ACT Accelerator COVAX Pillar - Independent Product Group

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.

The need for a vaccine has become more pressing than ever, as the prospect of containment with non-pharmaceutical interventions has become less feasible given their high economic and social costs.

The ACT Accelerator refers to the global initiative aimed at developing and accelerating access to COVID-19 diagnostics, therapeutics and vaccines. It includes three partnerships each of which is focused on one of the three tools. The COVAX Pillar is the partnership driving forward the work on vaccines. With the COVAX Pillar, the COVID-19 Global Vaccine Access Facility (COVAX Facility) will pool investments from participating countries to secure large volumes of vaccine to be allocated globally.

Vaccine development is moving at an unprecedented speed and scale and as promising candidate vaccines advance, practical realities will require a process that independently validates the most promising candidates to inform procurement decisions of the COVAX Facility.

Objectives

The Independent Product Group will be set up with the aim of establishing an independent process to advise the COVAX Facility and the COVAX Pillar more broadly on the candidates likelihood of meeting threshold criteria for purchase by the Facility, and subsequently, whether those criteria are met. Meeting those criteria would inform the criteria for purchase, along with e.g. price.

The working group is established with a program of work to:

(1) Review the data and information on all candidate vaccines proposed for procurement by the COVAX Facility, using the a priori defined attributes and criteria including agreed target product profiles, and review manufacturing data for scalability and quality;

(2) Provide individual scores for each candidate vaccine and a recommendation on the pertinence of prioritizing one or more given candidates for procurement including if there are vaccines more appropriate for some populations or use in some settings;

(3) Provide continuous review (monthly) of the potential timing and numbers of doses meeting threshold criteria that might become available

(4) Support COVAX Facility portfolio management and advise whether pivots to incorporate additional vaccines are required to ensure all high potential products are covered and that enough doses will be available in the desired time frames.

The Independent Product Group will work effectively with the COVAX portfolio governance structure under the Development and Manufacturing workstream, which is tasked with R&D and manufacturing

investment decision making for the COVAX portfolio of vaccine candidates and enabling sciences activities.

The COVAX Facility will consider the recommendations of this independent group and consult with other pertinent advisory bodies to inform their opinion.

Expertise required

The Working Group will be composed by 5-7 experts. Independent expertise in the following areas is sought:

- Coronavirus vaccines and/or COVID-19 vaccines
- Animal models and assays for vaccine evaluation
- Clinical evaluation of vaccines including vaccine evaluation in large randomised clinical trials
- Regulatory expertise in vaccine evaluation
- Vaccine manufacturing and GMP issues
- Epidemiology/public health expertise
- Expertise in immunization programmes and service delivery
- Vaccine safety evaluation and monitoring

Timeline for submission of nominations

Proposals for nominations should be sent by email to khari@gavi.org with a Curriculum Vitae, indicating area of expertise, years of experience and current involvement, if any, in COVID vaccines development and evaluation. **Deadline for submission is 17 July 2020.**

Evidence Review Process

There will be a standardized process for requesting information from developers, reviewing the evidence, decision-making, reporting and communicating the outcomes from the group. WHO TPPs, SAGE recommendations, and EUL/PQ processes will serve the roles of providing WHO's normative review of the evidence. Understanding that these are appropriately streamlined in the context of the pandemic, Gavi will aim to support procurement of candidates that are recommended by WHO as for other GAVI-supported vaccines. Gavi may further prioritize amongst vaccines that are supported by WHO recommendations following Gavi's governance processes.