MINISTRY
HEALTH
REPUBLIC OF SOUTH AFRICA

11 June 2021

Statement on the Status of Johnson and Johnson Rollout in South Africa based on the FDA Announcement

The Department of Health notes the statement issued by the US Food and Drug Administration (FDA) released on their website on Friday, 11 June 2021 in relation to the doses of Johnson and Johnson vaccines produced at the Emergent BioSolutions Plant in Baltimore, USA.

The FDA has been investigating the plant following revelations that some of the batches may have been contaminated.

We confirm that the FDA announced that two batches of these doses are safe and have been cleared for emergency use.

The implications for South Africa are as follows:

The vaccines awaiting distribution from the Gqebherha plant need further assessment by SAHPRA and SAHPRA will soon advise if they are suitable for use in South Africa. There is now a real possibility that they may not be, however this is for the regulator to rule on.

In total, 300 000 doses are cleared to be shipped to South Africa as a matter of extreme urgency. Furthermore, the FDA announced that, after careful evaluation of these doses, they approved an extension of the expiry date after determining that the vaccine can be stored in 2-8 degrees celsius (normal bar fridge) for 4,5 months instead of 3 months.

Work is being undertaken to identify more safe doses for the rest of the mass vaccination programme.

We further note that the FDA is still evaluating some batches and we will await those outcomes, in the hopes that this will make more doses of Johnson and Johnson available to the international community, including South Africa.

Further announcements will follow in due course. We remain committed to the success of the South African mass vaccination campaign and are doing everything in our power to source safe and effective vaccines four all people residing in South Africa.

ENDS