Context & Terms of Reference for the ACT-A Facilitation Council Vaccine Manufacturing Working Group

1. Introduction

The Facilitation Council of the Access to COVID-19 Tools Accelerator (ACT-A), co-chaired by South Africa and Norway, provides high-level advice and guidance to ACT A pillars, principals and partners, as well as global leadership and advocacy for ACT-A.

ACT-A operates with four main Pillars: i) COVAX for vaccines, with the overarching goal of ensuring equitable distribution of vaccines across the world, particularly to low and lower middle-income countries; ii) Diagnostics pillar for work related to the evaluation, procurement, allocation and uptake of tests; iii) Therapeutics pillar for leading the landscaping, policy and regulatory work, as well as procurement and distribution of therapeutics; and iv) Health Systems Connector for work across these pillars to support product uptake and use.

This document provides the Terms of Reference (ToR) for the Vaccine Manufacturing Working Group (VMWG). The need for either expanding these ToRs or creating an additional Working Group will be kept under review in case production and/or supply issues are found to be constraining access to other ACT-A products.

2. Context for the ACT-A Council's Vaccine Manufacturing Working Group

a. As the COVID-19 pandemic ravaged people and economies in 2020, global solidarity was agreed to be critical in ensuring an effective response. However, at mid-2021 that solidarity is at risk, with deeply inequitable access to key products. Most alarming, less than 1% of COVID-19 vaccines have reached the world's lowest income countries, particularly in Africa. This inequity is at risk of becoming even worse if policy decisions in high income countries extend vaccination to pediatric populations and to booster doses in advance of scaling up doses for low income countries through COVAX.

b. The urgent need to address this crisis of equitable access to vaccines, diagnostics and therapeutics is reflected in various proposals including the proposal of South Africa and India for a temporary waiver of certain TRIPS requirements in order to facilitate access to and application of IP, technology and know-how.

c. Rapidly expanding access to vaccines for low income and lower middle-income countries (LICs/LMICs) also requires high income countries to scale-up their support to expand existing manufacturing capacities and to share or donate vaccines in real-time to COVAX. Such actions would complement but not replace the work needed towards systemic changes to ensure equitable access to life saving medical products for all on a sustainable basis. The current crisis demonstrates that philanthropy-centered approaches is not a long-term solution; it requires increasing production capacities for vaccines, therapeutics and diagnostics in LIC/LMICs.

d. Urgent action in this area is needed to ensure implementation of the G20 commitment of extensive immunization as a global public good, including by seeking to address inequities in the production and consumption patterns.

e. ACT-A's support for country-driven proposals to reshape global public health could facilitate the systemic change needed for all countries to be better prepared for the next pandemic.

f. The participation of the ACT-A Council Co-Chairs and a number of Council Members in the Vaccine Manufacturing Working Group in support of COVAX can ensure that country views are represented and can strengthen the resolve of countries to remove barriers to access and produce vaccines. This Working Group will help ensure increased and equitable access to vaccines and, if necessary, could later consider diagnostics and therapeutics. ACT-A's leadership in addressing inequitable access to medicines and vaccines must be premised on the understanding that this requires tackling the root causes of the deep structural inequalities that currently hamper access.

3. Principle & Objectives of the ACT-Accelerator

a. In the pursuit of its two major objectives, ACT-A operates under the principle of global solidarity, knowing that no one is safe from COVID-19 until everyone is.

b. Adherence to the principle of global solidarity has facilitated the substantial progress that has been made in achieving the first objective of ACT-A – the accelerated development of new tests, treatments and vaccines against COVID-19. However, ACT-A's second objective – ensuring global access to and equitable allocation of these tools – is at real risk without a new and deeper commitment to this principle.

c. The increasing COVID-19 vaccine equity gap is now driving calls to leverage under-utilized and idle manufacturing capacity also in developing countries, especially in Africa, including through the removal of barriers in order to facilitate the sharing and usage of IP and access to production technology and know-how for vaccines, diagnostics and therapeutics on mutually agreed terms. Such technology transfer and capacity building could in turn enhance resilience in the response to the COVID-19 pandemic through diversification of production, while promoting and improving product affordability as well as the manufacturing capacity of countries and regions.

The ToRs for the Vaccine Manufacturing Working Group will focus on the actions needed to enhance supply of vaccines through COVAX, from the evolving supply chain issues to unleashing capacities in developing countries, such as in the African region, where there is no or limited production capacity.

4. Terms of Reference for VMWG

COVAX, the vaccines pillar of ACT-A, has established a Task Force which aims to address production and supply issues that impede equitable access to vaccines. The ACT-A Facilitation Council Co-Chairs endorsed this initiative in their Outcome Statement from the 5th Council meeting. In support of this COVAX initiative, the ACT-A Facilitation Council Co-Chairs are establishing a Vaccine Manufacturing Working Group (VMWG). The VMWG will aim to support the COVAX Task Force on Manufacturing by addressing political bottlenecks and barriers to increase vaccine supply through COVAX. The overarching goal is to ensure equitable distribution of vaccines across the world, particularly in LMICs.

VMWG's primary objective is to ensure the success of COVAX, specifically by providing political support for the work of COVAX's Manufacturing Task Force, which has the following aims:

- *to optimize, and prioritize for COVAX, the number of vaccine doses manufactured in the short term, with a special emphasis on the AMC92 countries to ensure greater equity,*
- *to kickstart the establishment of sustainable regional manufacturing of vaccines with a view to build long-term regional health security, and*
- *to mitigate the unintended impact of COVID-19 vaccines on other vaccines and health products*

4.1 Objectives

The VMWG will provide support to:

- increase supply of vaccine doses to COVAX to ensure equitable distribution by addressing supply chains of raw material and vaccines
- identify and address all barriers, including legal and political barriers to fully **utilizing existing** capacities and incentivizing greater and new production in developing countries
- facilitate the identification of potentially under-utilized/idle capacity for vaccine manufacturing for viral vector, mRNA and other vaccine technologies in all regions
- facilitate mutually agreeable solutions for technology transfer from vaccine manufacturing companies with approved products
- unlock political barriers for implementation of increased manufacturing at the regional level by stimulating regulatory, manufacturing workforce development
- increase information availability on vaccine production and deliveries to countries, ensuring more transparency of distribution of vaccines
- increase transparency on the affordability of vaccines, and encourage that vaccines supplied to COVAX AMC are priced at the cost of goods and production (i.e. not for profit pricing)

- increase political dialogue and build global political consensus around the above, particularly focusing on the G20 Global Health Summit, World Health Assembly and the G7 and G20 processes.

5. Operations and Representation

a. The VMWG will include a representative from South Africa and Norway and will be supported by relevant technical units from the COVAX co-convening agencies Gavi, CEPI and the World Health Organization, as well as the ACT-A Hub. South Africa and Norway will, as ACT-A Facilitation Council Co-Chairs, be participating in (Norway) or co-leading (South Africa) the Working Group. These Co-Chairs will ensure that the Working Group reports back to the Facilitation Council and that consultations are held with Council Members and countries, as needed, so that they are kept abreast of developments and are afforded their right to make inputs given the importance of countries in driving the global health agenda. The perspectives of countries could be facilitated by WHO Regional Offices which could submit brief reports related to vaccines, diagnostics, and therapeutics for their Regions.

b. ACT-A Facilitation Council Members who will be invited to participate in the Working Group include:

   i. Germany (as co-chair of the Working Group)
   ii. Brazil
   iii. China
   iv. India
   v. Indonesia
   vi. Republic of Korea
   vii. Rwanda
   viii. Saudi Arabia
   ix. USA

c. The Working Group will be co-chaired by South Africa and Germany.

d. Working Group co-chairs and representatives may meet with members of COVAX (including CEPI, GAVI, WHO, UNICEF) and relevant private sector organizations to ensure that blockages to access emanating from any sector are dealt with expeditiously when identified.

e. The COVAX pillar will be asked to support and complement the work and reports of the Working Group by providing updates on relevant areas such as:

   - the quantities of vaccines being procured or received as donations by COVAX,
   - COVAX allocation targets per country and the target timelines for distribution,
   - progress towards achieving targets,

- challenges and remedial actions to address challenges,
- measures to address key barriers identified in regional reports, and
- insights on the pricing of COVID-19 vaccines globally.

f. The Working Group will meet fortnightly to consider information and reports received from COVAX partners, WHO Regional Offices and other relevant public or private sector organizations and prepare a situational analysis and recommendations for the Facilitation Council through the Co-Chairs.