# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 1126**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 05 JUNE 2020**

**(INTERNAL QUESTION PAPER NO. 19)**

**Dr S S Thembekwayo (EFF) to ask the Minister of Health:**

With reference to his undertakings that the Republic’s participation in vaccination trials for coronavirus as the country is part of the Health Emergency Solidarity Trial under the auspices of the World Health Organizations and further made an assertion that fears raised by society around this should not be the case as the nature and ethics of the trials are unfounded because times have changed, in what way (a) have the ethics of the trials changed from their historical association with the abuse of human rights and dignity and (b) will the Republic be participating as guinea pigs and/or as collaborators of the scientific process from initial stages and not just on the receiving end?

###### NW1426E

**REPLY:**

1. The World Health Organisation (WHO) Solidarity Trial is a global study that is evaluating therapeutic interventions to support the treatment of patients admitted with COVID-19. This protocol describes a randomised trial among adults (age ≥18 years) hospitalised for COVID-19 that randomly allocates them between four treatment arms, each to be given in addition to the usual standard of care in the participating hospital. Randomisation is proposed into the following 4 arms: a) Standard of care; b) Remdesivir; c) Lopinavir-Ritonavir with Interferon β1b; and hydrochloroquine. This trial will be subjected to South African research standards to protect human rights through regulatory approval for clinical trials and ethics, besides similar processes being undertaken at a global level. The ethical review is rigorous and robust in ensuring that a relevant Research Ethics Committee protects potential participants by taking into account potential risks and benefits for the community in which the research will be carried out. In line with ethical principles, the Ethics Committee ensures protection of individual autonomy through informed consent; protecting participants against grievous bodily harm, and justice in assessing risks and benefits of the study

The South African Health Products Regulatory Authority (SAHPRA) is statutorily obliged to ensure that medicines, drugs and other health care products available in the country comply with the requirements for safety, quality and efficacy. It is also authorised to terminate a trial when serious breaches of Good Clinical Practice (GCP) occur, and where participants in clinical trials have had, their safety or well-being compromised. To date, a number of clinical trials have been approved in South Africa to determine the effectiveness of different therapeutic interventions to treat and prevent SARS-CoV-2 infection. SAHPRA has reviewed and approved one COVID-19 vaccine trial application submitted by Professor Shabir Madhi who is one of South Africa’s leading vaccinology experts and is the director of Wits University and the Medical Research Council Respiratory and Meningeal Pathogens Research Unit (RMPRU). The proposed vaccine study will be undertaken by RMPRU, in partnership with the Wits Reproductive Health and HIV Institute and the Setshaba Research Unit, organised under the auspices of Wits University’s flagship vaccinology programme, the African Leadership in Vaccinology Expertise (ALIVE).

1. The South African Solidarity Trial Team is led by Prof Helen Rees and senior academics and clinicians from eight medical schools who have made major contributions to the study design. These researchers have been conducting community advocacy, as well as engaging communities and healthcare workers on the ground.

The leading hospitals in South Africa are:

• Livingston Tertiary Hospital and Dora Nginza Hospital (Nelson Mandela University)

• Dr George Mukhari Hospital (Sefako Makgatho Health Science University)

• Tygerberg Hospital (Stellenbosch University)

• Groote Schuur Hospital (University of Cape Town)

• Military Hospital, NHLS Universitas Hospital, Pelonomi Hospital and a private hospital with Mediclinic (University of Free State)

• King Edward Addington and Inkosi Albert Luthuli Hospital (University of KwaZulu-Natal)

• Steve Biko Academic Hospital (University of Pretoria)

• Baragwanath and Charlotte Maxeke (Wits University)

The candidate COVID-19 vaccine that has been approved for study was developed by Oxford University in the UK and is called ChAdOx1. The Oxford University vaccine developers have completed the early Phase 1 trials in the UK and have demonstrated that the vaccine is safe and immunogenic. There is now a second phase clinical trial being undertaken in the UK to determine the safety and efficacy of the vaccine. There are over 1200 participants already enrolled, and a further 9,000 participants to be enrolled over the next few months. Brazil and Kenya will also be involved in clinical trials of the same vaccine. In South Africa, it is proposed that 2000 volunteers will be recruited to join the study, with similar numbers to be enrolled in the study planned in Brazil. The ability of RMPRU to lead the proposed study has been assessed and approved by the governing regulatory authorities in South Africa.

COVID-19 vaccine development is proceeding at an unprecedented speed, with many of the world’s leading scientific institutions contributing to this effort. There are currently over 100 vaccines in development and clinical trials have been undertaken in the UK, USA and France. For products such as vaccines, it is critically important that studies are performed in Southern Hemisphere countries including in the African region, concurrently with studies in Northern Hemisphere countries. This allows evaluation of the efficacy and safety of candidate vaccines to be assessed in a global context, failing which the introduction of many life-saving vaccines into public immunization programmes for Low Middle Income Countries (LMICs) frequently lags behind that in High Income Countries (HIC). Furthermore, if South Africa participates in the development of a vaccine it places an ethical obligation on the vaccine developers to allow early access to that vaccine in the countries where the research was undertaken.

END.