



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



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**INTERNAL MEMO**

Date:	17 September 2020		
To:	<b>Minister ZL Mkhize, Honourable Minister of Health</b>	From:	<b>Prof B Schoub: Chair of the Ministerial Advisory Committee (MAC) on COVID-19 Vaccines</b>

<b>ADVISORY: PARTICIPATION OF SOUTH AFRICA IN THE COVID-19 VACCINES GLOBAL ACCESS (COVAX) FACILITY</b>
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**Problem Statement**

Background

The 2019/2020 Covid-19 pandemic is unprecedented since the devastating influenza pandemic of 1918/1919. In South Africa, to date (16<sup>th</sup> September), 653 444 cases of Covid-19 infections have been cumulatively reported, representing just over 1% of the total population of the country. If it is assumed that an additional 40% of individuals who are infected are asymptotically infected, then approximately 1.6 million people could actually have been infected up to now with the virus, i.e. 2.7% of the population. Early seroprevalence data obtained from testing convenience samples from remnant laboratory samples suggest that SARS-CoV-2 infection rates may be considerably higher and a national seroprevalence survey is underway to provide community based seroprevalence data.

The Covid-19 outbreak in SA has had a significant impact on morbidity and excess mortality, with an estimated 44 467 deaths between 6 May and 8 September. In addition, several studies have shown the negative impact on the delivery routine services, including immunisation, Mother and Child Health (MCH), HIV, TB, chronic disease, and mental health. Moreover, the lockdown and cutbacks in health services coupled with fear of contracting the virus resulted in many patients not accessing services and chronic medications.

Regardless, this still leaves a substantial unprotected population in the country. Further, the durability of post-infection immunity is currently not clear as only a few reports of re-infection providing genotyping evidence of actual reinfection have been published. With daily new cases at approximately 1000 to 2000 per day in South Africa, the majority of the population still remain vulnerable to the virus. It is anticipated that the virus will still circulate in the community when the present epidemic wave diminishes and be responsible for second and subsequent epidemic waves.

Herd immunity to the virus is dependent on the reproductive number (R) which is currently being reduced by the implementation of non-pharmaceutical interventions (NPI's) and the restrictions enforced under lockdown regulations. However, these same restrictions have devastated the economy and social structures of the country and long term enforcement is unsustainable for the country. By far the most effective way of controlling the spread of infectious diseases is through vaccination and Covid-19 is no exception.

### Vaccines

Vaccine research has been proceeding at an unprecedented rate with the ambitious target of reducing development time of pre-clinical and clinical development to 12-18 months. Currently there are over 200 candidate vaccines in varying stages of development, with 20 in clinical testing and eight in phase 3 trials. Africa is involved in 5 of these trials, and South Africa is currently involved in clinical trials of two products with more in the pipeline. Given the high level of attrition during vaccine development, it is important that several candidate vaccines, utilising different vaccine platforms, are developed. Diversity in the vaccine candidates being tested is critically important. Furthermore, assuming that successful candidates are identified, even with the pooled capacity of all the vaccine manufacturers, supply will fall far short of vaccine needs for the global population in the short to medium term.

Against this background, wealthy countries have already secured over two billion doses in deals with vaccine manufacturers, with the aim of immunising their entire populations. South Africa has also been approached by vaccine manufacturers to consider bilateral purchasing agreements. The risk of this arrangement is that price negotiations are confidential, up-front payments may be lost should the vaccine not prove safe and efficacious, and South Africa will be limited to only a few vaccines through this mechanism and run the risk of not having a vaccine if these few candidates are not successfully licensed.

The emerging spectre of vaccine nationalism has made middle- and low-income countries anxious about their ability to access vaccines should they become commercially available. To address this looming threat to immunisation equity, Covid-19 Vaccine Global Access Facility (the "COVAX Facility") has been established as a component of the newly established vaccine pillar of the ACT (Access to Covid-19 Tools) Accelerator, launched in April 2020 by the World Health Organization (WHO). The COVAX Facility was created to establish a pooled procurement mechanism to secure adequate and equitable supplies of vaccines at competitive prices for countries throughout the world, irrespective of their wealth status. With respect to the current imperative of securing a supply of vaccines for the initial phase of vaccination of the highest priority groups in South Africa, the MAC on Covid-19 Vaccines has been tasked with providing appropriate advice to the Minister regarding procurement and allocation of vaccines.

### **Points considered**

The overarching goal is for the Covid-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being and to free the potential among all who live in South Africa.

In the consideration by the Committee the following key questions were deliberated:

- Does South Africa need the vaccines considering the current decline of the epidemic?
- Considering the currently constrained national fiscus, which vaccine procurement option will be viable for the country?
- Which procurement option will enable prioritized, fair and equitable access of the vaccine?
- There is evidence to suggest that the epidemic in South Africa is on the decline. However, in an analysis done by the South African Centre for Epidemiological Modelling and Analysis (SACEMA) as part of an assessment of the risk of a 2<sup>nd</sup> wave in South Africa, it was found that in 19 of 29 countries who experienced a resurgence of the pandemic, the peak of those waves has exceeded the magnitude of the first wave peak.
- Efficacy trials of at least nine vaccines are currently underway. Preliminary published analyses of phase 1 and 2 trials of these vaccines have shown favourable immunogenicity and safety data. It is difficult at this early stage to predict which vaccine(s) will be the most suitable and appropriate for South Africa. To optimise and reduce risks it would therefore be prudent to diversify and have access to a broad portfolio of vaccines. The COVAX Facility provides possible access to 9 candidate vaccines in their portfolio with the likelihood of expansion, and the agreement with manufacturers that for the duration of the pandemic, profit margins would be very small.
- Preliminary calculations have been made as to which priority groups would be covered for vaccine allocations for 3%, 10%, and 20% of the population (see Appendix 2). A factor of 60% and 70% coverage will be worked into the calculations. As there is likely to be early limitations of supplies, it is expected that countries will initially only receive vaccines for 3% of their populations through the COVAX Facility.

Financial considerations:

- The socio-economic impact that the Covid-19 pandemic has must be balanced against the potential cost of vaccine. According to Stats SA, it was reported that the gross domestic product (GDP) fell by just over 16% between the first and second quarters of 2020, giving an annualised growth rate of -51%, the worst decline since 1960.
- Nearly all industries experienced a decline, especially in construction and manufacturing.
- Household spending declined by 49.8% and it is expected that the economic divide between the rich and poor will worsen. In the National Income Dynamics Study, 47% of the adults interviewed reported that, in April their home ran out of money to buy food. Between May and June, it was reported that 15% of children in the study went hungry.
- The estimated price of the vaccine, as provided by the COVAX Facility, is in the range US\$10.55 to US\$22.10. This cost excludes logistics and implementation costs.
- While the estimated cost for various priority groups and proportions of the population were considered (i.e. 3%, 10%, and 20% of the population), a definitive recommendation for use in these priority groups cannot be made until efficacy of the vaccine, the actual cost per dose, implementation costs as well as available budget is known.

- Access to an effective vaccine and its appropriate use may save millions of lives and transform the economic prospects of governments and individuals.
- The COVAX Facility provides participating countries with the benefit of a pooled procurement mechanism. Eighty-three self-financing countries have indicated their intent to participate, which include several from G7, G20, EU countries, Japan, Australia, Canada, and other member states. Gavi-supported countries (through the Advanced Market Commitment [AMC]) are also included. The COVAX Facility would thus cover more than 50% of the world's population allowing economies of scale to influence price negotiations.
- Two purchase agreement arrangements were proposed by the COVAX Facility. Given the value of investment required to participate in this COVAX Facility, MAC is of the opinion that due diligence is necessary, and interrogation of both purchase agreement arrangements is needed.
- The NDoH will work with the South African Health Products Regulatory Authority (SAHPRA) to ensure that whichever vaccine being recommended or made available through the COVAX Facility has met all the regulatory requires of safety, efficacy, and quality.
- The NDoH should negotiate supplementary funding from e.g. the Medical Aid industry and the Solidarity Fund, in addition to funds from National Treasury for vaccine access.

## **Recommendations**

- The Committee recommends participation in principle in the COVAX Facility.
- Of the two COVAX purchase options, the Committee in principle recommends the Committed Purchase option (an outline of the two purchase options is attached, see Appendix1).
- The Committee recommends that the commitment made by South Africa should be to purchase sufficient vaccines for 10% of its population through the COVAX Facility.
- Identification of priority groups for the vaccine(s) will require further consultation with additional stakeholders.
- The Committee recommends continuing with the current ongoing bilateral discussions with vaccine manufacturers.

## Rationale for recommendations

- Vaccination, even with the limited initial allocation, could be used to immunise front-line health care workers who are of critical importance to both manage Covid-19 patients and to sustain all aspects of health service delivery.
- Partial coverage of the population with a vaccine combined with non-pharmaceutical interventions, would significantly contribute to achieving a herd immunity threshold, thus protecting the population against forthcoming future waves of COVID.
- If in the recurrent future outbreaks, the country would have to rely only on non-pharmaceutical interventions and lockdown restrictions, without the resource of vaccination, it could result in very significant socio-economic costs with concomitant adverse health impacts and further negative impact on population morale.
- The Committed Purchase option requires a significantly lower upfront payment.

## Considerations of risks

The Committee takes note of the following:

- Based on early clinical data, the Committee is optimistic that a Covid-19 vaccine is likely to be developed. However, these candidate vaccines are still being evaluated in clinical trials.
- The COVAX Facility is actively negotiating with vaccine manufacturers, and the final price of vaccines accessed through the Facility is expected to be between US\$ 10.55 – US\$22.10 (ex-factory), this does not include logistics cost of the vaccine(s) to the country.
- The operational cost of the delivery of vaccine(s) will not be included in the COVAX Facility cost, nor in any possible bilateral agreements.
- In the event that no vaccine(s) make it to market, a proportion of the down payment paid by the country, that the COVAX Facility had utilised for manufacturing preparedness, will be forfeited. Discussions with Gavi indicate that this is likely to be less than 20%.
- In the event that vaccine(s) are procured through the Facility, further clarification will need to be sought with specific manufacturers regarding liability.
- If the country does not join the COVAX Facility, it may hamper the country's access to vaccine(s).
- In addition, the proposed contract was only received on the 15<sup>th</sup> September 2020 and would need to be interrogated by the Committee. However, although there is pressure in meeting the timelines for commitment to the COVAX Facility, the Committee does recognise that there would be even greater risks for the people of South Africa should the country not avail itself of the opportunity to secure vaccine through the pooled procurement mechanism of the COVAX Facility.

- Although there are oversight committees that will engage participating countries, it is currently unclear how much influence these committees will have in the decision making of the COVAX Facility. It is also unclear what role South Africa will have in any of these committees or decision making.



**PROFESSOR BARRY SCHOUB**  
**CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES**  
**DATE:**

**CC:**

- » **Dr S Buthelezi (Director-General)**
- » **Dr T Pillay (Deputy Director-General: National Health Insurance)**
- » **Dr S Zungu (Project Lead: Sectoral Response to Covid-19)**

## Appendix 1 Outline of COVAX Purchase Options

Committed Purchase Agreement	Optional Purchase Agreement
Benefits	
<ul style="list-style-type: none"> <li>• Upfront lower payments</li> <li>• Certain volume</li> <li>• Guarantee full facility exposure</li> </ul>	<ul style="list-style-type: none"> <li>• Opt-out</li> <li>• Receive full share of doses (pro rata)</li> <li>• Country choice of available vaccines candidates</li> </ul>
<ul style="list-style-type: none"> <li>• Risk shared: vaccine effectiveness, multiple vaccine candidates; security of supply</li> </ul>	
Disadvantages	
<ul style="list-style-type: none"> <li>• No opt-out (Can only opt out if price &gt; US\$ 21.10)</li> <li>• Vaccine recommended and approved by Facility (country would have little choice in vaccine selection)</li> <li>• Efficacy of the vaccine unknown</li> </ul>	<ul style="list-style-type: none"> <li>• If no vaccine purchased, upfront payment plus risk sharing guarantee forfeit</li> <li>• Efficacy of the vaccine unknown</li> </ul>
Risks	
<ul style="list-style-type: none"> <li>• High financial risk – guarantee payment for full amount required</li> </ul>	<ul style="list-style-type: none"> <li>• Lower financial risk (despite higher upfront payment) – option to opt-out for any reason</li> </ul>
Price Exclusions both options:	
<ul style="list-style-type: none"> <li>• Cost of distribution estimated at an additional 15% per vaccine cost</li> <li>• Cost of additional cold chain capacity required in facilities</li> <li>• Cost of consumables</li> </ul>	
Factors not considered in volume estimation	
<ul style="list-style-type: none"> <li>• Vaccine presentation (number of doses per vial)</li> <li>• Expected vaccine wastage based on vaccine properties/presentation</li> <li>• Final cost to be payed to manufacturers (higher cost reduce number of doses)</li> <li>• Available cold chain capacity</li> </ul>	

## Appendix 2

Distribution of vaccines to priority groups given a 3, 10 or 20% vaccine allocation based on a population of 60 million with a 60 or 70% vaccine coverage / acceptance rate per group.

Priority group	Number	70% accept vaccination Option A	60% accept vaccination Option B	Proportion in groups that will be covered with available doses. Option A refers to 70% vaccine acceptance and Option B refers to 60% vaccine acceptance rate						
				3% - 1.8m Option A	3% - 1.8m Option B	10% - 6m(a) Option A	10% - 6m(b) Option B	10% - 6m (a) Option A	10% - 6m (b) Option B	20% - 12m Option A or B
		N	N							
Health workers	1 250 000	870 000	750 000	100%	100%					
Essential workers	2 500 000	1 750 000	1 500 000	57 %	70%					
Persons in congregate settings	1 100 000	770 000	660 000							
<i>Subtotal</i>	<i>4 850 000</i>	<i>3 395 000</i>	<i>2 910 000</i>							
At risk population										
60 yrs and older	5 000 000	3 500 000	3 000 000			75%	100%			
Persons with co-morbidities	8 000 000	5 600 000	4 800 000							
<i>Sub total</i>	<i>13 000 000</i>	<i>9 100 000</i>	<i>7 800 000</i>							
Total	17 850 000	12 495 000	10 710 000							100%

This is a preliminary analysis and will be subject to a more detailed assessment later. It serves as a possible guide for distribution of limited vaccine supply.