KENYA MEDICAL PRACTITIONERS AND DENTIST COUNCIL

ADVISORY ON COVID-19 PREVENTION STRATEGIES, TREATMENTS AND VACCINES

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A. Introduction and Background

The Kenya Medical Practitioners and Dentists Council ("Council" or "KMPDC") is a body corporate established under Section 3 of the Medical Practitioners and Dentists Act (CAP 253 - Laws of Kenya) with the mandate to regulate the training and practice of medicine, dentistry and community oral health within the Republic of Kenya. The Council also has the mandate to regulate all health institutions in the country.

Regarding the COVID-19 prevention strategies, treatment and vaccines, the Council wishes to state as follows:

The coronavirus disease 2019 (COVID -19) is a serious respiratory viral infection caused by a new coronavirus recently named SARS-CoV-2. The outbreak started in Wuhan City, Hubei Province in mainland China in December of 2019 and has since spread globally, infecting more than 116,897,152 people resulting in over 2,594,064 deaths and occurring in 192 countries as of 8th March 2021. On 11th March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.

The first COVID-19 case in Kenya was announced by the Cabinet Secretary for Health on 13th March 2020. Since then, Kenya has had 108,827 confirmed cases with 1,876 deaths as of 7th March 2021. The case fatality in Kenya stands at 1.7%. Ninety-nine (99%) percent of the cases have been local transmission and each of the 47 counties has established community transmission. Majority of the cases are asymptomatic infections or patients with mild symptoms. Among those who have lost their lives, majority (70%) were male and most had other diseases that increase the risk for severe disease such as diabetes, hypertension, heart

disease and chronic kidney disease

A total of 3254 health care worker infections have been reported with 32 deaths in this group.

B. SARS-CoV 2 Infection, COVID-19 Disease and Clinical Spectrum

Following infection by SARS-COV-2, the virus multiplies in the lining of the respiratory tract. From the time of exposure, the estimated incubation period for COVID-19 is up to 14 days, with a median incubation period of 4 to 5 days. The clinical spectrum of illness ranges from asymptomatic infection to severe pneumonia with acute respiratory distress syndrome (ARDS) and death.

Adults with SARS-CoV-2 infection can be grouped into 5 categories based on illness severity. However, a patient may progress from one category to another in a few days. These categories are:

- **Asymptomatic or Pre-symptomatic Infection:** Individuals who test positive for SARS-CoV-2 using a virologic test but who have no symptoms that are consistent with COVID-19.
- **Mild Illness:** Individuals who have various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who **DO NOT** have difficulty in breathing or any abnormal changes seen on the X-ray or CT scan of the chest
- **Moderate Illness:** Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2) ≥ 94% on room air at sea level.
- **Severe Illness:** Individuals who have low oxygen saturation (SpO2 <94%) on room air at sea level, a respiratory rate >30 breaths/min, or lung infiltrates.
- **Critical Illness:** Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

Globally as well as in Kenya up-to 80% to 90 % of SAR-CoV 2 infections are asymptomatic or result in mild illness that can be safely managed outside of hospital while 10 to 20% of patients require hospitalization.

Older patients (60 years and above) as well as patients with certain

underlying conditions are at a higher risk of progressing to severe COVID-19 and developing critical illness. These underlying conditions include having heart disease, chronic lung disease, sickle cell disease, diabetes, cancer, obesity, or chronic kidney disease; being pregnant; being a smoker; and being a recipient of transplant or immunosuppressive therapy. Patients with any of these conditions have to be monitored closely in a hospital setting.

C. COVID-19 Diagnostic Test

The reverse transcriptase polymerase chain reaction (RT-PCR)-based diagnostic tests (which detect viral nucleic acids) are considered the gold standard for detecting current SARS-CoV-2 infection and remain the test of choice in Kenya.

Antibody tests can detect recent or prior SARS-CoV-2 infection and are used for public health surveillance to determine the true extent of an outbreak, map its geographic distribution, and identify at-risk populations to inform control strategies.

D. COVID-19 Preventive Strategies

The main mode of transmission of SARS-CoV-2 is through respiratory droplets transmitted from an infectious person to others within six feet of the person. The prevention strategies for SARS-COV -2 include:

- Wearing a face mask;
- Performing hand hygiene regularly; and
- Maintaining a distance of at least six feet from others (Physical/social distancing)

E. SARS-CoV 2 (COVID-19) Therapy

Two main processes are postulated to drive the disease process of COVID-19. Early in the course of the infection, the disease is primarily driven by multiplication of SARS-CoV-2 virus (viral replication phase). Later in the course of infection, the disease is driven by an exaggerated immune/inflammatory response to the virus that leads to tissue damage

(Host inflammatory response phase). On the basis of this understanding, it is expected that antiviral therapies would have the greatest effect early in the course of disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

There are multiple studies going on around the world to identify drugs that may be useful in the treatment of COVID targeting the two phases of the illness.

Among those that have been shown to improve the outcomes of patients include:

- Dexamethasone used at a low dose in patients who require oxygen or ventilation;
- Remdesivir, currently the only antiviral drug approved by the United States Food and Drug Administration ("FDA" or "USA FDA") for use in the treatment of hospitalized COVID-19 patients who require oxygen as part of their treatment. It is **NOT** routinely recommended for patients who require mechanical ventilation due to the lack of data showing benefit at this advanced stage of the disease.

The usefulness of the following drugs continues to be studied and conclusions vary from various studies.:

- Hydroxychloroquine/Chloroquine;
- Azithromycin (or any other antibiotics); and
- Ivermectin

Studies are still going on looking at many other drugs and this is an area that will be updated regularly.

Any of drugs currently being studied should only be used in the context of a clinical trial and after discussion with a doctor and after a patient gives informed consent to receive the drug.

F. COVID-19 Vaccines: The WHO Emergency Use Listings (EUL) and USA FDA Emergency Use Authorization (EUA)

Currently, no SARS-CoV-2 vaccine has been approved or fully licensed by any regulatory authority globally. However, there are several vaccines in advanced stages of development. Several vaccines have undergone clinical trials to look at their efficacy and safety. Efficacy refers to **the**

ability of a vaccine to reduce the incidence of infection or to reduce the incidence of developing disease if one is infected. Safety looks at the side effects/harmful effects of a vaccine.

Different countries have already authorised use of various vaccines for use in the context of this pandemic (what is referred to as an Emergency Use Authorization (EUA))

The WHO Emergency Use Listings (EUL) is a risk-based procedure for assessing and listing candidate in vitro diagnostics (IVDs), therapeutics and vaccines for use during public health emergencies. The current procedure consists of three key components:

1. Review of the documentation relating to the manufacture of the product, including compliance with WHO manufacturing quality norms and standards;
2. Review of documentation relating to safety and efficacy/performance, especially with respect to use in the area of the public health emergency; and
3. Where applicable for diagnostics, an independent laboratory evaluation, coordinated by WHO, of the product's performance and operational characteristics.

Based on these 3 key components, the WHO issued Emergency Use Listings (EULs) for the Pfizer COVID-19 vaccine (BNT162b2) on 31st December 2020 and on 15th February 2021, WHO issued EULs for two versions of the AstraZeneca/Oxford COVID-19 vaccine, manufactured by the Serum Institute of India and SKBio.

The USA FDA Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic when certain statutory criteria have been met.

On 11th and 18th December 2020, the USA FDA issued EUAs for two mRNA vaccines, BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) BNT162b2 respectively and on 27th February 2021 for Janssen COVID-19 Vaccine.

The Council would like to reiterate the following:

1. The general public is encouraged to adhere to the public health measures that **prevent** the transmission of SARS-CoV 2 / COVID-19 namely: Wearing of facial masks, washing hands and avoiding public gatherings.
2. All experimental **treatment** and repurposed therapies against SARS-CoV2 are to be used only in the setting of a clinical trial with approval from institutional regulatory boards (IRBs), Institutional Ethics Committees (IECs) and Pharmacy and Poisons Boards (PPB). Patients receiving these therapies require to give informed consent to participate in the clinical trials and appropriate and periodic reporting to the PPB must be undertaken.
1. There is no licensed **vaccine** for use to prevent COVID-19. Vaccines are only available globally for use under WHO Emergency Use Listing (WHO EUL) procedure and USA FDA Emergency Use Authorization (USA FDA EUA) approvals. These vaccines available through the WHO EUL and US FDA EUA have a good safety record based on the safety data from the clinical trials. In the phase one of the Kenya COVID-19 Vaccine Deployment plan, Healthcare workers have been prioritized to receive the vaccine to protect them from getting COVID-19 in the course of their clinical duties (caring for the patients). Healthcare workers are encouraged to present themselves to receive these vaccines.

This Advisory has been prepared by the Kenya Medical Practitioners and Dentists Council and Infectious Disease Specialists