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GOVERNMENT NOTICE

Health, Department of

Government Notice

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 491

25 April 2008

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

AMENDMENT OF SCHEDULES: SCHEDULING OF EPHEDRINE, PSEUDO-EPHEDRINE, D-NOR-PSEUDOEPHEDRINE AND 1-BENZYLPIPERAZINE (BZP) BZP

The Minister of Health has, in terms of section 22A (2) and section 37A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), on the recommendation of the Medicines Control Council, amended the Schedules in the Schedule.

SCHEDULE

Definitions:

1. In this Schedule, "the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
2. In this Schedule, "Schedules" means the Schedules published under Government Notice No. R. 509 of 10 April 2003 as published in *Government Gazette* No. 24727
3. Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided for information only and shall not be used in the interpretation of the inscription.

Amendments to the Schedules

4. Schedule 1 of the Schedules is hereby amended by the substitution for the following expressions of the following:
 - (a) "Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules, intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export. (S2, S6)" and
 - (b) "Ephedrine, preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine, and not intended for export. (S2, S6)."

5. Schedule 2 of the Schedules is hereby amended by:

(a) the substitution for the following expression of the following:

- (i) "Ephedra alkaloids (natural or synthetic), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules:
 - (a) oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)
 - (b) except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)" and
- (ii) "Ephedrine, contained in products registered in terms of the Act, and not intended for export,
 - (a) oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)
 - (b) except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)".

(b) by the insertion of the following expressions in the correct alphabetical order:

- (i) "{(+)-norpseudoephedrine - see cathine (S6)}" and
- (ii) "Pseudoephedrine, contained in products registered in terms of the Act, and not intended for export,
 - oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S6)"

6. Schedule 6 of the Schedules is hereby amended by :

(a) the insertion of the following expressions in the correct alphabetical order:

- (i) "Beta-aminopropylbenzene and beta-aminoisopropylbenzene derivatives, being any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure);
 - a. except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
 - b. except when contained in appliances for inhalation in which the substance is absorbed in solid material; (S1) and
 - c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; (S1, S2, S5) and
 - d. except substances listed in Schedule 7. (S1, S2, S5)";

(b) by the substitution for the following expression of the following:

"Cathine ((+)-norpseudoephedrine / D-norpseudoephedrine),";

(c) by the insertion of the following expression in the correct alphabetical order:

"{D-norpseudoephedrine - see cathine.}";

(d) by the substitution for the following expressions of the following:

- (i) "Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules,
 - a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)
 - b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)." and

- (ii) "Ephedrine,
- a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)
 - b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1).";

(e) by the insertion of the following expressions in the correct alphabetical order:

- (i) "{(+)-Norpseudoephedrine see D-norpseudoephedrine / Cathine}." and
- (ii) "Pseudoephedrine, except contained in products registered in terms of the Act, and not intended for export, being oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S2).".

7. Schedule 7 of the Schedules is hereby amended by:

(a) the insertion of the following expression in the correct alphabetical order:

"1-Benzylpiperazine (BZP)";

(b) the substitution for the following expression of the following:

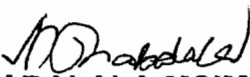
"Beta-aminopropylbenzene and beta-aminoisopropylbenzene, except any compound structurally derived from either beta-aminopropylbenzene or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure); and presented as:

- a. preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- b. appliances for inhalation in which the substance is absorbed onto solid material; (S1)
- c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine; (S1, S2, S5)

d. except substances listed in S1, S2, S5, and S6.”.

Commencement

These amendments to the Schedules come into operation on the date of publication in the Government Gazette.


ME TSHABALALA-MSIMANG
MINISTER OF HEALTH
