccine efficacy. CEPI has announced funding for additional clinical research to optimize and extend the use of existing vaccines, which could include "mix-and-match" studies of different vaccines used in combinations that may improve the quality and strength of the immune response. Such studies could be useful in optimizing the use of available vaccines, including the AstraZeneca/Oxford vaccine.

The WHO Strategic Advisory Group of Experts on Immunization (SAGE) convened today to review evidence on the AstraZeneca/Oxford vaccine, including emerging evidence on performance against viral variants, and to consider the demonstrated impact of the product and the risk-benefit assessment for use cases with limited data. These recommendations for use of the AstraZeneca product are being finalised and will be presented to the WHO Director-General on 9 Feb 2021.

Even though this recent news on effectiveness of the AstraZeneca/Oxford vaccine against the B.1.351 variant is based on a limited study size which focused on low-risk participants and used interval doses that were not optimized for immunogenicity, these results confirm **we must do everything possible to reduce the circulation of the virus, prevent infections and reduce the opportunities for the SARS-CoV-2 to evolve resulting in mutations that may reduce the efficacy of existing vaccines.** This means that additionally:

- **Manufacturers must be prepared to adjust to the SARS-CoV-2 viral evolution, including potentially providing future booster shots and adapted vaccines, if found to be scientifically necessary.**
- **Trials must be designed and maintained to allow any changes in efficacy to be assessed, and to be of sufficient scale and diversity to enable clear interpretation of results.**
- **Enhanced genomic surveillance must be backed by rapid sharing of genetic and meta-data to allow for global coordination and response.**
- **Priority should be given to vaccinating high-risk groups everywhere in order to ensure maximum global protection against new strains and minimize the risk of transmission.**
- **Governments and donors, as well as development banks, should further support COVAX in order to ensure equitable access and delivery, as well as meet ongoing research and development costs for next-generation vaccines.**
- **WHO is enhancing an existing mechanism for tracking and evaluating variants that may affect vaccine composition and expanding that mechanism to provide guidance to manufacturers and countries on changes that may be needed for vaccines.**

COVAX was set up to ensure global equitable access to safe and effective COVID-19 vaccines. With the world's largest actively managed portfolio of COVID-19 vaccine candidates, the COVAX Facility offers its self-financing participants and those eligible for support through the Gavi COVAX Advance Market Commitment access to a diverse range of vaccine candidates, suitable for a broad range of contexts and settings. The ability to deploy vaccines globally to address the evolving pandemic is more critical than ever, as is the importance of coordination to ensure we do not put the impact and value of vaccines at risk. If new vaccines are required, ensuring global access to these is even more essential, as we continue to see that we are all safe only if everyone is safe.

With regards to the AstraZeneca/Oxford vaccine, COVAX has signed advance purchase agreements with AstraZeneca and Serum Institute of India and has published plans to distribute nearly 350 million doses in the first half of the year. We expect a decision this month from WHO on whether the vaccines will be granted emergency use listing (EUL) as well as a SAGE recommendation on its optimal use. Should EUL be forthcoming, we expect the vaccine to play a key role in our effort to protect high risk persons and to help end the acute phase of the pandemic.