



Non-Pharmaceutical Application guidelines

Despite improved processes at the Ministry of Health, applications to prescribe Non Pharmaceutical Cannabis based products are taking longer than desired to reach a decision. Part of this is due to the form not asking for the correct level of detail that the MOH is looking for when approving a decision, leading to frequent correspondence with the applicant. This guide is intended to help ensure that applications are as complete as possible, expediting the application process for all involved.

Severe or life-threatening condition

Patients don't need to be bedridden or dying to be classified as severe, patients with treatment refractory chronic pain that prevents them working more than part time have been approved under this category before. Explaining the condition, its duration, cause and impact on the patient's quality of life, including socially and economically will satisfy these criteria, the definition *severe* has been demonstrated to be broad by MCANZ assisted approvals to date.

Evidence that reasonably applicable conventional treatments have been trialed and that symptoms are still poorly controlled.

A thorough list of treatments, past and present should be provided, this must include a thorough list of prescriptions. If there is a standard prescription that has been avoided, justification must be made for why this was inappropriate, such as adverse reactions. It should also outline surgical interventions, or alternatively explaining why a surgical intervention may not be appropriate if it typically is for the condition indicated. It should also include other conservative therapies such as psychological treatments, (CBT etc) diets, (Ketogenic etc) and other complimentary treatments, Acupuncture, Physiotherapy etc.

Evidence that the risk/benefit has been adequately considered by qualified clinical specialists.

Outlining the benefits of the product, cost is a benefit that is considered, also alternative ratios of cannabinoids in products could be considered as favorable compared to Sativex, offering improved treatment options when managing benefits versus side effects. Also outline how clinical success is going to be measured, regular follow up with simple Visual analogue scale measurements for pain will suffice, but more comprehensive questionnaires for specific pain conditions as the Oswestry Disability Index or the Fibromyalgia impact questionnaire is preferred for pain, and may have an impact on potential patient funding via insurance schemes.

Applicant or specialist prescriber has sought adequate peer review.

Applications have been approved without peer review, though typically for more straightforward cases such as balanced Cannabis based products for MS as a quasi-generic Sativex replacement. For complex cases, it is preferred to get peer review from a specialist in the relevant field to cosign the form where the DHB Chief Medical Officer would sign, crossing out the title and inserting the peers title and credentials. The DHBs Chief medical officer is rarely the source of peer review. A supporting letter of endorsement from a relevant specialist further afield geographically may also suffice if local peer review is hard to come by. This is particularly pertinent for specialists acting in their secondary fields of scope, as the MOH would prefer applications from pain specialists for chronic pain (the leading adult use case), however due to the Faculty of pain medicine's stance, and that of the NZ Pain Society on Medical Cannabis, such applications for patients are typically from specialties where chronic pain is a secondary factor, such as Rheumatology, Oncology, Neurology and Muscular Skeletal medicine. MCANZ through its network of known prescribers may be able to help a prescriber seek adequate peer review.