



REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Ref. No.: 10/6

Date: 22 October 2021

PRESS RELEASE

RE: MINISTRY OF HEALTH AND SOCIAL SERVICES' POSITION FOLLOWING THE MEDIA RELEASE FROM SAHPRA ON THE REVIEW OF THE SPUTNIK V VACCINES

The Minister of Health and Social Services, after consultation with the Namibia Medicine Regulatory Authority (NMRC) granted authorization for the use of Sputnik V in the Namibia COVID-19 Vaccination Program as gazetted in Government Notice No.7479 published on 09 March 2021. The authorization for use of Sputnik V was granted under sections 45 of the Medicine and Related Substances Control Act, 2003 (Act No. 13 of 2003) and in line with the National Deployment and Vaccination Plan for COVID-19 Vaccines (NDVP) Regulatory approval by way of reliance for use of vaccines approved by other Stringent Regulatory Authorities (SRAs).

Namibia received 15, 000 doses of Component 1 and 15, 000 doses of Component 2 of the Sputnik V vaccine a donation from the Government of Serbia. The Sputnik V vaccine was rolled out to certain vaccination sites in the country as from 18 September 2021. As at 20 October 2021, 108 doses of Component 1 and 7 doses of Component 2 of Sputnik V were administered.

The Ministry became aware of a Media Release issued by the South African Health Products Regulatory Authority (SAHPRA) on 18 October 2021, on the outcome of the review of data submitted to SAHPRA by Lamar International (Pty) Ltd. SAHPRA indicated concerns with safety and effectiveness of an Ad5-vectored vaccines in populations at risk of HIV infection and with high presence of pre-existing Ad-specific neutralizing antibodies (Nabs) in the general population. SAHPRA reported and associated the vaccine technology used by Sputnik to the vaccine technology used in the STEP and PHAMBILI Trials that were halted in the past due to the Ad5-vector vaccine being associated with enhanced susceptibility or acquisition of HIV in men.

Based on the above background, the Ministry of Health and Social Services will discontinue the use of Sputnik V vaccine in the national vaccination program with immediate effect until it has received the WHO Emergency Use Listing. However, patients who received the first dose (component) of Sputnik V will be offered their second dose (component) to complete the vaccination schedule. The reason for discontinuation of the administration of the vaccine is being done out of abundance of caution that men received Sputnik V may be at higher risk of contracting HIV when exposed to it. The Ministry will continue to engage with the WHO, African CDC and other relevant instances on further scientific developments on the matter.

For further enquiries, kindly contact the Ministry of Health and Social Services, Public Relation Officer at +264-61-203 2054 or email Public.relations@mhss.gov.na

Issued by:

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