MEDICINES CONTROL COUNCIL

SCHEDULING MATTERS

RESCHEDULING EPHEDRINE, EPHEDRA ALKALOIDS AND PHENYLPROPANOLAMINE

TO ALL APPLICANTS

Kindly be advised that at a recent meeting of the Medicines Control Council. Council resolved to reschedule ephedrine, ephedra alkaloids and phenylpropanolamine due to safety and control concerns, in line with regulatory authorities the MCC currently aligns itself with, as follows:

Words in **[bold and in square brackets]** indicate omission from a Schedule

Words underlined with a solid line indicate insertions in a Schedule.

Schedule 1

Ephedrine,

a. 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; (S6)

b. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Ephedra alkaloids (natural or synthetic), **[unless listed separately in the Schedules],**

a. when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export; (S6)

b. except oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Schedule 2

Ephedrine, contained in products registered in terms of the Act, and not intended for export,

a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 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)

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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 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)

Schedule 6

Ephedrine,

a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 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)

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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of **[720]** 360 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)

Schedule 2

Phenylpropanolamine (norephedrine), 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 where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S6)

Schedule 6

Phenylpropanolamine (norephedrine),

a. except products registered in terms of the Act, not intended for export and oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer (S2)

Please be advised that the office of the Registrar is in the process of drafting an amendment to the published Schedules, for consideration by the Minister of Health and publication in the Government *Gazette.*

Dr JC GOUWS

REGISTRAR OF MEDICINES