DEPARTMENT OF HEALTH

NO. R. 756

23 MAY 2019

EXCLUSION OF CERTAIN PREPARATIONS CONTAINING CANNABIDIOL (CBD) FROM OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

I, Dr Aaron Motsoaledi, Minister of Health, in terms of section 36(1) of Medicines and Related Substances Act, 1965 (Act No.101 of 1965) and on the recommendation of the South African Health Products Regulatory Authority (the Authority), hereby exclude from the operation of the Schedules to the Act published in terms of section 22A(2) of the Medicines and Related Substances Act, 1965, preparations containing cannabidiol (CBD) that-

- a) contain a maximum daily dose of 20 mg cannabidiol (CBD) with an accepted low risk claim or health claim which only refer to:
 - i. General health enhancement without any reference to specific diseases;
 - ii. Health maintenance; or
 - iii. Relief of minor symptoms (not related to a disease or disorder); or
- b) Consist of processed products made from cannabis raw plant material and processed products, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain not more than 0,001 % of tetrahydrocannabinol (THC) and not more than 0,0075 % total cannabidiol (CBD).

This exemption is effective immediately for a period not exceeding twelve (12) months from the date of signature of this Notice.

DR A MO/TSOALEDI, MP

DR & MOTSOALEDI, MP MINISTER OF HEALTH DATE: 5594