SAHPRA Statement – Update on Sisonke Phase 3B Implementation Study

Pretoria, 14 April 2021

SAHPRA, together with its scientific expert committees, has recently reviewed the data from the Sisonke Phase 3b implementation study. This study involves the administration of the COVID-19 vaccine Janssen, which is also referred to as the Johnson and Johnson (J&J) vaccine. Based on these data, no major safety concerns have been identified. No causal relationship between vaccination and the development of blot clots is evident at this stage.

However, following the decision by the United States Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to pause the use of the J&J vaccine in that country, SAHPRA met with the Sisonke study team and the manufacturer (Janssen Pharmaceutical) on 13 April 2021. SAHPRA was provided with updated data on the Sisonke study. Further data are being obtained from the manufacturer and the US FDA.

SAHPRA has requested a pause in the implementation of the Sisonke study to enable it to review the relevant data and further updates will be communicated in due course. It is envisaged that this process will take a few days.