



2nd January 2019

QUEENSLAND PARLIAMENT

The Health, Communities,
Disability Services and Domestic
and Family Violence Prevention Committee

To The Queensland Parliament,

This is a submission on the Public Health (Medicinal Cannabis) Act 2016 and Health Act 1937. The following points are our recommendations:

1. While THC and CBD are the focus of this legislation, there are many other cannabinoids and terpenes found in other plants and organisms used in medicine, health products and foods. We believe a consistent framework and a consistent categorisation of cannabinoid medicine will better assist patient access, better assist doctors in learning how to practically apply to prescribe medical cannabis and better assist the State Government in aligning to the TGA federal approach to medical cannabis production and prescription.
2. We believe a **SCHEDULE 4** status should be applied to all medical cannabis whole plant extract prescriptions. The benefit to this approach would be:-
 - A. It would give the current 300,000 estimated Australian patients (Australian Federal Dept Health estimates) who are still seeking black market products a legal and regulated way to more easily access medical cannabis.
 - B. It would limit the current (and ongoing) recreational cannabis debate to ensure that the medical system, for which the regulation and pathways are well proven, is the single framework of coordination under which this operates in Australia.
 - C. It would further enhance Australia's leading medical cannabis export laws whereby some other European and Asian countries consider CBD to be an over the counter medication. The obvious financial benefits and significant employment opportunities to the local Australian economy are great.



BACKGROUND

Hundreds of thousands of Australians suffer from debilitating conditions that clinically proven cannabis products can assist with and yet the product access to date has not met the patient demand, nor the patient expectations. Australia has the best legislative framework and one of the world's best reputations for agriculture and healthcare, two industries that allow us to emerge as a leading, quality assured medical cannabis country. As a proud Queensland company, MEDIFARM believes that our State should lead the way in providing affordable and accessible medical cannabis to Australian patients in first position. The above mentioned recommendations have been formulated on this foundation.

We would like the opportunity to make a supplementary submission once the draft regulations are made public.

We would like to speak to this submission.





MEDIFARM has formed an exclusive partnership with TIKUN OLAM, the first and foremost supplier of medical cannabis in Israel, and the world's leading cannabis brand globally recognised as the pioneer of modern medical cannabis.

VISION

Bringing Cure and Alleviation, Using Research Based and Clinically Proven Medical Cannabis Products to Patients Worldwide.

Since its establishment in 2015, **MEDIFARM** is a vertically integrated company from plant cultivation to patient care.

MEDIFARM grows medical cannabis cultivated in state-of-the-art standards. Through its exclusive partnership with Tikun Olam it has access to multiple proprietary award winning strains, including the first-ever, high-CBD, "high-less" strain Avidekel™, its popular high-THC strains Alaska™ and Erez™, and "one-to-one" CBD/THC strain Midnight™.

MEDIFARM prides itself on the world leading research of Tikun Olam who holds unprecedented patient clinical data collection. The company products are used in ongoing clinical trials in regulated medical cannabis markets around the world.



2016-Tikun Olam USA

Established 'Tikun Olam USA' operating in Delaware, Nevada, Washington, Rhode Island, Maryland, Massachusetts and Illinois.



2017-MEDIFARM

Co-founded '**MEDIFARM**' Australia; Queensland's first licensed medicinal cannabis developer.



2018-

Entering European market.

CANNABIS PLANT AND HUMAN BODY

There is considerable evidence of medicinal uses of the cannabis plant throughout history, from ancient Egypt and Victorian England. Furthermore, until the 1930s medicine that contained extracts of the cannabis plant were part of the known Pharmacopoeia and sold in pharmacies with no special authorization.

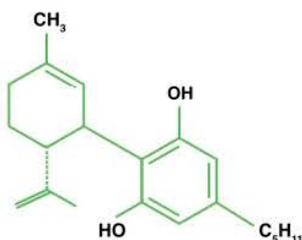
Laboratory studies and clinical research carried out in the last 50 years, mostly in Israel, have greatly promoted the global knowledge and therapeutic ability of the cannabis plant.

The Cannabis plant belongs to a family called Cannabaceae and has three forms: Sativa, Indica and Hybrid.

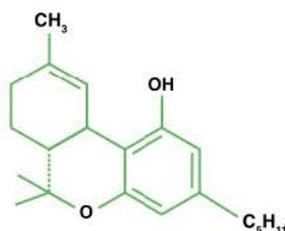
Mammals' bodies have an Endocannabinoid System consisting of receptors that absorb the compounds produced by the plant, called Cannabinoids, and respond to them.

The Cannabis plant contains over 113 Cannabinoids. Science has not yet shown the exact role or mechanism for all compounds. Evidence is mounting that these compounds work better together than in isolation, and it is called the "Entourage Effect".

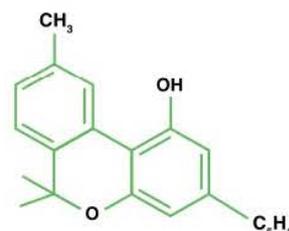
These are the main Cannabinoids:



A major non-psychoactive compound, works mainly by anti-inflammatory and antioxidant mechanisms.



Responsible for the psychoactive element, in addition to pain relief, stimulation of appetite and alleviation of sleep disorders.



A metabolite of THC, its levels rise when THC levels start to decrease. Effects of relaxation, bone healing and alleviation of sleep disorders.

CLINICAL ASPECTS OF CANNABIS TREATMENT

Clinical data supports the efficiency of medical cannabis treatment in many diseases and symptoms such as:

- Spastic diseases accompanied by pain* (such as Multiple Sclerosis*, CP, spinal cord injuries)
- Chronic pain* (particularly neuropathic pain)
- PTSD* Post Traumatic Stress Disorder
- Epilepsy*
- Tourette Syndrome*
- Inflammatory Bowel Disease (Colitis and Crohn's disease)*
- Glaucoma
- Rheumatic and inflammatory diseases
- Cancer* and AIDS* supportive care - prevents nausea and vomiting, relieves pain, encouragement of appetite, prevents weight loss.
- Palliative care*

*Indicated for Medical Cannabis treatment by Israel's Ministry of Health



MEDIFARM is privileged to cultivate and manufacture Tikun Olam's products that have been used in ongoing clinical trials in Israel's regulated medical cannabis market, treating over 20,000 patients for a variety of medical conditions. Tikun Olam's peer-reviewed scientific research and unprecedented accumulated clinical data, achieved exceptional results and unparalleled success.

MEDIFARM draws great resource from Professor Zvi Bentwich, Tikun Olam Chief Scientist, who is a leading AIDS researcher, board member of Physicians for Human Rights, and the first doctor in Israel to treat patients with medical cannabis. **MEDIFARM** works closely with Tikun Olam's research team who led by Lihi Bar-Lev Schleider, a PhD student at the Ben-Gurion University of the Negev, conducting strong partnerships with leading institutions:

- Hebrew University
- Tel Aviv Sourasky (Ichilov) Medical Center
- Sheba Medical Center
- Laniado Hospital
- Edith Wolfson Medical Center
- Soroka University Medical Center • Meir Medical Center
- Assaf Harofeh Medical Center

Name of the study	Type of the study	Number of participants	Study objective	Study results	Principal investigator	Medical institution	Study product	Phase
Crohn's disease	Retrospective cohort study	30	30 Crohn's disease patients with cannabis license were interviewed	A highly positive effect of medical cannabis on the symptoms of inflammatory bowel diseases was demonstrated	Dr. Timna Naftali	Meir Hospital	None	IMAJ - The Israel Medical Association Journal, 2011
Crohn's disease	Clinical random trial	20	To test in a controlled manner the effect of cannabis in Crohn's disease	Verification of significant reduction of symptoms in 90% of participants with no side effects; verification of full remission in 50% of participants	Dr. Timna Naftali	Meir Hospital	Erez rolls vs. placebo	Clinical Gastroenterology & Hepatology 2013
Inflammation	In-vivo laboratory experiment	None	To examine the effect of Avidekel vs. CBD on inflammatory symptoms in mice	Verification of strong effectiveness of "Avidekel" in comparison to infection counteracting medicines Tramadol and Aspirin, as well as a strong reactive strength in comparison to the administration of pure CBD.	Prof. Ruth Gallily	Hadassah Ein Kerem	Extracts of company strains, using Avidekel in particular	Pharmacology & Pharmacy, 2015
Parkinson's disease	Retrospective cohort study	47	To test the effect of cannabis in Parkinson's disease and Tourette syndrome	76.9% reported positive effect on their general condition and mood, 64% reported improvement in pain and spasticity, 59% reported decreased tremors and improved quality of sleep	Tanya Gurevich	Tel Aviv Sourasky	Without investigational product	Clinical Neuropharmacology: November/December 2017
Immune system	In vitro laboratory study	None	The effect of cannabis on immune response in blood samples in which infection was induced	Verification of a suppressing effect of natural cannabisoids on the release of inflammation triggering cytokines; indication of a possible inflammation preventing effect of CBD on the immune system	Dr. Yishay Sekely	Tel Aviv Sourasky	Extracts of Avidekel, Erez and Midnight	Completed Publication forthcoming
patients population	Prospective cohort study	2,191	To examine the beneficial effects and side effects of products and strains of Tikun Olam	97.3% of the active patients reported significant improvement of their symptoms at six months with only minor side-effects.	Lihi Bar-Lev Schleider	Soroka	All cannabis strains offered by Tikun Olam in different dosage and consumption forms	Completed Publication forthcoming
IBD community	Retrospective cohort study	127	To examine the long-term effects of cannabis on a large number of IBD patients	The patients showed a 50% reduction in the HBI index, positive gain of 2 kg of weight in average, consumption of all medications significantly decreased and the quality of life improved with 92.5% satisfaction rate and mild side effects	Dr. Timna Naftali	Meir Hospital	Without investigational product	Completed

Name of the study	Type of the study	Number of participants	Study objective	Study results	Principal investigator	Medical institution	Study product	Phase
Crohn's disease	Clinical double blind study	50	To test the effect of Avidekel cannabis oil vs. placebo on Crohn's disease patients	The interim results showed a decrease in DAI index and reduced drug consumption	Dr. Timna Naftali	Meir Hospital	Avidekel oil vs. placebo	Recruiting
Colitis	Clinical double blind study	30	To test the effect of Erez rolls vs. placebo in patients with colitis	The interim results showed a decrease in DAI index, improvement of colitis in endoscopy and reduced drug consumption	Dr. Timna Naftali	Meir Hospital	Erez rolls vs. placebo	Recruiting
Paediatric Patients	Clinical random trial	40	To examine the effects of Avidekel oil on dystonia and spasticity in children who suffer from CP or genetic impairment	Significant improvement in spasticity and dystonia, sleep difficulties, pain severity, and quality of life was observed. Adverse effect included worsening of seizures in two patients; behavioral changes in two patients; somnolence in one patient.	Dr. Luba Blumkin	Wolfson Hospital	Avidekel	Recruiting. Midterm analysis publication forthcoming
Cancer	Prospective cohort study	2,970	To examine the beneficial effects and side effects of products and strains of Tikun Olam	95.3% of the active patients reported significant improvement of their symptoms at six months with only minor side-effects.	Lili Bar -Lev Schleider	Soroka	All cannabis strains offered by Tikun Olam in different dosage and consumption forms	Completed Publication forthcoming
Autism	Retrospective cohort study	53	To examine the effects of cannabis in children diagnosed with ASD (Autistic spectrum disorder)	75% of patients shown improvement in ASD comorbidities symptoms, 43.1% Stated a Significant Improvement	Dr. Orit Stoler	Assaf Harofeh Medical Center	Avidekel oil 1:20 and Erez oil 3%	Publication forthcoming
Epilepsy	Retrospective cohort study	74	examined the experience of the 5 epilepsy treatment leading centers of pediatric and teenagers that are resistant to drugs	89% Decreasing Epilepsy seizure frequency, 18% Showed 75-100% seizure decrease	Dr. Michal Tzadok	Sheba Medical Center, Sourasky, Wolfson Medical Center, Assaf Harofeh Medical Center, Medical Cannabis Unit M OH, Israel	Extracts of CBD strains mainly Avidekel	Seizure, 2016
Dementia	Randomized double blind placebo controlled	40	To examine the effects of cannabis on agitation and aggression related to dementia	Recruiting	Dr. Vered Hermush	Laniado medical center	Avidekel oil	Recruiting
Geriatric	Prospective	2755	To examine the safety and efficacy of medical cannabis use in patients over the age of 65	Cannabis is safe and efficacious in elderly, decrease use of prescription medicines, including opioids	Lili Bar -Lev Schleider		All cannabis strains offered by Tikun Olam in different dosage and consumption forms	The article is being written
Fibromyalgia	Prospective	467		Positive effect on Fibromyalgia patients with minor side-effects	Lili Bar -Lev Schleider		All cannabis strains offered by Tikun Olam in different dosage and consumption forms	The article is being written

ANALYTICAL LABORATORY

MEDIFARM conducts in house extraction and isolation of active compounds, terpenes and solvent residues, allowing a complete control of the concentrations of compounds in the company's products and the development of new strains and product, treating specific clinical conditions.

Using high-end technologies with state of the art equipment including the HPLC cannabinoid separation device and GC gas chromatograph.

In addition, validation is gained from regular laboratory tests that are conducted at other accredited and advanced external laboratories.



ABSORPTION OF CANNABINOIDS IN THE HUMAN BODY

There are several forms of cannabis consumption, and we highly recommend following the instructions of a doctor or nurse. The absorption depends on the physiological differences between the patients.

ORALLY

In the digestive tract (Oil or Capsules) the cannabis is absorbed more slowly compared to inhalation and with great variance between different patients. Absorption* speed depends on the patient and whether the product is consumed with food or not. Consumption together with fatty and/or sweet foods accelerates and improves absorption. The effect last from 6 to 8 hours. Cannabis oils contain the plant extract combined with olive oil. Cannabis capsules are filled with ground cannabis blossom, heated until decarboxylation.

INHALATION

Cannabinoids are absorbed through the lungs into the blood within minutes, resulting in maximum blood concentration within 10-15 minutes. Absorption within this method of administration depends very much on the differences in the time periods between the aspirations, the number of aspirations, the length of each aspiration and lung endurance.

The effect of administration through aspiration lasts up to 4 hours. Inhalation may be through vaporization. Vaporization has advantage in terms of health since it does not involve a burning process. The evaporation machine produces high temperature steam, allowing the dissolution of the active ingredients without burning, so that the patient inhales fumes containing only the active ingredients without a fire or smoke.

VERTICALLY INTEGRATED COMPANY – FROM PLANT TO PATIENT

- Breeding
- Developing
- Analysing
- Producing
- Supplying
- Training
- Counselling
- Researching





TIKUN OLAM STRAINS

BREED NAME	CANNABINOID PROFILE			MAYBE SUITABLE FOR TREATING SYMPTOMS OF:	EFFECT RATIO
	THC	CBD	CBN		
ALASKA Dominant Sativa	18%	1%	<1%	Severe Chronic pain, Migraines, Sleep Disorders, Loss of Appetite, Fatigue, palliative care	Strong
SHIRA Dominant Sativa	16%	1%	<1%	Moderate to Severe Pain, Mood enhancer	
OZ Dominant Sativa	16%	1%	<1%	Moderate to Severe Pain, Mood enhancer, Spasm, daily use	
SIBIRIA Dominant Sativa	15%	1%	<1%	Moderate to Severe Pain, Sleep Disorders	
GREENLAND Dominant Sativa	22%	1%	<1%	Treatment for very severe pain, fatigue, depression, and loss of appetite	
ANTARCTICA Dominant Sativa	18%	1%	<1%	Moderate Pain, Sleep Disorders, Loss of Appetite	Day Care
DAVID Dominant Sativa	12%	1%	<1%	Moderate Pain, Sleep Disorders, Loss of Appetite	
MANGO Dominant Sativa	7%	7%	<1%	Mild Pain, Fatigue	
REFAEL * Dominant Sativa	1%	18%	<1%	Inflammatory diseases (arthritis and gastrointestinal), Fatigue, Convulsions, Inflammatory origin pain, Increases concentration	
MICHAEL* Dominant Sativa	1%	16%	<1%	Inflammatory diseases (arthritis and gastrointestinal), Migraines, Inflammatory origin pain, Fibromyalgia pain, Convulsions	
MIDNIGHT Dominant Sativa	8%	11%	<1%	Inflammatory diseases (arthritis and gastrointestinal), Nausea and vomiting, fatigue, sleep disorders, loss of appetite	Moderate
METATRON* Hybrid	1%	16%	<1%	Inflammatory diseases (arthritis and gastrointestinal), Migraines, Inflammatory origin pain, Fibromyalgia pain, Convulsions	

BREED NAME	CANNABINOID PROFILE			MAYBE SUITABLE FOR TREATING SYMPTOMS OF:	EFFECT RATIO	
	THC	CBD	CBN			
EREZ Dominant Indica	18%	1%	<1%	Severe Chronic pain, neuropathic pain, Sleep disorders, Spasm movement disorders, Nausea and vomiting, PTSD symptoms	strong	Night Care
OR Dominant Indica	16%	1%	<1%	Severe pain, May support respiratory disorders, Sleep disorders, movement disorders Nausea and vomiting		
ERAN ALMOG Dominant Indica	20%	1%	<1%	Severe Sleep disorders, Loss of Appetite, Severe pain, PTSD symptoms		
OMER Dominant Indica	16%	1%	<1%	Moderate to Severe Pain, Sleep Disorders, Loss of Appetite		
DORIT Dominant Indica	16%	1%	<1%	Moderate Pain, mild sleep disorders, Loss of Appetite, Nausea and vomiting	Moderate	Night Care
EDEN Dominant Indica	12%	1%	<1%	Mild to Moderate Pain, Sleep Disorders, Loss of Appetite		
NOGA Dominant Indica	18%	1%	<1%	Moderate Pain, Sleep Disorders, Loss of Appetite		
EL-NA Dominant Indica	5%	7%	<1%	Mild to Moderate Pain, night and daily use for Chronic pain		
AVIDEKEL* Dominant Indica	1%	16%	<1%	Inflammatory diseases (arthritis and gastrointestinal), Migraines, Inflammatory origin pain, Fibrmyalgia pain, convulsions	Moderate	Day Care

*Strains without psychotropic effect. Day care and evening care characteristics – according to patient’s preferences in Each product is labeled with the percentage of active ingredients. The composition of the active ingredients varies slightly according to the seasons and are updated and published accordingly. The products contain additional cannabinoids, such as: Cannabigerol (CBG), Cannabichromene (CBC), Cannabidiol (CBD), Tetrahydrocannabivarin (THCV) and others.



NAME OF PRODUCT	SYMPTOMS SUPPORTED	PERCENTAGE OF ACTIVE INGREDIENTS	
		CBD	Δ ⁹ -THC
EREZ OIL 3%	Treatment for severe pain, tremors, sleep disorders, nausea, spasms, tics and to encourage appetite	0.25 mg/drop	1.5 mg/drop
EREZ OIL 15%	Treatment for severe pain, tremors, sleep disorders, nausea, spasms, tics, and to encourage appetite	0.5 mg/drop	7.5 mg/drop
AVIDEKEL OIL 3%	Treatment for convulsions, pain and inflammatory diseases (joints and digestive system) in conjunction with Δ9-THC products to reduce side effect of Δ9-THC	1.5 mg/drop	0.25 mg/drop
AVIDEKEL OIL 1:6 5%	Treatment for convulsions, pain and sleeping disorders	2.5 mg/drop	0.4 mg/drop
AVIDEKEL OIL 1:6 15%	Treatment for convulsions, pain and inflammatory diseases (joints and digestive system)	7.5 mg/drop	1.25 mg/drop
AVIDEKEL OIL 1:20 15%	Treatment for convulsions and inflammatory diseases (joints and digestive system)	7.5 mg/drop	0.35 mg/drop

Oil



GROW.
IMPROVE.
DISCOVER.



SPECIALIST AND GP APPROVAL PROCESS

Medical Specialists or General Practitioners may apply to the Therapeutic Goods Administration for approval to prescribe medical cannabis to their patients. There may also be a State Health Department approval. However this differs between states.

Secure online applications can be made at:

TGA - <https://sas.tga.gov.au>

MEDIFARM PRODUCTS - ACCESS

MEDIFARM cultivates and manufactures its medical cannabis oils in Australia in accordance with TGA Order No. 93 for pharmacovigilance. Our products must be prescribed by an authorised medical specialist or general practitioner and are dispensed through pharmacies.

MEDIFARM PRODUCTS - AVAILABILITY

MEDIFARM has established its Cultivation and Manufacturing Facility for the Australian production of Medical Cannabis Oil. Locally produced medical cannabis oil will be available by Q1 2019. In the interim, **MEDIFARM** can assist medical practitioners with free clinical support and guidance on the application process to prescribe medical cannabis. Please call our Client Services Team to arrange a complimentary phone consultation.

CARE. BELIEVE. PROGRESS.





CLIENT SERVICES TEAM

MON - FRI 8:30 - 4:30

TEL. +61 7 5430 2244

FAX. +61 7 5430 2246

EMAIL ENQUIRIES@MEDIFARM.COM.AU



MEDIFARM



@MEDIFARM_AUSTRALIA



@MEDIFARM_AU



WWW.MEDIFARM.COM.AU

IN PROUD AND EXCLUSIVE PARTNERSHIP
WITH TIKUN OLAM



The New York Times

BusinessWeek

The Washington Post