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Report 12/ 2021

Ref: Health Update and the South African Health Products Regulatory Authority (SAHPRA) on the COVID-19 vaccine/'Adjusted' Alert Level 3 lockdown

Report of the Ad Hoc Committee on COVID-19, in performing oversight over the work of the provincial executive authority as it responds to the COVID-19 pandemic, including oversight over any part of the provincial executive authority, any provincial department, any organ of state and any provincial entity involved in activities dealing with the pandemic, on the themes/meetings covered for March 2021, as follows:

The Ad Hoc Committee on COVID-19 consists of the following members:

Mr R Allen (DA)
Mr D America (DA)
Ms D Baartman (DA)
Mr G Bosman (DA)
Mr F Christians (ACDP)
Mr C Dugmore (ANC)
Mr B Herron (GOOD)
Ms P Lekker (ANC)
Mr P Marais (FFP)
Mr D Mitchell (DA)
Ms W Philander (DA)
Mr A van der Westhuizen (DA)
Ms M Wenger (DA) (Chairperson)
Ms R Windvogel (ANC)
Mr M Xego (EFF)

Alternative Members:

Ms L Botha (DA)
Mr R MacKenzie (DA)
Ms M Maseko (DA)
Ms N Nkondlo (ANC)
Mr K Sayed (ANC)
Mr D Smith (ANC)

Procedural Staff:

Ms W Hassen-Moosa, Procedural Officer
Ms S Jones, Procedural Officer
Ms B Daza, Senior Procedural Officer
Mr M Sassman, Manager: Committees

1. Introduction and Background

The Ad Hoc Committee on COVID-19 (the Committee) was established by the Speaker of the Western Cape Provincial Parliament on 14 April 2020 in accordance with Standing Rule 119(1)(b) of the Standing Rules of Western Cape Provincial Parliament. The Committee was tasked with the responsibility to perform oversight over the work of the provincial executive authority as it responds to the COVID-19 pandemic, including oversight over any part of the provincial executive authority, any provincial department, any organ of state and any provincial entity involved in activities dealing with the pandemic.

The meetings have been held virtually, so as to comply with COVID-19 lockdown regulations issued by National Government, as well as a decision of the Programming Authority, to enforce social distancing rules.

2. Election of Chairperson, Adopted Themes and the Rules of Engagement

On 17 April 2020, Member M Wenger (DA) was elected to serve as the Chairperson of the Committee in accordance with Standing Rules 82(1) and 85. The Committee adopted 12 themes around which it would address the COVID-19 pandemic. The 12 adopted themes were as follows:

2.1 Health Department Responses and Preparations
2.2 Policing, Security and Police Brutality
2.3 Food Security
2.4 Protection of the Vulnerable
2.5 Disaster Management and Local Government Oversight
2.6 Economic Recovery, Support and Livelihoods
2.7 Transport and Infrastructure
2.8 Schooling and Education
2.9 Human Settlements
2.10 Citizen Surveillance
2.11 Intergovernmental Relations and Community Cooperation
2.12 Government Finance and Budgets

3. Additionally, the Rules of Engagement during virtual meetings were indicated as follows:

3.1 All meetings would be open to members of the public and media via livestreaming;
3.2 All Members microphones must be muted at the beginning of the meeting to avoid background noise;
3.3 Members are to flag Points of Order in the Chat Function of Microsoft Teams (the application through which virtual meetings are held);
3.4 All videos and audio must be switched off to improve the quality of the connection; however, if a Member/Minister/HOD/Official is speaking, they may put on their audio and video;
3.5 Participants must switch off their microphones once they are finished speaking;
3.6 In terms of maintenance of order, in accordance with the "Directives for Sittings of the House and Meetings of Committees by Electronic Means", ATC'd on Friday, 17 April 2020, Section 8 states that "when a Member is considered to be out of order by the presiding officer, the presiding officer may mute the microphone of such a Member and call such a Member to order"; and
3.7 Section 10 of the Directives ATC'd on 17 April 2020 speaks to the application of Standing Rules. Section 10 states that "in instances where these directives are not clear or do not cover a

particular eventuality in respect of sittings of the House or meetings of the committees by means of videoconferencing, the Standing Rules must apply as far as this is reasonably and practically possible and, in instances where they cannot be applied, the ruling by the presiding officer must be final".

4. The themes/meetings covered in March 2021 included:

Health Department Responses and Preparations

The Department of Health briefed the Committee on its preparations for the third wave; and on the vaccine planning and rollout.

Intergovernmental Relations and Community Cooperation

The South African Health Products Regulatory Authority (SAHPRA) briefed the Committee on the regulatory environment pertaining to vaccines in general and the COVID-19 vaccine.

5. THEMES: Health Update, 'Adjusted' Alert Level 3 lockdown and rollout of the vaccine

5.1 Overview and background

The Committee requested a briefing from the provincial Minister of Health and the provincial Department of Health on an update on the COVID-19 pandemic in the Western Cape, preparations made for the third wave: and the vaccine planning and rollout on 04 March 2021.

5.2. Briefing by the provincial Minister of Health and the Head of the Department of Health

5.2.1. Observations and challenges

5.2.1.1. The Minister of Health, Dr N Mbombo, informed the Committee that the current vaccinations were within Phase 1 of the implementation study by the Johnson and Johnson Research Council which was supported by, and formed part of the partnership with the National Department of Health.

5.2.1.2 Regarding the Third Wave, there was a lot of uncertainty as to when and if it would take place and the modelling scenario which inevitably made it extremely difficult as there was a new variant (COVID – 501 YV2) which had been detected at the end of October 2020.

5.2.1.3 The Minister further indicated to the Committee that the data had indicated that those who had been exposed to the variant had the antibodies and elements of immunity which could neutralize another exposure for reinfection, however, more research was being done on that.

5.2.4. Health update

5.2.4.1. Dr K Cloete, Head of the provincial Department of Health, informed the Committee that the Western Cape was at a historical moment in time to turn the tide against the pandemic globally. Mass vaccination was the central weapon to reduce mortality, protect the health system from being overwhelmed, and achieve adequate population coverage and develop herd immunity to reduce transmission. There is a very real risk of a Third Wave as the Western Cape would not achieve herd immunity in the next few months.

5.2.4.2. The risk was accentuated by a range of potential risk factors including viral mutation, greater population movement as restrictions got lifted, the winter seasons when people tended to stay indoors, amongst others.

5.2.4.3. Public Health and Social Measures includes the following:

- The World Health Organisation (WHO) highlights the key role of Public Health and Social Measures (PHSM) in limiting COVID-19 transmission and reducing deaths, especially in the context of constrained health services.
- Both introducing and lifting PHSM therefore requires a firm commitment to agile decision making.
- Since the introduction of Level 3 measures on 28 December 2020, all epidemic measures have declined rapidly and we are approaching pre-wave 2 levels of transmission with daily incidence of 300 new cases, 80 hospital admissions and 30 deaths.

5.2.4.4. On 28 February 2021, the President of South African, Mr C Ramaphosa announced the following restrictions:

- SA placed on Alert level 1 from 1 March 2021;
- Curfew: from midnight to 4am;
- Alcohol sales permitted as normal (not during curfew);
- Mask wearing was made compulsory;
- Gatherings of 50% of venue capacity to a 100 max inside; 50% of venue capacity to a 250 max. Outside and the health protocols have to be maintained;
- Stay away from closed or crowded places; and
- Encouraged the use of the SA COVID alert app.

5.2.4.5. Community prevention indicates that the National Income Dynamics Study – Coronavirus Rapid Mobile Survey (NIDS-CRAM) study shows 40% compliance with mask wearing, which is concerning. Also that COVID-19 fatigue and reduced vigilance is a setting which increases risk of transmission. Even with vaccination, the protection is not 100% - so non-pharmaceutical interventions (NPIs) [like mask wearing, social distancing and hand washing] must still be adhered to.

5.2.4.6. Testing Strategy of the Department:

- Polymerase chain reaction (PCR) testing is expensive. Antigen (AG) testing is cheaper and provides more rapid results but is less sensitive (it misses about 30% of cases as detected by the gold standard PCR).
- The positive cases that antigen testing misses are those that are late in their infection, who are considerably less infectious, and so the impact on disease control is (arguably) not too severe.
- The COVID-19 AG test result is available within 15 minutes – so there are implications for responding to results at the same time as opposed to remote action via call centre.
- Off-site Testing: there should be a place for 'off-site' testing to try and control recognised outbreaks - in 'containable' populations (Old Age Homes, prisons, schools) – this is better suited to antigen testing.
- The Surveillance and Testing Advisory Group (STAG) will be sustained to advise on changes in testing criteria and strategies.

5.2.4.7. Outbreak Response by the Department of Health:

- Perhaps the most important lesson to be learnt from the previous two waves of COVID-19 is the need to adapt policies and strategies to ensure that they are rapidly flexible and appropriate to the stage of the wave.

- Importantly, policies should not be wasteful of resources – they should either be directly contributing to disease control or be withdrawn.
- It would be preferable to have the policies clarified beforehand and 'implementation-ready'.
- Have 'pre-specified' trigger points at which different policy switches are implemented.

5.2.4.8. Prioritisation for Phase 1 for J&J Vaccine (Sisonke Programme): Limited doses of the J&J vaccine has been secured as part of the Sisonke Programme (300 000 – 500 000 doses). The J&J Vaccine will be arriving in four tranches over eight weeks. The first tranche, received on 17 February 2021, contained 13 160 doses for private and public sectors. It is anticipated that this will cover 40% of health care workers over the eight week period.

5.2.4.9. The launch took place at the Khayelitsha District Hospital on 17 February from 14:00 where President Ramaphosa and Minister Z Mkhize were among the first South Africans to receive the vaccine. Groote Schuur Hospital (GSH) and Tygerberg Hospital (TBH) commenced vaccinations on the same day as the launch. Karl Bremer Hospital started vaccinations on 23 February 2021.

5.2.4.10. Dr Cloete reported that there were 378 vaccination sites for Phase two, which included the False Bay Hospital. He assured the Committee that scientists had not picked up any other variant other than the one which South Africa had, called 501-B2. There was no documented proof of any other variant within the South African setting. There was no backlog in labs and testing.

5.2.4.11. The issue of the farmworkers was one which needed to be dealt with by the District Disaster Management. Each district municipality had a Joint Operation Centre which brought the various government departments together.

5.2.4.12. When vaccinations started, more than 83% of healthcare workers agreed to take the vaccine. The moment the vaccination process started, people became less anxious and wary of taking it.

6. The themes/meetings covered in 31 March 2021 included:

The Committee requested a briefing from the Provincial Minister of Health, the Western Cape Department of Health and the South African Health Products Regulatory Authority (SAHPRA) respectively.

The purpose of the meeting was to get a briefing on the situational analysis and a health synopsis of the pandemic in the Province. In addition hereto, information was requested on the results of the sero-prevalence study and projections for a possible third wave as well as an update on the vaccine roll-out in the Western Cape.

Furthermore, SAHPRA briefed the Committee on the regulatory environment pertaining to vaccines in general and the COVID-19 vaccine. SAHPRA also briefed the Committee on how pharmaceutical companies apply for and obtain approvals for COVID-19 vaccines and the turnaround time for COVID-19 vaccine approvals. SAHPRA further briefed the Committee on the status of the recent emergency-use approval of Pfizer-BioNTech COVID-19 vaccine in South Africa and information on other COVID-19 vaccine applications.

6.1 Observations and challenges

6.1.1 Overview and background

Dr Nomafrench Mbombo, the Western Cape Provincial Minister of Health, indicated that predictions pertaining to the commencement of the third wave would be unrealistic as no one knows when the third wave would commence. However, data showed, while some countries experienced a long second wave, others like South Africa had a different experience because there was a plateau that was experienced between the waves. The number of infections decreased only to eventually dramatically increase.

The Minister reported that the virus contagion reflects differently in various countries, regions, provinces and sub-districts. This meant a large amount of people could be infected in one area whereas in a different area the infection rate would not be as great. She mentioned that the Eastern Cape was the epicentre of the virus during the second wave of the pandemic.

Statistics show a marked increase of 5% in the COVID-19 related infections. This is attributed to tests conducted by the private sector on persons who were scheduled to travel or were being scheduled for an operation. Admissions to hospitals and death rates showed a marked decrease by a 22% and 62% respectively. This indicates that the virus has reached a plateau.

Water samples collected from Waste Water Treatment Plants were tested for possible new strains of the SARS-CoV-2. Water samples collected from the Theewaterskloof and four other treatment plants showed no indication of the SARS-CoV-2 in the wastewater system. Tests conducted at the Caledon Waste Water Treatment Plant indicated no trace of the SARS-CoV-2 since 1 March 2021.

The National Ministerial Advisory Committee released a Ministerial Advisory Model (the Model), which portrays key factors that may influence the commencement of the third wave and the extent of the resurgence infection rate. The Model depicts the mitigating factors that may affect the scale and the cause of the acceleration of the contagion and/or transmission of the infection through the change in seasons, behavioural patterns and movement between provinces.

A sero-prevalence study was conducted of patients that attend health care facilities for non-Covid related incidents. This is to ascertain the sentinel sero-prevalence results, which tested residual (“leftover”) convenience samples from patient groups attending health services for the following:

- Public sector diabetic HbA1c specimens (Metro 1661; Rural 1000);
- Private sector diabetic HbA1c specimens (Metro 1000);
- Public sector HIV VL specimens (Metro 1529); and
- Public sector children (ages 15 years) attending RXH & TBH (53% outpatients).

High sero-prevalence may provide a measure of protection against a significant impact in the third wave, but the Department is still planning for appropriate mitigation. Low sero-prevalence indicates a risk of potentially a more severe impact in the third wave, and this should be taken into consideration in planning mitigation strategies for specified areas.

6.1.2 Health update

6.1.2.1 Statistics on COVID-19 cases

The Department indicated that there were 794 COVID-19 patients in acute condition in hospitals of which 471 were located in public hospitals and 323 in private hospitals. COVID-19 hospitalisations have continued to decline but there has been an increase in trauma cases.

The metro hospitals have an average occupancy rate of 86% and the George drainage area hospitals at 64%. The Paarl area hospitals are at a 71% occupancy rate and the Worcester area hospitals are at 76% occupancy rate.

Metro hospitals have an 11% COVID-19 occupancy rate. The George area hospitals has a 16% occupancy rate, the Paarl area hospitals a 21% occupancy rate and the Worcester area hospitals are at a 21% occupancy rate.

6.1.2.2 Oxygen utilisation

In preparation for the third wave, healthcare facilities have to ensure that there is enough oxygen to meet the demand requirements. Currently the public sector total bulk oxygen consumption has reduced to 15.45 tons/day, or 21.44% of the Afrox Western Cape plant for the seven day period ending 19 March 2021. This is compared to 51 tons per day in the first week of January 2021. The Western Cape still has four bulk oxygen tankers allocated for the daily delivery of oxygen supplies.

6.1.2.3 Vaccine approvals

The Sisionke Programme is currently implementing the fourth tranche of the Johnson and Johnson vaccine. The Pfizer and Johnson and Johnson vaccine approvals have since been granted by SAHPRA. The Covishield vaccine approval was granted, but the roll-out of the vaccine has been postponed. No submissions were made to SAHPRA on the Moderna and the Novavax & Bharat Biotech vaccines. Sputnik, Sinovac, and Sinopharm vaccines submitted applications to SAHPRA for approval but currently no approvals have been granted.

6.1.2.4 Vaccine acquisition

Dr Cloete informed the Committee that the Sisonke was a research project. He indicated that the Department has not made use of any procured vaccines in South Africa as yet. The Johnson and Johnson vaccines were leftover research vaccine stock from across the world that was returned in batches to South Africa. A total of 80 000 batches of the vaccine were dispatched to South Africa, with another 200 000 batches that must still be returned. Once the additional 200 000 batches are received, it will be allocated to the Sisonke program. This would then conclude the rollout of the Sisonke vaccine role out.

The Department indicated that both the private and public sector hospitals opted to receive vaccines from the national programme. The process to acquire vaccines to supplement the national programme could commence from August 2021 to September 2021. A total of 2000 batches of the vaccine will be rolled out to hospitals and clinics. Melomed applied to be the vaccine centre for the whole of the metro. Special concession will be given to old age homes, people over the age of 60 and frail care facilities.

6.1.2.5 Vaccine rollout

Phase one of the vaccine will be rolled out in the Central Karoo, Caledon and Overberg regions. The Johnson and Johnson vaccine will be the preferred vaccine mainly due to a single dose administration being cheaper and easier to administer. The Pfizer vaccine will be utilised to supplement the shortfall of the Johnson and Johnson vaccine.

In South Africa, only 50 percent of the health care workers have been vaccinated. Despite socio-economic circumstances, vaccinations are to be distributed and made available equitably to

everyone. A Steering Committee will be considering specific areas to deal with the vulnerable groups. The vaccinations will be administered free of charge at the designated vaccination centres for persons who cannot afford the vaccine.

Participants will be required to have a valid South African identity document to be registered on the database that will be established for persons who have received the vaccine. A challenge would be to register vagrants without an identity document into the system. Registered refugees would also be assisted. Persons with a valid medical aid would be charged for the vaccine. The public and private sector will collaborate in administering the vaccine to everyone. Three sites have been earmarked for the administration of the vaccine in rural areas and Caledon was earmarked for the administration of the vaccine to healthcare workers. The George Hospital has completed 3 618 vaccinations, and was due to complete another 9 760.

No separation between private and public institutions are being made for the roll out of the vaccine in rural areas due to the lack of sufficient capacity. Once, the Pfizer vaccine arrives, additional sites would be allocated to deal with the vaccine rollout programme. The red dot transport system was identified as a possible solution to help transport people to vaccination sites.

6.1.2.6 501Y.V2 variant and the United Kingdom variant

The Department reported that the 501Y.V2 variant was detected globally. There is no evidence that the 501Y.V2 variant, which originated in South Africa, causes more severe illnesses.

The United Kingdom strand of the virus had been detected at Tygerberg Hospital in South Africa. Currently the variant has not spread and samples of the variant were not found amongst other test subjects. Statistics have shown that the United Kingdom variant is more transmissible and severe.

6.1.2.7 Job appointments

A total of 1 132 contract appointments have been made for the year. Due to budgetary constraints the contracts would have to be reviewed. Critical posts across all categories were mostly looked at when making the appointments. The Department indicated that the budget was already under pressure and that the pandemic only added to the pressure.

6.1.2.8 Preparedness for the third wave

To ensure preparedness for the third wave, containment measures were put in place in the West Coast, Overberg, and the private sector respectively, with adequate beds and oxygen supply particularly in rural districts.

6.1.3 Briefing by the South African Health Products Regulatory Authority (SAHPRA)

6.1.3.1 Overview and background

South African Health Products Regulatory Authority (SAHPRA) is a Section 3A public entity that was formed by the South African government to oversee the regulation of health products which includes medicines, medical devices, in-vitro diagnostic tests and devices, radiation emitting products and devices used in health care and industry. SAHPRA replaced the Medicines Control Council (MCC) as well as the Directorate of Radiation Control (DRC).

6.1.3.2 Vaccine application requirements

Prior to the approval of any vaccine, all information on the vaccine must be established. All lab based data is monitored as per the available data on the vaccines performance. Ongoing data is received in batches for review. Evaluation reports is generated for the outcome of each review.

6.1.3.3 Registration of medicine

The Johnson and Johnson vaccine was at an advanced stage of review. Government is in a position to access any other vaccine which was not under a clinical study. Despite Section 21 being for emergency use, it meant government could procure it to be able to implement it into the different phases, if the quantities authorised were insufficient. The applicant could request for the quantities to be increased. Any new product developed still had to undergo clinical trials to generate sufficient data to make sure it met the correct requirements. Vaccine registration is done in terms of Section 15(6a) of the Medicines and Related Substance Act 101 of 1965, which allows SAHPRA to register a medicine, subject to certain conditions.

6.1.3.4 Utilisation of Ivermectin

The Pretoria High Court issued a court order pertaining to four cases that were brought against SAHPRA and the Minister of Health regarding access to Ivermectin for use in COVID-19 treatments. The court order was as a result of settlement agreements reached between SAHPRA, the Minister of Health and the applicants in the four cases. A National Advisory Committee reviewed the evidence and data pertaining to the utilisation of Ivermectin as a potential vaccine. SAHPRA advised that there is insufficient scientific evidence on the efficacy of Ivermectin for the prevention or treatment of COVID-19. Continued monitoring will be conducted on emerging data regarding the use of Ivermectin for the treatment of COVID-19. SAHPRA has received no application for the registration of an Ivermectin-containing medicine for COVID-19.

6.1.3.4 Utilisation of resources

The total staff complement was approximately 450. However, currently the entity is running with a staff complement of about 280. While the entity was understaffed, it was not only putting mechanisms in place to recruit employees, but was also working on raising funds from National Treasury to be able to fully capacitate the Organisation. A big challenge faced during the COVID-19 period was other areas of work could not be neglected. The entire SAHPRA team was working non-stop since the start of the pandemic.

6.1.4 Acknowledgements

The Chairperson thanked the Ministry, the Provincial Department of Health and SAPHRA for the presentations. The Chairperson also thanked the Members for their participation in the meetings.

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MS M WENGER (MPP)
CHAIRPERSON OF THE AD-HOC COMMITTEE ON COVID-19
DATE: 25 May 2021