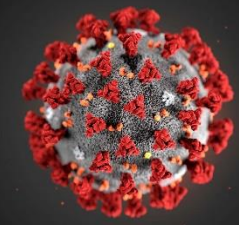




Covid-19 Vaccine Rollout Strategy

03 January 2020

Introduction



- Covid-19 pandemic had a multi-sectoral impact on South Africa, including a significant socioeconomic impact, and an impact on healthcare cost.
- One intervention to rapidly interrupt Covid-19 transmission is an effective **vaccination**.
- There are currently over 240 Covid-19 vaccines in development worldwide, with over 42 in clinical trials and several that have emerged as being effective after phase 3 studies.
- The data suggests these vaccines are safe and effective
- A Ministerial Advisory Committee on Covid-19 Vaccines has been appointed consisting of experts in the field. They have developed a **strategy** to ensure equitable access to vaccines.
- The strategy includes the various purchasing mechanisms, funding implications, local manufacturing opportunities and **identifying priority groups for vaccination**.

Purpose and Scope of Ministerial Advisory Committee on Covid-19 Vaccines

Primary objective of the MAC on Vaccines - developing the National COVID-19 Vaccine Framework; provide Minister of Health with advice on:

- Current scientific evidence and best practices;
- The appropriate vaccine options based on evidence-based medicine reviews;
- vaccine purchasing options that are available globally (e.g. COVAX Facility);
- The budget implications of the vaccine options;
- the priority groups for vaccination;
- the vaccine rollout strategy; and
- the development and manufacture of a COVID-19 vaccine.

Ministerial Advisory Committee on Covid-19 Vaccines

- The Ministerial Advisory Committee (MAC) on Vaccines is a non-statutory, advisory Committee appointed by the Minister of Health.
- **Members of the Ministerial Advisory Committee on Vaccine include:**

| | | |
|---------------------------------|--------------|--|
| Prof Barry Schoub | Chair Person | Vaccinology and virology |
| Dr Anban Pillay | Member | DDG: NDOH |
| Dr Morena Makhoana | Member | CEO Biovac |
| Ms Glaudina Loots | Member | DSI |
| Dr Boitumelo Semete-Makokotlela | Member | CEO SAHPRA |
| Prof Greg Hussey | Member | UCT training programme: VACFA |
| Prof Jeff Mphahlele | Member | MRC; immunologist; SAHPRA board |
| Prof Helen Rees | Member | Expert adviser WHO, Gavi, CEPI. WHO's RITAG and NAGI |
| Prof Ames Dhai | Member | Ethicist |
| Dr Mark Blecher | Member | National Treasury |
| Prof Salim Abdool Karim | Observer | Chairperson: MAC on Covid-19 |
| Bishop Malusi Mpumlwana | Observer | Chairperson: Multi-Sectoral MAC on Social Behaviour |

Vaccines Acquisition Task Team

Primary objective of the task team is to co-ordinate the private sector vaccine financing, procurement, logistics and administration.

The Task Team is made up of the ffg members:

Mr Adrian Gore

Mr Sandile Zungu

Mr Lex Cochrane

Prof Schoub

Dr Aquina Thulare

Dr Anban Pillay

WHY ARE VACCINES IMPORTANT

The aim of vaccination is to:

- To prevent **morbidity and mortality**.
- To **achieve herd immunity** and **prevent ongoing transmission**.

When a person gets vaccinated against a disease, their risk of infection is also reduced – personal protection

'Herd immunity', also known as **'population immunity'**, is the indirect protection from an infectious disease that happens when immunity develops in a population either through vaccination or through previous infection.

Herd immunity does not mean unvaccinated or individuals who have not previously been infected are themselves immune. Instead, herd immunity exists when individuals who are not immune, but live in a community with a high proportion of immunity, have a reduced risk of disease as compared to non-immune individuals living in a community with a small fraction of immunity.

Lowering the possibility for a pathogen to circulate in the community protects those who cannot be vaccinated (due to health conditions, like allergies, or their age) from the disease targeted by the vaccine.



Vaccine Rollout Framework

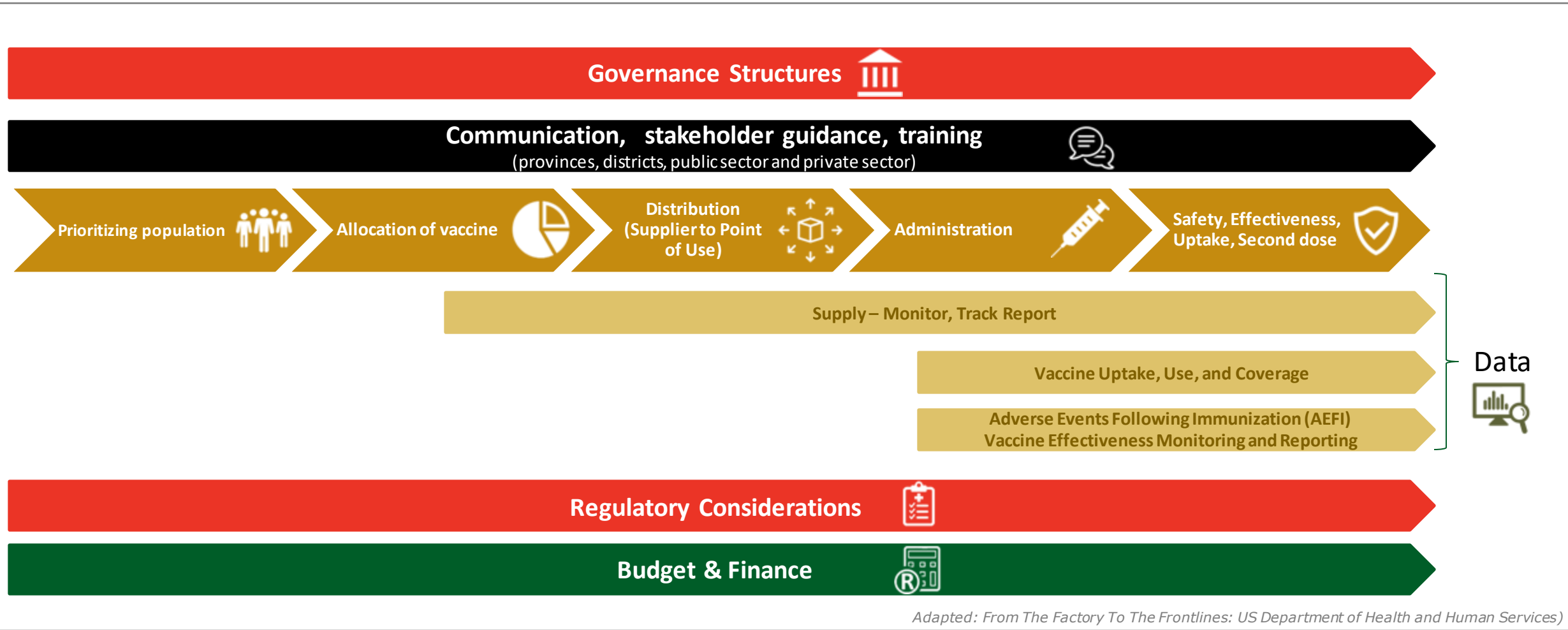


health

Department:
Health
REPUBLIC OF SOUTH AFRICA



FRAMEWORK FOR VACCINE IMPLEMENTATION

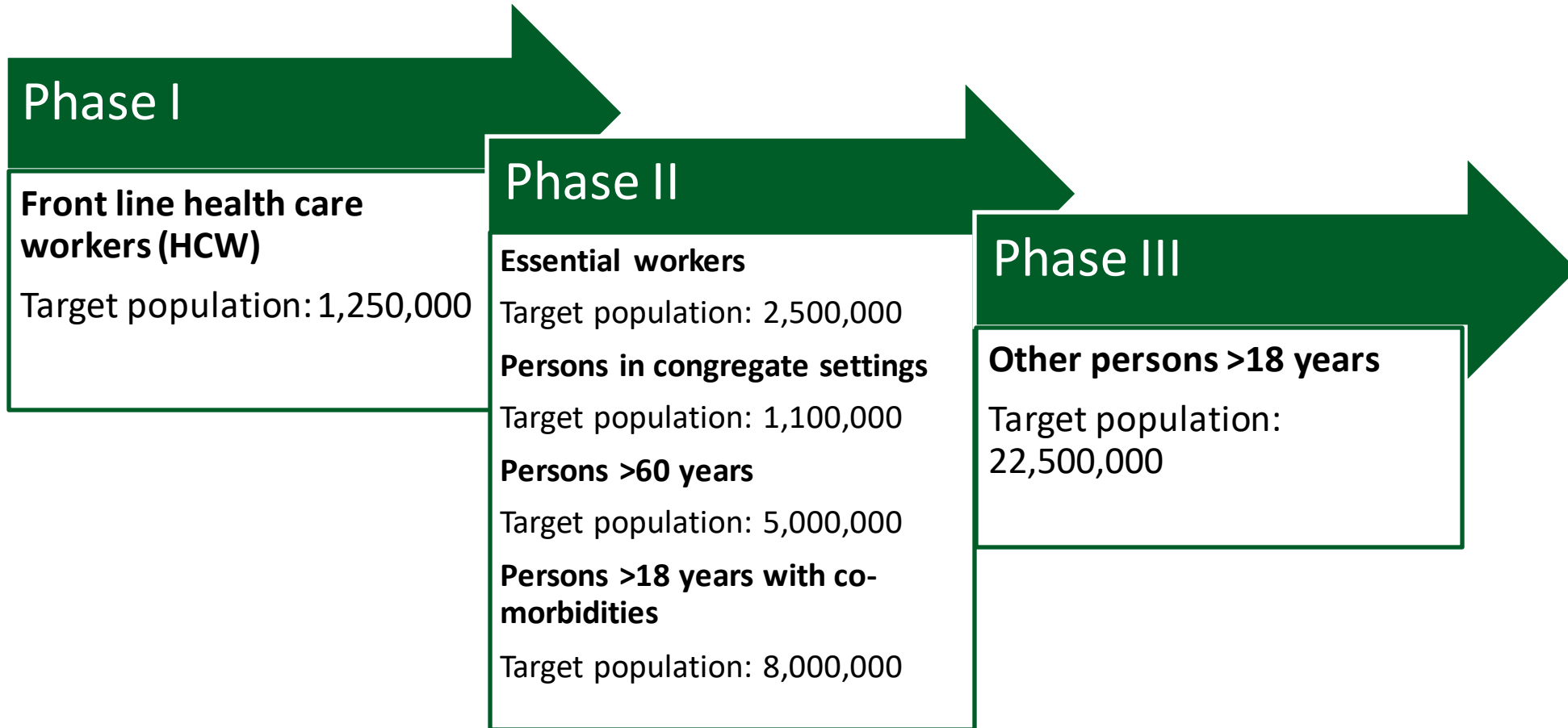


Adapted: From The Factory To The Frontlines: US Department of Health and Human Services)

LEADERSHIP AND CO-ORDINATION

- The vaccine rollout will be lead nationally in close co-ordination with provincial health departments and the private healthcare sector. Committee will be established at various levels with the relevant stakeholders and expertise to co-ordinate the rollout of the various phases of the vaccine delivery.
- A **national vaccine co-ordinating committee** established at the NDOH by the DG with representatives from various clusters involved:
 - Expanded Programme for Immunisation (EPI), Communicable Disease Cluster (CDC), Medicines, Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and evaluation,
 - The chair of the provincial co-ordinating committees
 - The chair of the national private sector, co-ordinating committee
 - World Health Organisation
 - Committee chaired will be chaired by Dr Bamford
- **Provincial co-ordinating committees** appointed by HODs with representation from Expanded Programme for Immunisation (EPI), Communicable Disease Cluster (CDC), Medicines , Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and evaluation and the provincial private sector co-ordinating committee. Provinces will have to establish structures at district level to manage the mass rollout
- **Private health sector co-ordinating committee** which includes medical schemes, private hospital association, pharmacies groups, general practitioner and specialist associations, nursing association, allied health professions associations, logistics providers, pharmaceutical manufacturers, employers, labour unions, business associations.

PHASED APPROACH FOR VACCINE INTRODUCTION



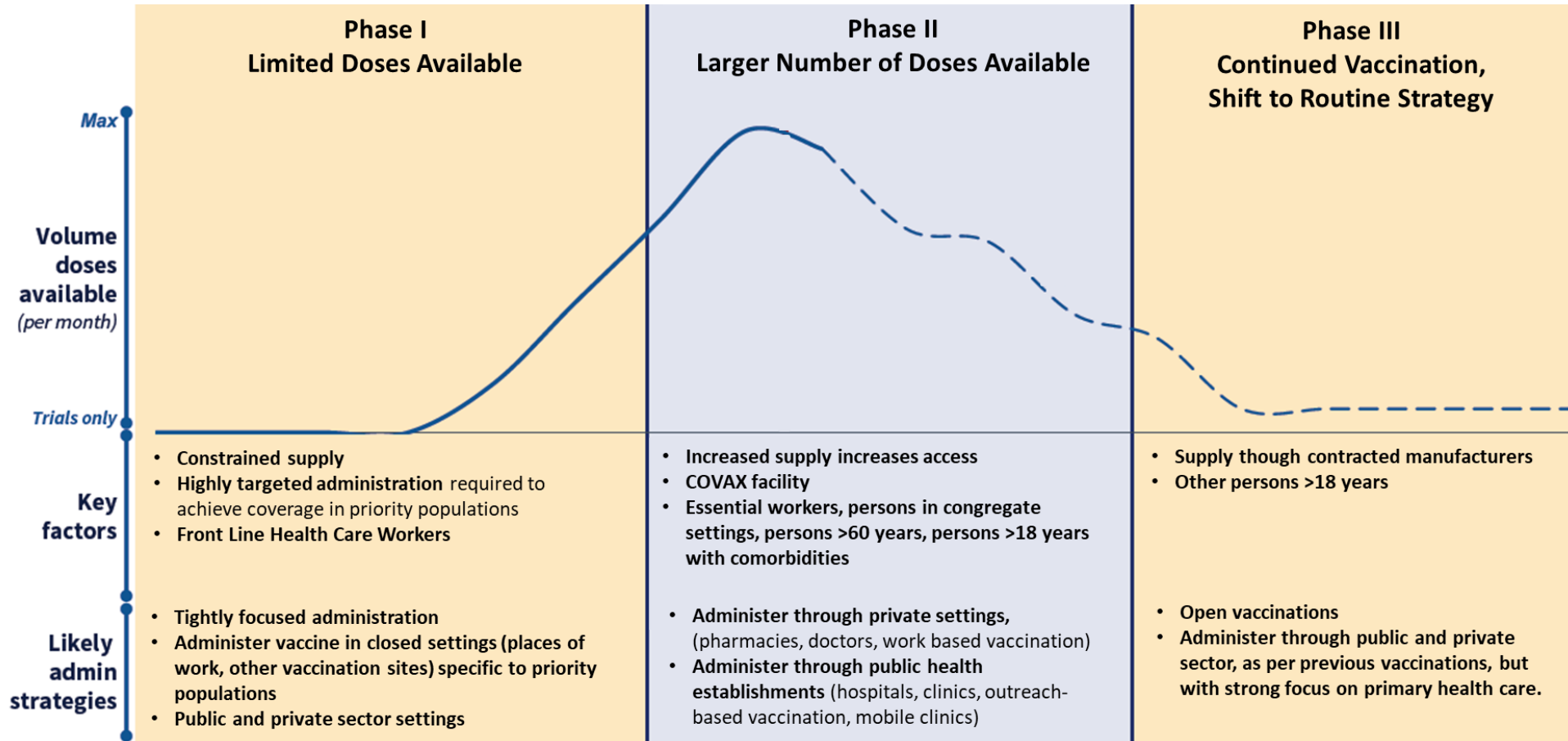
IDENTIFICATION AND PRIORITISATION OF TARGET POPULATION



| Phase | Priority Group | Definition |
|-------|---|---|
| II | Essential workers (2 500 000) | Police officers, miners and workers in the security, retail food, funeral, teachers banking and essential municipal and home affairs, border control and port health services. |
| | Persons in congregate settings (1 100 000) | Persons care homes, detention centres, shelters and prisons . In addition, people working in the hospitality and tourism industry, and educational institutions are also at risk. |
| | Persons 60 years and older (5 000 000) | |
| | Persons older than 18 years with co-morbidities | Persons living with uncontrolled diabetics, chronic lung disease , poorly controlled cardiovascular disease, renal disease, HIV, tuberculosis and obesity. |

PHASED APPROACH BASED ON AVAILABILITY OF VACCINES

Distribution will adjust as volume of vaccines increases, moving from targeted to broader population reach (phased approach)



PHASE 1: HEALTH CARE WORKER SERVICE DELIVERY PLATFORM

Work-based vaccination programme:
District level private and public hospitals



- Most suitable for hospital linked HCWs

Outreach work-based vaccination programme:
Mobile teams move from facility to facility



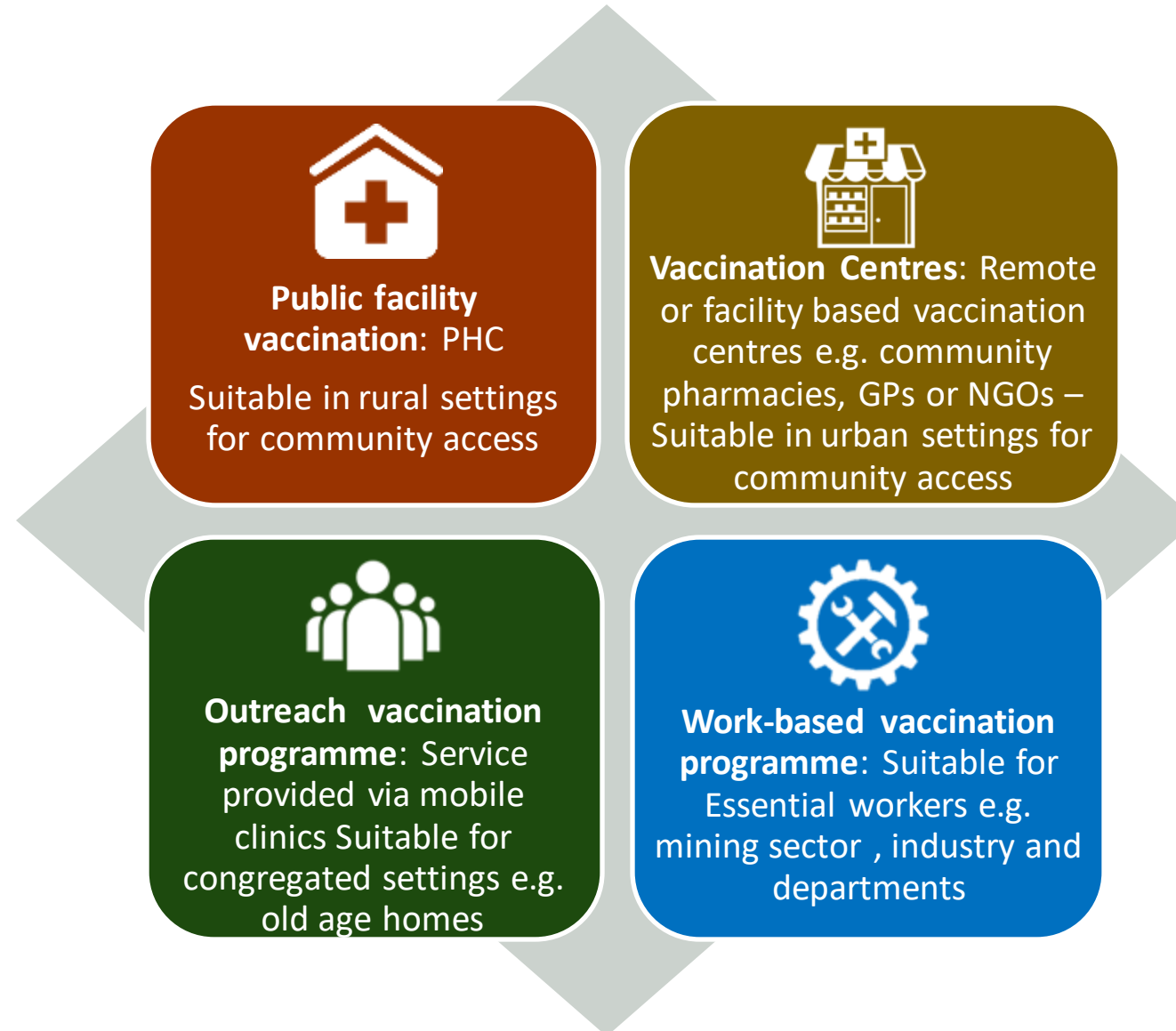
- Most suitable for HCWs in PHC, CHC and private medical centres

Vaccination Centres: Remote or facility-based
vaccination centres e.g. community pharmacies



- Suitable for independent HCWs

PHASE 2 AND 3: HIGH RISK PRIORITY GROUPS AND GENERAL PUBLIC SERVICE DELIVERY PLATFORMS



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



VACCINE SELECTION

- **Six key considerations in the selection of Covid-19 vaccines** for the South African setting:
 - The key consideration is **AVAILABILITY** of vaccine that is also:
 - **Safe, efficacious and good quality - SAHPRA**
 - **Ease of use** and schedule (including number of doses required)
 - Stability during **storage and distribution**
 - **Supply and sustainability** (i.e. supplier capacity)
 - **Cost**

REGULATORY MATTERS

- Vaccines must be **safe and effective** - Medicines and Related Substances Act 101 of 1965
- South African Health Products Regulatory Authority (SAHPRA) put several measures in place to ensure expedited regulatory approvals of safe vaccines. These measures include:
 - **Agreements with EMA, USFDA, MHRA, and TGA** – SAHPRA will thus be able to use their assessment reports as a reliance approach to reduce timelines in the evaluation process.
 - **SAHPRA has adopted a priority review approach for all COVID-19 vaccine applications** since the onset of the pandemic. Thus, the process of expedited review will apply to any COVID-19 vaccine registration application.
 - **Flexibility in relation to labelling and packaging requirements** effected in terms of effect Section 36 of the Medicines Act (exemption of medicines by the Minister of Health from certain requirements of the Medicines Act) for specific labelling and packaging requirement exemptions.
 - **Authorisation in terms of Section 21** of the Medicines Act where manufacturers have not submitted dossiers to SAHPRA

Note: NDoH has been meeting with vaccine manufacturers who are being encouraged to submit dossiers to SAHPRA

PROCUREMENT

- Governed by
 - **Public Finance Management Act 1 of 1999**
 - **Medicines and Related Substances Act 101 of 1965**
- **Emergency procurement procedures** for vaccine, service providers in logistics, training, communication, HR where no contracts are available.
- **Request deviation from NT** for deviation from normal supply chain processes for vaccines
- **SAHPRA registration/approval required**
- Competitive bid process based on registration status, available stock and cost effectiveness - shortened time frames to be considered

DISTRIBUTION: SECURITY



- **Distribution security**
 - Vehicle tracking and monitoring (central distributor / contract distributors)
- **Safety and security at administration sites**
- **Track and traceability** of vaccines using **barcode scanning**
- **Safe and secure disposal** of all vaccine packaging and vials
- **Data verification** of volumes distributed vs volumes administered
- Monitoring of **vaccine wastage**



DATA FOR VACCINE MANAGEMENT AND SURVEILLANCE

- Data needed for monitoring vaccine **uptake and coverage, prioritization, planning, safety monitoring and vaccine effectiveness studies.**
- To meet anticipated needs of stakeholders, **electronic vaccination data system (EVDS)** is in the process of being developed.
- EVDS will **leverage off existing systems** which are currently deployed and implemented at scale.
- **EVDS must support collection and provision of the following information**
 - **Patient information** (including demographics, number of doses, etc.)
 - **Health establishment** where service is accessible (name and type, e.g. clinic)
 - **Vaccine administered** (manufacturer, batch number, etc.)
 - **Safety information** as part of a pharmacovigilance plan (Adverse Events Following Immunization – AEFI)
 - **A record of vaccination issued to individuals where appropriate and required**



Negotiations with Vaccine Manufacturers



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

VACCINE OVERVIEW



- We have met with vaccine producers in China and Russia
- Since last year the National Department of Health and the Ministerial Advisory committee has had discussions with potential vaccine suppliers. The suppliers that we have met with include:
 - Pfizer
 - Astra Zenca
 - Johnson and Johnson
 - Moderna
 - Cipla
- Many of the manufacturers requested a non disclosure agreement before they could share details of their vaccine offer.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

VACCINE OVERVIEW

Pfizer /BioNTech Vaccine

- Regulatory: EUA by FDA and a number of other countries (with bilateral deals) including WHO PQ. SAHPRA filing not completed.
- Efficacy: 95% protection – 2 dose vaccine
- Rollout has happened in a few countries already where bilateral deals had occurred very early on.
- Storage: minus 70 deg C which is a limitation for SA as we have limited commercial ultra low cold chain storage in SA only suitable for small volume.

AstraZeneca/ University of Oxford Vaccine

- Regulatory: Product has been approved as EUA by MHRA and DCGI
- Efficacy: 70% efficacy – 2 dose vaccine
- AZ has outsourced the production of the vaccine to various sites globally. The largest vaccine producer globally is Serum institute of India (SII). SII does not have a presence in SA and its local partner is Cipla.
- This vaccine is likely to be widely used globally due to temp stability and volumes that AZ committed to produce through partners and their tiered price model
- Storage: 2 – 8 deg C

VACCINE OVERVIEW

Johnson and Johnson

- Regulatory: Product has been approved as yet – dossier submission expected in January
- Single dose product that is much easier for administration and more cost effective
- Product will also be manufactured at the Aspen facility on a contract basis

Moderna

Regulatory: EUA by FDA

Two dose vaccine

Storage: **minus** 20 deg C

No office in SA and no expectation of filing the dossier with SAHPRA

Vaccine Procurement

- The COVAX facility has focused most of its agreements on vaccines suitable for developing nations where capacity for ultra cold storage is limited or non-existent
- Pfizer was the first vaccine to become available and developed nations particularly have already signed up bilateral agreements before development was even complete. Hence we see the rollout of the Pfizer vaccine across various countries with bilateral deals.
- Covax has focused on vaccines that can be stored at usual cold storage facilities produced by Astra Zenca, Johnson and Johnson and others. The Astra Zeneca vaccine has just been approved in the UK and India which will now allow for mass production to proceed. Astra Zeneca has established contract manufacture agreements with several manufacturers across the world to achieve their target of 2 billion doses by year end. The largest vaccine producer globally is Serum Institute of India and will be producing the Astra Zeneca Vaccine for mainly developing and developed countries.

Vaccine Procurement

- **We are working to secure a sufficient supply of vaccines in the shortest possible time to protect the most vulnerable in our community**
- South Africa is part of the global pooled procurement initiative co-ordinated by Covid-19 Vaccines Global Access Facility, commonly known as COVAX. We are part of the first group of countries that will receive an allocation of vaccines from COVAX. We have been advised that we should expect the vaccines in the second quarter of 2021. We have been in constant contact with COVAX who have advised us that they are working very hard to bring the bring batches releases forward to quarter one.
- We are also having parallel bilateral discussions with a number of vaccine manufacturers as indicated earlier and will make further announcements once firm agreements are in place.
- These bilateral negotiations with some of the suppliers hves progressed well and we are fairly confident that we will have supply in quarter one. We cannot announce the details of this supply until this is confirmed by a signed contract.
-