

Call for nominations for experts to serve on a Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 Vaccines and Vaccination

Context

In December 2019 a novel coronavirus (SARS-CoV-2) emerged in Wuhan, China, resulting in a rapidly spreading outbreak of coronavirus disease (COVID-19). On Jan 30, 2020, the World Health Organization (WHO) declared COVID-19 a public health emergency of international concern (PHEIC), and by 12 March 2020, due to its rapid global spread, the outbreak was declared a pandemic. By 22 April 2020, more than 2 million SARS-CoV-2 infections have been recorded around the world, with more than 160,000 deaths. The need for a vaccine has therefore become more pressing than ever, as the prospect of containment with non-pharmaceutical interventions has become less feasible.

More than 100 vaccine candidates are now in development, with more than 5 candidates in Phase 1 human clinical trials. It is expected that candidate COVID-19 vaccines will be developed at accelerated pace and will be deployed to countries under expedited regulatory regimes, such as compassionate use/expanded access schemes, and/or under an Emergency Use Listing (EUL) (termed subsequently pre-licensed vaccines). While these processes may provide some assurance on quality, safety and efficacy, they will not provide sufficient guidance for countries to make informed decisions on their use, and on the most effective vaccination strategies.

To this end, the SAGE working group will be set up with the aim of establishing an independent process through SAGE to advise WHO and its Member States on the use of initially pre-licensed vaccines, followed by updates as additional information on product use becomes available. The timeliness of setting up this group will ensure a coordinated approach with the vaccine Research and Development (R&D) community, in order to accelerate timelines and maximize global efforts to make evidence-informed policy decisions for the best use of a vaccine against COVID-19. The ultimate goal of a vaccine against COVID-19 is to rapidly contain the pandemic, save lives, protect health care systems, and restore global economies.

The SAGE Working Group is established with a program of work to:

- (1) Provide **continuous review** of the available evidence on the progress of candidate vaccines against COVID-19, and provide regular updates to SAGE;
- (2) Provide **guidance** for the development of prediction models to determine the optimal age groups and target populations for vaccine introduction and guide vaccine introduction for optimal impact, and contribute to updates of target product profiles of vaccines for outbreak and for endemic use;
- (3) Prepare **policy advice** to SAGE on the accelerated use of vaccines (pre-licensure and post-licensure) to mitigate the public health impact of COVID-19, to possibly curtail the ongoing pandemic, as well as to prevent or reduce the risk of spread of disease in the future. This will include recommendations for early allocation of vaccines when vaccine supply is still limited;
- (4) Provide **guidance** to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available, in close collaboration with Global Advisory Committee on Vaccine Safety (GACVS).

The Working Group will consult with other WHO advisory bodies, including the Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH), the R&D Blueprint Scientific Advisory Committee, Product Development Vaccine Advisory Committee (PDVAC) and GACVS, as well as with WHO Regional Immunization Technical Advisory Groups as needed in relation to operationalization

of immunization delivery. Information will be consolidated into reports to SAGE with recommendations on potential strategies for the deployment of vaccines.

Specific assignments of the SAGE working group will include (to be reviewed and adjusted over time) the following reviews:

1. Essential evidence required for making policy recommendations and on strategies for pre-licensed vaccines.
2. Available epidemiological data to define the risk of disease and morbidity/mortality in different population groups; identify main sources of transmission in order to guide prioritization of vaccination.
3. Data on the projected impact of different vaccination strategies generated by mathematical models, in accordance with the epidemiological situation.
4. Social, anthropological and ethical considerations for the use of pre-licensed vaccines, as well as the criteria for allocation of a potential limited amount of vaccine.
5. Projections of vaccine supply and funding available for deployment.
6. Safety features/evidence of candidate vaccines to propose safety monitoring strategies and provide guidance on vaccination especially for high risk groups.
7. Evidence on the safety, immunogenicity/efficacy of candidate vaccines, including the optimal vaccination schedules to be used for each vaccine, and issue recommendations on monitoring of vaccine performance (safety, effectiveness, impact).

The mandate is to draft recommendations based on the synthesis of the above evidence to SAGE to decide on policy recommendations.

We are looking for experts in the following areas:

- Immunology of SARS-CoV-2 and other coronaviruses
- COVID-19 vaccines
- Clinical evaluation methods and trial designs
- Epidemiology/public health expertise, with particular experience in low- and middle-income countries and vaccine effectiveness studies.
- Health economics
- Ethics of vaccination and vaccine programmes including equitable access
- Immunization programmes and service delivery
- Social anthropology
- Mathematical modelling of vaccine preventable infectious diseases
- Vaccine safety evaluation and monitoring
- Immunization policies

Proposals for nominations should be sent by email to sageexecsec@who.int with a Curriculum Vitae, indication of relevant expertise, and a completed declaration of interest form. Only complete nominations received by Monday, 11 May 2020 will be considered.

Information on the purpose, structure and functioning of SAGE Working Groups is available at http://www.who.int/immunization/sage/SAGE_Working_Groups_general_information.pdf?ua=1