

16 DECEMBER 2020

TGA ANNOUNCES FINAL CBD DOWN-SCHEDULING DECISION

MAXIMUM DAILY DOSE INCREASED TO 150MG/DAY

Highlights:

- 🌿 Therapeutic Goods Administration (TGA) final down-scheduling decision for cannabidiol (CBD) increases maximum daily dose up from 60mg/day, to 150mg/day
- 🌿 Increase represents a significant step-change for Australian medicinal cannabis industry
- 🌿 Registered CBD products to be dispensed over-the-counter by pharmacists without the need for a prescription
- 🌿 Implementation brought forward to 1 February 2021
- 🌿 Increased incentive for sponsors, including LGP, to seek Australian Register of Therapeutic Goods (ARTG) CBD medicine registrations

Little Green Pharma Ltd (ASX: LGP, “LGP” or the “Company”) welcomes the TGA’s final decision to both down-schedule certain medicinal cannabidiol (“**CBD**”) products from Schedule 4 to Schedule 3 (Pharmacist Only Medicine) as well as increase the maximum daily dosage to 150mg/day.

The decision will mean registered medicinal CBD products can be dispensed over-the-counter by pharmacists without the need for a prescription. The change in scheduling applies to CBD products with a maximum recommended daily dose of 150mg in packs containing 30 days or less supply, and where CBD comprises at least 98% of the total cannabinoid content in the preparation. Other CBD products will continue to be scheduled as Schedule 4.





Commenting on the TGA's final scheduling decision, LGP Managing Director Fleta Solomon said:

"This final scheduling decision demonstrates both the TGA's commitment to patient safety and product quality as well as its appreciation of prescriber and patient needs. We wish to congratulate the TGA on its decision and look forward to the significant benefits it will bring to both Australian patients and prescribers and the Australian medicinal cannabis industry as a whole."

The final decision change reflected additional safety information, public submissions, and the updated advice of the Joint Committee of the Advisory Committees for Medicine Scheduling and Chemicals Scheduling. In addition to increasing the maximum daily dosage, the TGA also brought forward the implementation date from 1 June 2021, to 1 February 2021.

Critically, the decision to increase the maximum daily dose to 150mg will likely give Australian medicinal cannabis manufacturers the confidence necessary to progress Australian Register of Therapeutic Goods ("ARTG") CBD medicine registrations.

Previously, the interim low-dose scheduling decision had provoked industry concerns over the viability of demonstrating the rigorous efficacy data required for registration. ARTG registration requires sponsors to undertake time-consuming and expensive clinical trials and product registration activities to demonstrate the medicine's safety, quality and efficacy for the relevant registered indication, and with this revised decision it is anticipated sponsors will be far more confident progressing ARTG registrations at this higher dosing level.

LGP commends the final decision as a nuanced and careful scheduling decision by the TGA that has resulted in a very welcome outcome for Australian patients. LGP anticipates the decision will drive registration applications across a range of eligible CBD conditions and will serve to only further increase the accessibility and affordability of medicinal cannabis for Australian prescribers and patients.

In the meantime, the Company will continue to assess its registration options for an eligible CBD product, including a formulation of its current LGP Classic CBD50 or soon-to-be-released LGP Classic 1:100 cannabis oil medicines.





ENDS

BY ORDER OF THE BOARD

A handwritten signature in dark ink, appearing to read "Alistair Warren", is written over a horizontal dashed line.

Alistair Warren
Company Secretary

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About Little Green Pharma

Little Green Pharma is a vertically integrated medicinal cannabis business with operations from cultivation and production through to manufacturing and distribution.

The Company has an indoor cultivation facility and manufacturing facility in Western Australia for the production of its own-branded range of GMP-grade medicinal cannabis products.

Little Green Pharma products comply with all required Therapeutic Goods Administration regulations and testing requirements. With a growing range of products containing differing ratios of active ingredients, Little Green Pharma supplies medical-grade cannabis products to Australian and overseas markets.

The Company has a strong focus on patient access in the emerging global medicinal cannabis market and is actively engaged in promoting education and outreach programs, as well as participating in clinical investigations and research projects to develop innovative new delivery systems.

For more information about Little Green Pharma go to: www.littlegreenpharma.com

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To easily update your communication preferences, visit: www.computershare.com.au/easyupdate/lgp