

14 September 2020

ASX Code: MXC

MGC Pharma well positioned in Australian market to capitalise on TGA move to down-schedule CBD products

Key Highlights:

- Therapeutic Goods Administration (TGA) has recently confirmed its intention to down-schedule certain low-dose medicinal cannabidiol (CBD) products from Schedule 4 to Schedule 3 status
- MGC Pharma is uniquely positioned to benefit from the proposed changes through its existing EU production facilities, increasing market penetration, and clinical programs
- The Company has already launched a clinical program to develop new products that meet the proposed Schedule 3 registration requirements, with the aim of being one of the first companies to see the new products on Australian pharmacy shelves
- Proposed TGA changes allows registered Schedule 3 CBD products to be dispensed over-the-counter by pharmacists without a prescription, significantly reducing the costs and time for patients to access these products
- Proposed TGA changes are aligned with MGC Pharma’s strategy to make medicinal cannabis more accessible and affordable for patients in Australia while maintaining the highest levels of product quality

MGC Pharmaceuticals Ltd (ASX: MXC, ‘MGC Pharma’ or ‘the Company’), a European based biopharma company specialising in the production and development of phytocannabinoid-derived medicines, welcomes the proposed changes by the TGA to down-schedule certain low-dose CBD products in Australia to Schedule 3 status.

The proposed changes would allow specific low-dose medicinal CBD products to be dispensed over-the-counter by pharmacists to patients without a prescription. This move by the TGA significantly improves patient accessibility to medicinal CBD products while at the same time reducing the costs and time involved for patients to acquire them.

MGC Pharma is uniquely positioned to benefit from this as one of the current market leaders of CBD products in Australia, having recently imported the first shipment of the entire EU-GMP certified Mercury Pharma product line, which significantly expands the current range of medicines available in Australia for the Company. This, combined with the upcoming completion of the Medicinal Cannabis Clinics acquisition (refer ASX release 20 July 2020), greatly enhances MXC’s distribution capabilities of its own CBD based products into the Australian market and patients.

The Company’s growing commercial presence in Australia along with its targeted clinical program, places MXC in a unique position to take advantage of the proposed changes announced by the TGA. Eligible CBD products under Schedule 3 are still required to be registered on the Australian Register of Therapeutic Goods (ARTG), which requires companies to comply with strict Good Manufacturing Practices (GMP). The GMP certification and ARTG registration is expected to restrict a number of companies ability to supply Schedule 3 products in Australia.



Figure 1 – MXC’s Mercury Pharma Product: MP100

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MGC Pharma has launched a clinical program to develop new CBD products under its Mercury Pharma line that meet the proposed Schedule 3 requirements, with the aim of being one of the first companies to see Schedule 3 CBD products on pharmacy shelves when the proposed changes come into effect in June 2021.

While meeting the regulatory requirements of Schedule 3 may be difficult for a number of operators, MGC Pharma welcomes the proposed changes from the TGA as they align with the Company's strategy to make medicinal cannabinoid products more accessible and affordable to patients, while at the same time maintaining the highest levels of product quality.

Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented: "We are very pleased to see the proposed down-scheduling changes from the TGA. We are one of the market leaders in Australia for CBD products and these changes provide MGC Pharma with the ability to further increase our product offering and market penetration, while at the same time improving accessibility and affordability of high-quality CBD products for patients."

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About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC) is a European based bio-pharma company developing and supplying affordable standardised phytocannabinoid derived medicines to patients globally. The Company's founders were key figures in the global medical cannabis industry and the core business strategy is to develop and supply high quality phytocannabinoid derived medicines for the growing demand in the medical markets in Europe, North America and Australasia. MGC Pharma has a robust product offering targeting two widespread medical conditions – epilepsy and dementia – and has further products in the development pipeline.

Employing its 'Nature to Medicine' strategy, MGC Pharma has partnered with renowned institutions and academia to optimise cultivation and the development of targeted phytocannabinoid derived medicines products prior to production in the Company's EU-GMP Certified manufacturing facility.

MGC Pharma has a number of research collaborations with world renowned academic institutions, and including recent research highlighting the positive impact of using specific phytocannabinoid formulations developed by MGC Pharma in the treatment of glioblastoma, the most aggressive and so far therapeutically resistant primary brain tumour.

MGC Pharma has a growing patient base in Australia, the UK, Brazil and Ireland and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market.

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