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# THE GAVI COVAX AMC

## AN INVESTMENT OPPORTUNITY

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# 123 → PRECLINICAL VACCINE CANDIDATES

## 10 → VACCINES IN HUMAN TRIALS

### SUMMARY

The world urgently needs COVID-19 vaccines. To maximise the probability of success, we need urgent investment in a wide portfolio of vaccine candidates and a scale-up of production capacity at risk. We know that vaccine supply will be constrained for some time.

The vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator is launching a COVID-19 Global Vaccine Access Facility (Covax Facility), which will pool resources and share vaccine development risk. Demand guarantees for vaccine manufacturers will create access to substantial volumes of vaccines that will ultimately be safe and efficacious; better allocate capital; and support the manufacturing and procurement of sufficient volumes of vaccines to support equitable access globally. All countries will be invited to participate in the Covax Facility.

This investment opportunity of US\$ 2 billion will provide vital seed funding to the Gavi Advance Market Commitment for COVID-19 Vaccines (Gavi Covax AMC) to support high-risk populations in low-income countries (LICs) and lower middle-income countries (LMICs), as part of the new Covax Facility. This is needed to signal urgently to manufacturers that they should scale up production and reserve capacity for all countries, and to create contingent agreements with them to purchase doses for all participating countries.

### CONTEXT

The world urgently needs vaccines that protect against COVID-19. Vaccine development is moving at an unprecedented speed and scale, with more than 123 pre-clinical candidates in development and 10 in human trials. If left to market dynamics or individual government investment, there is no scenario in which the aggregate supply of safe and effective COVID-19 vaccines over the next 18 months will meet potential demand. As a result, before successful COVID-19 vaccines are licensed, we need to move equally fast to accelerate the capacity to research, develop and make vaccines for clinical trials; scale up manufacturing capacity; and make sure vaccines are allocated effectively. This will allow us to contain the pandemic, mitigate its health impact and restart economies as quickly as possible.

Unless we act quickly, there will be continued national competition for vaccines, inefficient use of scarce vaccine resources, prolongation of the pandemic, additional and unnecessary deaths and, potentially, a deepening economic crisis.



Gavi/2007/Atul Loke

UNICEF/2020/Arinacs Wilander

Gavi/Christophe Da Silva/Hans Lucas

### WE NEED TO ADDRESS THREE URGENT ISSUES:

**Leaders are facing intense demands from their populations to secure vaccines and support the recovery of their economies. Vaccine developers report that they are being approached by an increasing number of countries seeking to establish advance purchase arrangements. In addition, the competition for vaccine candidates, manufacturing supplies and capacity, R&D capacity, clinical trial sites, principal investigators, and hospitals is driving up prices and reserving resources.**

**While some governments are already investing in vaccine candidates, inevitably individual governments can only support a small number of candidates. Many countries have no access to the resources needed to develop a vaccine. COVID-19 vaccine programmes that have not yet entered human trials are estimated to have a 7% probability of succeeding, and 17% once they have entered human trials.<sup>1</sup>**

**We know that vaccine supply will be constrained for some time. The vaccines must be deployed with the vision of ending the pandemic. To strengthen global health security, low-, middle- and high-income countries alike need rapid and affordable access as part of global equitable scale-up.**

Unless we act quickly, there may be continued national competition for vaccines, inefficient use of scarce vaccine resources, prolongation of the pandemic, additional and unnecessary deaths, and potentially a deepening economic crisis. In addition, the broader health impact of COVID-19 on other health programmes may only get worse.

On 26 March, the G20 leaders called for a new initiative “to align priorities in global preparedness and act as a universal, efficient, sustained funding and coordination platform to accelerate the development and delivery of vaccines, diagnostics and treatments.”<sup>2</sup> On 24 April, the World Health Organization (WHO) hosted the launch of the Access to COVID-19 Tools (ACT) Accelerator, a new global collaboration to accelerate development, production, and equitable access to COVID-19 diagnostics, therapeutics, and vaccines. The European Commission hosted a pledging conference in support of the ACT Accelerator, with high-level representation from countries across the globe; and successfully launched funding for the ACT Accelerator, showing global commitment to this collective approach. Then, most recently, the 73rd World Health Assembly recognised “the role of extensive immunization against COVID-19 as a global public good”; supported the Accelerator; and also called for “equitable and timely access to quality, safe, affordable and efficacious vaccines.”

# THE COVAX FACILITY

The COVID-19 Global Vaccine Access Facility (Covax Facility) is being developed to address these unprecedented challenges. It will invite global participation to pool demand and resources to support procurement of COVID-19 vaccines. The Facility will be supported by financing instruments to facilitate pooled procurement for all participants. The funding for vaccines for upper middle-income countries (UMICs) and high-income countries (HICs) will be pooled from domestic health funds to secure doses for contributing countries, and the Gavi Covax AMC is being established to support procurement and delivery of vaccines for developing countries.

Just as an insurance policy manages uncertainty, so the uncertainty that is inherent in the current situation – about which vaccine candidates will be effective and safe, and about the course of the pandemic – needs to be managed. The Covax Facility, and the financing for LICs and LMICs provided by the Gavi Covax AMC, which will form part of the Facility, will do this by:

- **ensuring that funding of vaccines is available for lower-income countries**
- **pooling resources and sharing risk**
- **supporting the scale-up of supply**
- **allocating supply to contain the pandemic**

The Covax Facility is an umbrella mechanism. **Currently being developed in the Vaccine Task Force of the ACT Accelerator, the Covax Facility:**

- **is a global mechanism open to any country and manufacturer that wishes to participate**
- **requires participants to make commitments to allocation principles for the Facility's doses, which are reflected in the Facility's contracts**
- **pools funding commitments; by creating security of demand – and incentivising scale-up of research & development, clinical trial investments, and manufacturing for a portfolio of vaccine candidates – provides its participants with insurance against the risk of particular vaccine candidates not being successful**
- **supports pricing principles consistent with manufacturers seeking appropriate returns and affordability for participating countries**

For those governments that have contracts with manufacturers to supply vaccines for their citizens, the Facility complements these contracts; but allocations of a proportion of those doses to the Facility will also be invited.

THE AMC REQUIRES  
START-UP FUNDING OF **US\$ 2BN**

# THE GAVI COVAX AMC

Building upon two decades of experience in accelerating the availability of billions of doses of vaccines, Gavi is launching an investment opportunity: the Gavi Advance Market Commitment for COVID-19 Vaccines (Gavi Covax AMC) – the ODA-supported financing instrument of the Covax Facility.

The Gavi Covax AMC will use official development assistance (ODA) funds from OECD donors to incentivise manufacturers through guarantees to ensure sufficient global capacity is installed before vaccines are licensed. It will then procure vaccines and assist in delivery for LICs and LMICs, including International Development Association (IDA)-eligible small island economies.

Combined, these countries account for almost half of the world's population. Without such an intervention, they may not be able to obtain and use vaccines as part of a global effort to slow and ultimately stop the pandemic.

The Gavi Covax AMC will be the first building block of the Covax Facility and will incentivise investments so that capacity is secured to guarantee access to substantial volumes of safe and efficacious vaccines. It will be supported by additional building blocks to enable self-financed advance commitments towards pooled procurement of doses by HICs and UMICs.

**The Gavi Covax AMC** will:

- **Fund volume guarantees to specific manufacturers for vaccine candidates before they are licensed**
- **Commit to market-wide demand guarantees available to any manufacturer**
- **Purchase doses when they are licensed and WHO prequalified**

The Gavi Covax AMC will give manufacturers confidence to invest in scale-up of manufacturing capacity for vaccine candidates in advance of their licensure and create economies of scale.

The AMC is a self-standing Gavi innovative finance mechanism, which will be limited to the duration of the pandemic, and which will have tailored governance. Gavi will manage the AMC funds and will draw upon its Alliance capabilities for the implementation of the AMC.

The AMC requires seed capital of US\$2 billion. This will be sufficient for Gavi-supported countries to immunise health care workers, as well as high-risk individuals, and create a flexible buffer to be deployed where it is needed most. Donors are invited to pledge towards this target as soon as possible. Funding flows to the AMC could include concessional finance allocations from multilateral development banks (MDBs). Costings for the overall facility and for the other phases of vaccine roll-outs in LICs and LMICs are available and will become more precise by Q4 as vaccine candidates progress.

**The Covax Facility and the Gavi Covax AMC** will support each other by:

- **Applying consistent principles of equitable access based upon the epidemiology of the pandemic as it evolves, with the objectives of containing the pandemic, mitigating its health impact and supporting economic recovery**
- **Linking funding for manufacturing scale-up through the Covax Facility to commitments under the Gavi Covax AMC, with the aim of achieving resilient global scale-up of vaccine availability**

Gavi's **International Finance Facility for Immunisation (IFFIm)** frontloads funding for immunisation by issuing Vaccine Bonds. IFFIm has already been used to fund vaccine development for the Coalition for Epidemic Preparedness Innovations (CEPI) and is available to fund the Gavi Covax AMC in a similar manner, provided it receives new pledges – even long-dated ones – from donors. In the current circumstances, with an urgent need for a way to make commitments to manufacturers, IFFIm is a particularly attractive instrument.

# THE AMC FOR PNEUMOCOCCAL VACCINES

HAS HELPED VACCINATE  
MORE THAN

225

MILLION CHILDREN<sup>3</sup>

The Gavi Covax AMC has been inspired by a previous highly successful Advance Market Commitment – for pneumococcal vaccines. The Pneumococcal AMC accelerated the development and availability of vaccines tailored to developing countries' needs – to address childhood pneumococcal disease, one of the largest killers of children under five. Instituted as a pilot in 2009 with capital of US\$ 1.5 billion from Italy, the United Kingdom, Canada, the Russian Federation, Norway and the Bill & Melinda Gates Foundation, and with World Bank support, the AMC was designed to incentivise vaccine manufacturers with a "top up" payment for vaccines that: correspond to the Target Product Profile; are prequalified by WHO; are deemed eligible by the AMC Independent Assessment Committee; and are awarded by UNICEF Supply Division. From a standing start in 2010, 60 Gavi-supported countries have now introduced this powerful vaccine, with 1 more country planning to introduce before the end of the year. Based on current projections, routine pneumococcal vaccination in Gavi-supported countries is expected to have averted 700,000 deaths between 2000 and 2020.

As a result of the AMC, the price of pneumococcal conjugate vaccines (PCV) has continuously dropped in the past decade from an initial tail price of US\$ 3.50 in 2010, to US\$ 2.00 in 2020 (a 43% reduction), supply has been able to meet growing demand, and market health for PCV is improving – with three manufacturers now supplying Gavi-supported countries. US\$ 187.5 million of the original US\$ 1.5 billion pilot AMC is anticipated to remain when the AMC concludes as scheduled in December 2020 – having more than achieved its objectives – and AMC donors are now considering options for how the remaining funds may be used.



Gavi/Christophe Da Silva/Alamy Live!

## ENDNOTES

- 1 Pronker ES, Weenen TC, Commandeur H, Claassen EH, Osterhaus AD. Risk in vaccine research and development quantified. PLoS One. 2013;8(3):e57755. doi:10.1371/journal.pone.0057755
- 2 [https://g20.org/en/media/Documents/G20\\_Extraordinary%20G20%20Leaders%E2%80%99%20Summit\\_Statement\\_EN%20\(3\).pdf](https://g20.org/en/media/Documents/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_Statement_EN%20(3).pdf)
- 3 Projected data. Actual 2019 data will become available in July/August 2020.



GAVI HAS HELPED IMMUNISE ALMOST **1 BILLION PEOPLE**  
IN **20 YEARS** THROUGH VACCINATION CAMPAIGNS