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To: Victorian Law reform Commission

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RE: Public Submission in response to the Victorian Law Reform Commission

Medicinal Cannabis: Issues Paper

In response to the questions posted in the “Victorian Law Reform Commission Medicinal Cannabis: Issues Paper”. Our group welcomes the opportunity given to help the commission in the assessment of a Law Proposal on Medicinal Cannabis by answering the questions presented at the end of the issue paper with the aim of contributing to give helpful advices thanks to our expertise and knowledge within the queries raised. We are working in collaboration with Sergio Pagliuzzi, Chief Executive Officer of Under The Tree Biopharmaceuticals Pty Ltd whom will give their view in a separate statement.

These are our viewpoint concerning the questions raised in the request:

1. Which of the following considerations should determine whether there are exceptional circumstances for medicinal cannabis to be made available to a patient:
 - (a) the circumstances of the patient
 - (b) the state of clinical knowledge about the efficacy or potential efficacy of using Cannabis in treating the patient's condition
 - c) both of the above?

OWC ANSWER: those are not separated cases. Both things should be taken into consideration when discussing a unique patient case. We suggest to form an

indication committee for establishing the general clinical under which CTP can be made available to a patient and an exemption committee for special cases, which do not fall under the previous guidelines.

2. For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of cannabis to justify allowing sufferers to use it lawfully in Victoria?

OWC ANSWER: The main indication for CTP (Cannabis for Therapeutic Purposes) is pain syndromes and there are many published papers in the medical literature on the subject. All countries that have a CTP project allow treatment for this symptom among others. All the other medical conditions treated by CTP have, at least for the moment, much less proven evidence. When prescribing CTP, apart from the appropriate indication, the physician should also consider the patient's medical past (especially psychosis) in order to avoid serious side effects.

3. What special considerations, if any, justify access to medicinal cannabis for:
 - (a) patients who are under 18 years of age
 - b) patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal cannabis?

OWC ANSWER: through CTP we consider the severity of the illness or symptoms and their impact on the quality of life with the relief that the patient will probably receive with the treatment of cannabis. CTP should also consider not only initiation of treatment but also continuation according to results and success of treatment and if they are not satisfactory the cannabis treatment should be stopped.

4. On which of the following should the law creating a medicinal cannabis scheme base a person's eligibility to use medicinal cannabis:
- (a) a list of medical conditions
 - b) a list of symptoms
 - c) a list of symptoms arising from certain medical conditions
 - d) evidence that all reasonable conventional treatments have been tried and failed?

OWC ANSWER: Items C + D should be on the law parameter; symptoms or conditions by themselves are not sufficient but we recommend the need of both in order to foresee a plausible cause for cannabis treatment success.

5. Should there be a way to allow for special cases where a person who is otherwise Ineligible may use medicinal cannabis? If so, what should that be?

OWC ANSWER: we believe that there should be an option by a way of an appeal to an exemption committee (see answer 1). Otherwise there will be an opening for a lot of futile litigation.

6. If Victoria acted through a state agency, in what circumstances would it be legally entitled to establish a medicinal cannabis scheme which manufactured cannabis products without breaching the terms of the Therapeutic Drugs Act 1989 (Cth) or the Narcotic Drugs Act 1967 (Cth)?

OWC ANSWER: NA. It's a legal and political decision

7. Are the regulatory objectives identified by the Commission appropriate? What changes, if any, would you make to them?

OWC ANSWER: You should consider that there is not enough validated information through clinical trials on the long-term side effects as of the continuous CTP use and the patient should be aware of this - as part his informed consent.

8. Would the creation of a defense to prosecution for authorized patients and carers in possession of small amounts of dried cannabis or cannabis products be an adequate way of providing for people to be treated with medicinal cannabis in exceptional circumstances?

OWC ANSWER: First, we recommend to define what is considered a "small amount" because the permit has to be at least a dosage for a monthly use of CTP.

9. What mechanism should Victoria use to regulate the cultivation of medicinal Cannabis (CTP)?

OWC ANSWER: When we designed and implemented the Israeli CTP project, we started with a "grow your own" methodology. It has proved to be unworthy due to the following three main reasons:

- A. There was no quality control on breeds, yield quantity and cannabis quality.
- B. Cancer patient who used cannabis to cope with their chemotherapy treatment, needed to use medical cannabis immediately and could not wait three to four months for first self-harvest.
- C. The police should enforce an effective control legislation on diversion.

For those reasons, Israel decided on a state control cultivation where there are selected licensed growers with a control limitation permit for the quantity they are allowed to grow for 6 – 12 months. Israel also decided for a division between growers and supply to patients for the same reasons Israel does not allow any pharma companies straight access to patients.

10. What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?

OWC ANSWER: please review answer 9 where we are explaining why we believe that there should be a division between cultivators and patients. It is the reason why we advocate a separate distributors' approach. This distributor will also be the long arm of the national cannabis agency to purchase and hold all the cannabis products that has been harvested. The distributor will also perform quality assurance on the cannabis it buys from the cultivators or refuses to buy due to lack of quality. The distribution itself can be done through dispensaries, distribution centers, hospitals or secured delivery "door to door".

11. How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?

OWC ANSWER: this requires more study on our side with the Victorian administration to provide our recommendation.

12. What responsibilities should be given to health practitioners in authorizing a patient's Use of medicinal cannabis?

OWC ANSWER: We propose a system derived from the Israeli and Czech experience where Dr. Yehuda Baruch, OWC's Director of Medical Cannabis Regulations, was managing and advising respectively: Physicians will be allowed to prescribe cannabis for certain approved indications. Indications by themselves are not sufficient enough and severity of disease and specific symptoms should also be taken into account. Furthermore we recommend that all cannabis prescriptions will be computerized through a national secured network. This is an essential tool for the agency to know how much cannabis has been prescribed and purchased and thus be able to foresee

usage growth pattern for CTP for the next upcoming months and issue permits, accordingly, to the cultivators. All Physicians who wish to be eligible to prescribe cannabis should enlist with the national system and be authorized by the national cannabis agency. The agency will be able to monitor 24/7 the prescriptions and their dosage. The most severe action that can be taken against a physician who does not comply with the regulation (apart from criminal litigation) is to be removed from the national system and thus lose the ability to prescribe cannabis. All this does not decrease anything from the usual responsibilities that a physician has when prescribing any other drug or therapy.

13. Who should have the authority to assess whether a patient is an appropriate

candidate to be treated with medicinal cannabis:

- (a) all registered medical practitioners
- (b) certain designated specialist medical practitioners
- (c) registered health practitioners who have prescribing entitlements
- (d) a subset of these?

OWC ANSWER: as stated in answer 12, we believe that all physicians will be able to prescribe cannabis under specific clinical guidelines that will be issued by the national cannabis agency and to enlist in the computerized system.

OWC is offering training services to physicians and other medical staff to target that specific question.

14. What requirements, restrictions, guidance or other assistance should health

Practitioners be given in monitoring a patient's use of medicinal cannabis?

OWC ANSWER: The first requirement we recommend is to conduct a training session on when and how to start treatment by cannabis; How to monitor success of

treatment and when and how should cannabis treatment be stopped. Cannabis treatment should be viewed like any other treatment with an abuse and dependence potential mainly with the demand for at least 2 -4 follow up visits a year. It also will prevent patients' abuse of prescription administrated by more than one physician, (preventing physician shopping and multiple prescription).

15. What additional restrictions or requirements, if any, should apply to patients who are vulnerable by reason of age or lack of capacity, so as to provide adequate protection for their welfare?

OWC ANSWER: Cannabis prescription for juvenile patients should be restricted to severe diseases and symptoms, which do not respond positively to other treatments and the consent needed by law of a caregiver. Please bear in mind that up to now the evidence links early (juvenile) use of cannabis with higher rates of schizophrenia and lower I.Q. Lack of capacity poses even a bigger problem since there will be an obstacle in assessing the success of treatment. We propose that such request will be passed to the exemption committee for approval.

16. In what form(s) should medicinal cannabis be permitted to be supplied and used?

OWC ANSWER: In Israel we allow for dried flowers to be smoked or preferably vaporized which we hope the physician states as a better way of consumption due that it is less associated with the harm caused by smoking, and oil extract (which can be with a better quality controlled concerning stability and content). We allow eatables such as cookies only for children consumption. We are also looking into the option of skin patches and suppositories.

17. In what ways could Victoria's medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?

OWC ANSWER:

1. We recommend that the medical cannabis regulations should hold an option for R&D that will be authorized by a national ethics committee that will also serve as an IRB (the committee should have the capacity to discuss all kind of research i.e. medical, agriculture and others).
2. The use of the national system (described above) is essential to allow future data mining concerning and monitoring the correct use of CTP.

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