Government Notices • Goewermentskennisgewings

DEPARTMENT OF HEALTH

NO. 1502 15 November 2021

EXCLUSION OF COVID-19 VACCINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

I, Dr M.J. Phaahla, Minister of Health, in terms of section 36(1) of the Medicines and Related Substances Act 101 of 1965 (the Act), and on the recommendation of the South African Health Products Regulatory Authority (the Authority) hereby exclude any vaccine registered, or authorised by the Authority for use in the prevention of COVID-19 (COVID-19 vaccine) from the requirements of section 22A(5) of the Act to the extent that—

- (a) COVID-19 vaccines may also be sold by the National Department of Health; and
- (b) such vaccines are only sold by the Department to a wholesaler or distributor that holds a licence issued in terms of section 22C(1)(b) of the Act to act as a wholesaler or distribute such medicines, a community or institutional pharmacy licensed by the Director-General and recorded with the South African Pharmacy Council, in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974), or to a person or organisation performing a health service (including a health establishment), authorised to acquire, possess, use or supply COVID-19 vaccines in terms of section 22A(15) of the Act.

This Notice is effective immediately from the date of publication in *government gazette* for a period of twenty four (24) months.

DR.M.J. PHAAHLA, MP MINISTER OF HEALTH

DATE: