NICM
Health Research Institute

Joint Advisory Committee on Medicines and Chemicals Scheduling
Australian Therapeutic Goods Administration
By email: medicines.scheduling@health.gov.au

Re: Proposed Amendments to the Poisons Standard (Medicines/Chemicals) for Cannabidiol.

The recent Senate Community Affairs Reference Committee inquiry into the current barriers to patient access to medicinal cannabis highlighted various challenges facing legal access in Australia. These included a potential bottleneck to patient access limited by the small number of appropriately trained medical practitioners. In response to this, the delegate-initiated proposal to down schedule Cannabidiol (CBD) from S4 (Prescription only) to S3 (Pharmacist only medicine) goes some way to opening up patient access in a measured approach, by safely reducing the restrictions around CBD and aligning better with similar international jurisdictions, including the United Kingdom and various states in the US.

CBD has a low potential for abuse and has an acceptable tolerability and safety profile. This is consistent with preliminary reports from the World Health Organization's Expert Committee of Drug Dependence (ECDD) and the Therapeutic Goods Administration's own recent internal review on low dose cannabidiol. Allowing CBD to be a pharmacist only medicine appropriately reflects this safety profile. The delegate-initiated proposal also outlines appropriate recommendations specific to packaging, dosage, formulation and labelling of CBD products in accordance with Section 52E of the *Therapeutic Goods Act (*1989). However, we would also recommend appropriate training be provided for prescribing pharmacists. It should be noted however, that with the potential remaining presence of small amounts of tetrahydrocannabinol (THC) in such preparations, under the current Australian drug driving laws, legitimate patients may be at risk of criminal persecution or loss of driving privileges. This issue would need to be addressed.

Once down-scheduled and in time, low dose CBD products may demonstrate a favourable risk profile under various adverse event monitoring programs. Should the safety of low dose CBD products continue to demonstrate a favourable profile over coming years, this may allow for the future consideration of low dose CBD preparations to be further down-scheduled to S2 or made available to other regulated healthcare practitioners with suitable qualifications and specific prescribing training.

Western Sydney University's NICM Health Research Institute (NICM HRI) at Western Sydney University is Australia's leader in integrative and complementary medicine research. NICM HRI is proudly one of the first medical research institutes in Australia to be licensed by the Federal Government's Office of Drug Control to undertake a wide variety of medicinal cannabis research activities. We look forward to assisting in any future testing and research requirements.

With best wishes in fulfilling this proposed regulatory reform.

Yours sincerely,

[redacted]

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