SAHPRA Statement – Update on Sisonke Phase 3B Implementation Study

Pretoria, 17 April 2021

SAHPRA has engaged with the Sisonke Phase 3B Implementation Study team and Janssen Pharmaceutica. The focus of the engagement was on the safety data reported from the Sisonke study, following administration of the COVID-19 vaccine Janssen, as well as the adverse events reported in the United States of America.

Based on their review of the available data, SAHPRA has recommended that the pause in the Sisonke study be lifted, provided that specific conditions are met.

These conditions include, but are not limited to, strengthened screening and monitoring of participants who are at high risk of a blood clotting disorder. In addition, measures are to be implemented to ensure the safe management of any participants who develop vaccine-induced thrombosis and thrombocytopenia (VITT). The participant information sheets and informed consent forms will be updated to include the newly identified adverse events.

Participants in the Sisonke study will be informed about the possible risks of developing a blood clotting disorder after vaccination. They will also be advised to seek immediate medical assistance if they develop early signs and symptoms associated with blood clots or low platelet counts. The study team will submit the required updated documents, procedures and study arrangements to SAHPRA for approval.

Resumption of the Sisonke Phase 3B Implementation Study will also require approval from the relevant Research Ethics Committees.