

MEDICINES CONTROL COUNCIL



DEPARTMENT OF HEALTH
Republic of South Africa



SCHEDULING MATTERS

PROPOSAL TO RESCHEDULE ACETYLDIHYDROCODEINE, CODEINE, DIHYDROCODEINE and NORCODEINE

TO ALL APPLICANTS

The Medicines Control Council is considering the rescheduling of acetyldihydrocodeine, codeine, dihydrocodeine and norcodeine. The reasons include the following:

1. the high abuse potential of codeine and codeine derivative products;
2. the limited clinical application of norcodeine and acetyldihydrocodeine containing products;
3. the global regulatory approach to codeine control.

Thus Council is considering implementing the following measures:

1. **Schedule 2 listing**

- Reducing 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;
- Reducing 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.

Council regards this matter as extremely urgent. Interested persons are hereby requested to submit any comments, suggestions or recommendations regarding the above-mentioned proposals to the Registrar not later than 30 September 2014 for further consideration by Council.

Yours faithfully

MS M HELA
REGISTRAR OF MEDICINES

The intention of the Medicines Control Council is to remove the current inscription of *Acetyldihydrocodeine* and *Norcodeine* from Schedule 2 and to amend the Schedule 6 inscription accordingly.

The Medicines Control Council further intends to amend the current inscription of codeine and dihydrocodeine in Schedule 2, include an inscription in Schedule 3 and amend the Schedule 6 inscription accordingly.

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 (methyilmorphine),

- 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, 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 (methyilmorphine)

- 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)

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 (methylnorphine),

- 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)