MEDICINES CONTROL COUNCIL

SCHEDULING MATTERS
RESCHEDULING OF ACETYLDIHYDROCODEINE, CODEINE, DIHYDROCODEINE and NORCODEINE

TO ALL APPLICANTS

Kindly be advised that at a recent meeting of the Medicines Control Council, Council resolved to reschedule acetyldihydrocodeine, codeine, dihydrocodeine and norcodeine, as follows:

1. Schedule 2 listing
   - Reduce the maximum quantity of codeine and dihydrocodeine per dosage unit from 20 mg to 10 mg and limiting the maximum daily dose to 80 mg and maximum treatment period to 5 days for oral solid preparations;
   - Reduce the maximum quantity of codeine and dihydrocodeine per 5 ml dosage unit from 20 mg to 10 mg and limiting the maximum daily dose to 80 mg and maximum pack size to 100 ml for oral liquid preparations.

2. Schedule 3 listing
   - Inclusion of a listing and inscription for codeine and dihydrocodeine for oral solid and liquid preparations exceeding the maximum quantity of active per dosage unit i.e. 10 mg.

3. Schedule 6 listing
   - Rescheduling of norcodeine and acetyldihydrocodeine from Schedule 2 to Schedule 6.

Please be informed 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 J C Gouws
REGISTRAR OF MEDICINES
Words in **[bold and in square brackets]** indicate omission from a Schedule

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

Schedule 2

**Acetyldihydrocodeine:**

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit; and

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)]

**Norcodeine,**

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit; (S6) or

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S6)]

Schedule 6

Acetyldihydrocodeine.

a. [except oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit; and

b. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S2)]

Norcodeine.

a. [except oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit; (S2) and

b. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S2)]

Schedule 2

**Codeine** (methylmorphine),

a. oral solid preparations, in combination with one or more therapeutically active substances, **[and]** containing **[20 milligrams or less]** not more than 10 milligrams of codeine (calculated as base) per dosage unit, **[and]** with a maximum daily dose not exceeding 80 milligrams, **[and]** in packs containing sufficient dosage units for a maximum treatment period of 5 days;
b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less] not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres;

c. except oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit; (S3)

d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit; (S3)

e. except single component codeine preparations. (S6)

Dihydrocodeine,

a. oral solid preparations, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less] not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days;

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less] not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres;

c. except oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit; (S3)

d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit; (S3)

e. except single component dihydrocodeine preparations. (S6)

Schedule 3

Codeine (methylmorphine)

a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit;

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit;

c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days (S2);

d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres; (S2)

e. except single component codeine preparations. (S6)
Communication to industry

Dihydrocodeine,

a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit;

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit;

c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days; (S2)

d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres; (S2)

e. except single component dihydrocodeine preparations. (S6)

Schedule 6

Codeine (methylmorphine),

a. single component codeine preparations;

b. except oral solid preparations, in combination with one or more therapeutically active substances, [and containing 20 milligrams or less of codeine (calculated as base) per dosage unit]; (S2, S3)

c. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit]. (S2, S3)

Dihydrocodeine,

a. single component dihydrocodeine preparations;

b. except oral solid preparations, in combination with one or more therapeutically active substances, [and containing 20 milligrams or less of codeine (calculated as base) per dosage unit]; (S2, S3)

c. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit]. (S2, S3)