

DEPARTMENT OF HEALTH

NO. 1233

20 NOVEMBER 2020

AMENDMENT OF GOVERNMENT NOTICE 514, PUBLISHED ON 07 MAY 2020, GOVERNMENT GAZETTE 43294: EXCLUSION OF SCHEDULE 2, SCHEDULE 3 AND SCHEDULE 4 SUBSTANCES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)**NOTE**

- [] *Words in bold type in square brackets indicate omissions from the notice published on 30 April 2020.*
- _____ *Words underlined with a solid line indicate insertions in the notice published on 30 April 2020.*

I, Dr Zwelini Lawrence Mkhize, the Minister of Health, in terms of section 36(1) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Act), and on the recommendation of the South African Health Products Regulatory Authority (the Authority) hereby exclude Schedule 2, Schedule 3 and Schedule 4 substances from the requirement in section 22A(6)(f) of the Act that such substances may be dispensed for no longer than six months:

Provided that Schedule 2, Schedule 3 and Schedule 4 substances may not be dispensed for a period longer than twelve (12) months from the date of issue of a prescription issued by an authorised prescriber, in accordance with regulation 33 of the General Regulations made in terms of the Act (the Regulations), where the date of issue of the prescription is:

- (a) up to six (6) months before the date of publication of this notice, in which case additional repeats may be issued for a period not exceeding six months, and in accordance with the original prescription in order to ensure that therapy is not disrupted, **[if the person dispensing the prescription is satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued,] and that the intention to continue such therapy is confirmed by the initial prescriber or another authorised prescriber designated to provide care to the patient and such confirmation is documented**, and that the particulars of such sale are recorded in a prescription book or permanent record in terms of regulation 35 of the Regulations; or
- (b) on or six (6) months after the date of publication of this notice, and the authorised prescriber who issued the prescription, has indicated thereon the number of times it may be dispensed (but not longer than 12 months).

And provided:

Further that the prescribing and dispensing of prescriptions is done in accordance with the ethical rules, code of conduct and practice guidelines provided by the applicable regulatory body.

This Notice is effective immediately for a period not exceeding 18 months from the date of signature of the original Notice, GNR. 514, published on 07 May 2020, *Government Gazette* 43294.



DR ZWELINI LAWRENCE MKHIZE, MP

MINISTER OF HEALTH

DATE 06/10/2020