To:
The Joint Advisory Committee on Medicines and Chemicals Scheduling
Therapeutic Goods Administration

22 May 2020

Dear Joint Advisory Committee members,

Proposed amendments to the Poisons Standard (Medicines) – CBD down-scheduling proposals

Background
Pursuant to Public Notices dated 17 April 2020 and 24 April 2020, the Joint Advisory Committee on Medicines and Chemicals Scheduling requested public submissions in relation to two separate proposals to amend the Poisons Standard scheduling for cannabidiol ("**CBD**") at its June 2020 Joint ACMS/ACSS meeting (ACMS-ACCS #25), copies of which are attached as Schedule 1.

Little Green Pharma Ltd ("**LGP**" or "**the Company**") is pleased to make the following submissions in connection with these rescheduling proposals.

General comments
LGP supports all Poison Standard re-scheduling, clarifications or other TGA initiatives that serve to enhance access to medicinal cannabis products for Australian patients; generate additional patient safety and efficacy data on cannabinoid medicines; and assist practitioners and pharmacists make the appropriate choices in prescribing and dispensing cannabinoid medicines.

To that end, LGP supports a down-scheduling of certain cannabidiol medicines on the basis that:

(a) the global literature and overseas and industry experience with CBD medicines has demonstrated reasonable safety grounds for certain dosing levels of CBD products derived from whole-plant extract sources;

(b) activities from certain down-scheduling proposals would generate additional safety and efficacy data for registered products in connection with certain indications; and

(c) down-scheduling would significantly improve access to categories of CBD products currently demanded by patients.

Public Notice 17 April 2020 – Item 2.2 rescheduling proposal
For the reasons given in LGP's submissions to the Item 2.5 rescheduling proposal below, while LGP broadly supports CBD down-scheduling it believes the proposal in Item 2.5 represents a preferred alternative to Item 2.2 in the current CBD environment. (It is anticipated that the Joint Committee would only recommend one of the two rescheduling pathways.)

In particular, LGP submits that the safety data and efficacy data requirements to reschedule CBD from a Schedule 4 medicinal product to an unscheduled or list good would be significant and likely require in-market use for a substantial period of time, which could in turn result in unnecessary delay for patient access to lower-dose CBD products.

Public Notice 24 April 2020 – Item 2.5 rescheduling proposal
LGP generally endorses the Item 2.5 rescheduling proposal put forward by the TGA on the basis that:

(a) the existing global and industry literature on full-plant extract CBD suggests the existing Schedule 3 dosage levels are within an appropriate safety range;

(b) Schedule 3 status will require sponsors to demonstrate adequate safety and efficacy data for their registered indication, which will benefit pharmacists dispensing these medications, while enhancing industry and practitioner knowledge around the safety and efficacy profiles of CBD more generally; and

(b) the proposed scheduling excludes synthetic (+) enantiomers, for which very limited safety or efficacy data exists.

LGP also proposes that the Schedule 8 Cannabis entry be amended to ensure the requirements of Schedule 8 (a) – (d) expressly apply to Schedule 3 and Schedule 4 medicinal cannabis products. This is to continue to ensure all cannabinoid medicines supplied to Australian patients are cultivated, handled, and manufactured under conditions appropriate to the production of therapeutic goods. LGP would propose amending the existing Schedule 8 definition for Cannabis as follows:

"….
except when:
(i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
(ii) separately specified in the NABIXIMOLS entry in this Schedule; or
(iii) it is a product that meets the conditions in (a), (b), (c) and/or (d) above and is captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3."

We thank the Joint Advisory Committee for the opportunity to comment on the proposed changes.

Kind regards

[redacted]

Schedule 1 – Rescheduling proposals

Public Notice 17 April 2020 – Item 2.2 rescheduling proposal

Schedule 8 - Amend Entry
CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

(a) cultivated or produced, or in products manufactured, in accordance with the Narcotic Drugs Act 1967; and/or

(b) for use in products manufactured in accordance with the Narcotic Drugs Act 1967; and/or

(c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Therapeutic Goods Act 1989; and/or

(d) in therapeutic goods supplied in accordance with the Therapeutic Goods Act 1989,

except when:

i) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
ii) separately specified in the NABIXIMOLS entry in this Schedule; or
iii) captured by the CANNABIDIOL entry in Schedule 4; or
iv) it is a whole plant cannabis product or distillate or isolate which contains at least 98 per cent cannabidiol and less than or equal to 0.2 per cent tetrahydrocannabinol (THC).

Schedule 4 - Amend Entry
CANNABIDIOL in preparations for therapeutic use where:

(a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation and any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; or

(b) ~~any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation.~~ cannabidiol is a synthetic or semi-synthetic copy of the molecule and comprises 98 per cent or more of the total cannabinoid content of the preparation and any other synthetic or semi-synthetic cannabinoids, other than cannabidiol, must comprise 2 per cent or less of the total cannabinoid content of the preparation.

except when cannabidiol comprises 98 per cent or more of the total cannabinoid content and the tetrahydrocannabinol (THC) content is less than or equal to 0.2 per cent of the total cannabinoid content of the preparation.

Public Notice 24 April 2020 – item 2.5 rescheduling proposal

Schedule 4 - Amend Entry
CANNABIDIOL in preparations for therapeutic use where:

(a) cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and

(b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation;

except when included in Schedule 3.

Schedule 3 - New Entry

CANNABIDIOL in preparations for therapeutic use when:

a. the cannabidiol is either plant derived, or when synthetic only contains the (-) CBD enantiomer; and

b. the maximum recommended daily dose is 60 mg or less of cannabidiol; and

c. in packs containing not more than 30 days' supply; and

d. cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and

e. any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; and

f. for adults aged 18 years and over.