

National Medical Cannabis Programs (NMCP) Netherlands, Canada, Israel

**Comparative analysis, lessons and implications to
governments, patients and the public**

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Overview

- Netherlands, Canada and Israel are the only three countries in the world that launched a “National Medical Cannabis Program” (NMCP) in adherence (with modifications) to UN drug conventions.
- 23 states in the USA passed MC laws (2 states legalized cannabis) but the US Federal Government still does not recognize the medical value of cannabis.
- The Czech republic is in the process of launching a NMCP for a while now.

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

Final Act of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs

Article 23

NATIONAL OPIUM AGENCIES

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
 - a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
 - b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
 - c) Each licence shall specify the extent of the land on which the cultivation is permitted.
 - d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
 - e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

Article 28

CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.
2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

UN DRUG CONVENTION MEDICAL CANNABIS PROGRAM MODEL

1. Need (political) will to launch
2. Medical use of prohibited drugs is possible
3. Need to set up a designated “Agency” to manage the NMCP (similar to Opium Agency)
4. Same rules that apply to Opium for medical use (cultivation, use, safe guards etc) applies to Medical cannabis.
5. Issue tender to choose growers
6. Agency takes possession within 4 months after harvest
7. Distribution through Pharmacies
8. By prescription only by physician

Indications for use (Official guidelines for Doctors)

Grounds for use (Holland)

Data currently available shows that medicinal cannabis can help relieve:

- Pain and muscle spasms/cramps associated with (MS) or spinal cord damage
- Nausea, reduced appetite, weight loss and debilitation associated with cancer and AIDS
- Nausea and vomiting caused by medication or radiotherapy for cancer and HIV/AIDS
- Long-term neurogenic pain (i.e. originating in the nervous system) caused by, for example, nerve damage, phantom limb pain, facial neuralgia or chronic pain following an attack of shingles
- Tics associated with Tourette Syndrome

Grounds for use (Israel)

- Chronic Pain Due to a Proven Organic Etiology
- Orphan Diseases
- HIV patients with loss of body weight >10% or CD4 < 400
- Inflammatory Bowel Disease (as opposed to Irritable Bowel Syndrome)
- Multiple Sclerosis
- Parkinson's Disease
- Malignant Tumor in Various Stages of the Disease
- PTSD (mostly war related)

"Information for Health Care Professionals"

by 'Health Canada', the Canadian Health regulatory authority over seeing the medical cannabis program published a list of potential Therapeutic Uses of cannabis:

- [4.1 Palliative Care](#)
- [4.2 Nausea and vomiting](#)
- [4.3 Wasting syndrome and loss of appetite in AIDS and cancer patients](#)
 - [4.3.1 To stimulate appetite and produce weight gain in AIDS patients](#)
 - [4.3.2 To stimulate appetite and produce weight gain in cancer patients](#)
 - [4.3.3 Anorexia nervosa](#)
- [4.4 Multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury](#)
 - [4.4.1 Multiple sclerosis](#)
 - [4.4.2 Amyotrophic lateral sclerosis](#)
 - [4.4.3 Spinal cord injury \(or spinal cord disease\)](#)
- [4.5 Epilepsy](#)
- [4.6 Pain](#)
 - [4.6.1 Acute Pain](#)
 - [4.6.1.1 Experimentally-induced acute pain](#)
 - [4.6.1.2 Post-operative pain](#)
 - [4.6.2 Chronic pain](#)
 - [4.6.2.1 Experimentally-induced pain](#)
 - [4.6.2.2 Neuropathic pain or chronic non-cancer pain](#)
 - [4.6.2.3 Cancer pain](#)
 - [4.6.2.4 Headache and migraine](#)
- [4.7 Arthritides and musculoskeletal disorders](#)
 - [4.7.1 Osteoarthritis](#)
 - [4.7.2 Rheumatoid arthritis](#)
 - [4.7.3 Fibromyalgia](#)
 - [4.7.4 Osteoporosis](#)
- [4.8 Other diseases and symptoms](#)
 - [4.8.1 Movement disorders](#)
 - [4.8.1.1 Dystonia](#)
 - [4.8.1.2 Huntington's disease](#)
 - [4.8.1.3 Parkinson's disease](#)
 - [4.8.1.4 Tourette's syndrome](#)
 - [4.8.2 Glaucoma](#)
 - [4.8.3 Asthma](#)
 - [4.8.4 Hypertension](#)
 - [4.8.5 Psychiatric disorders](#)
 - [4.8.5.1 Anxiety and depression](#)
 - [4.8.5.2 Sleep disorders](#)
 - [4.8.5.3 Post-traumatic stress disorder](#)
 - [4.8.5.4 Alcohol and opioid withdrawal symptoms](#)
 - [4.8.5.5 Schizophrenia and psychosis](#)
 - [4.8.6 Alzheimer's disease and dementia](#)
 - [4.8.7 Inflammation](#)
 - [4.8.7.1 Inflammatory skin diseases](#)

Holland

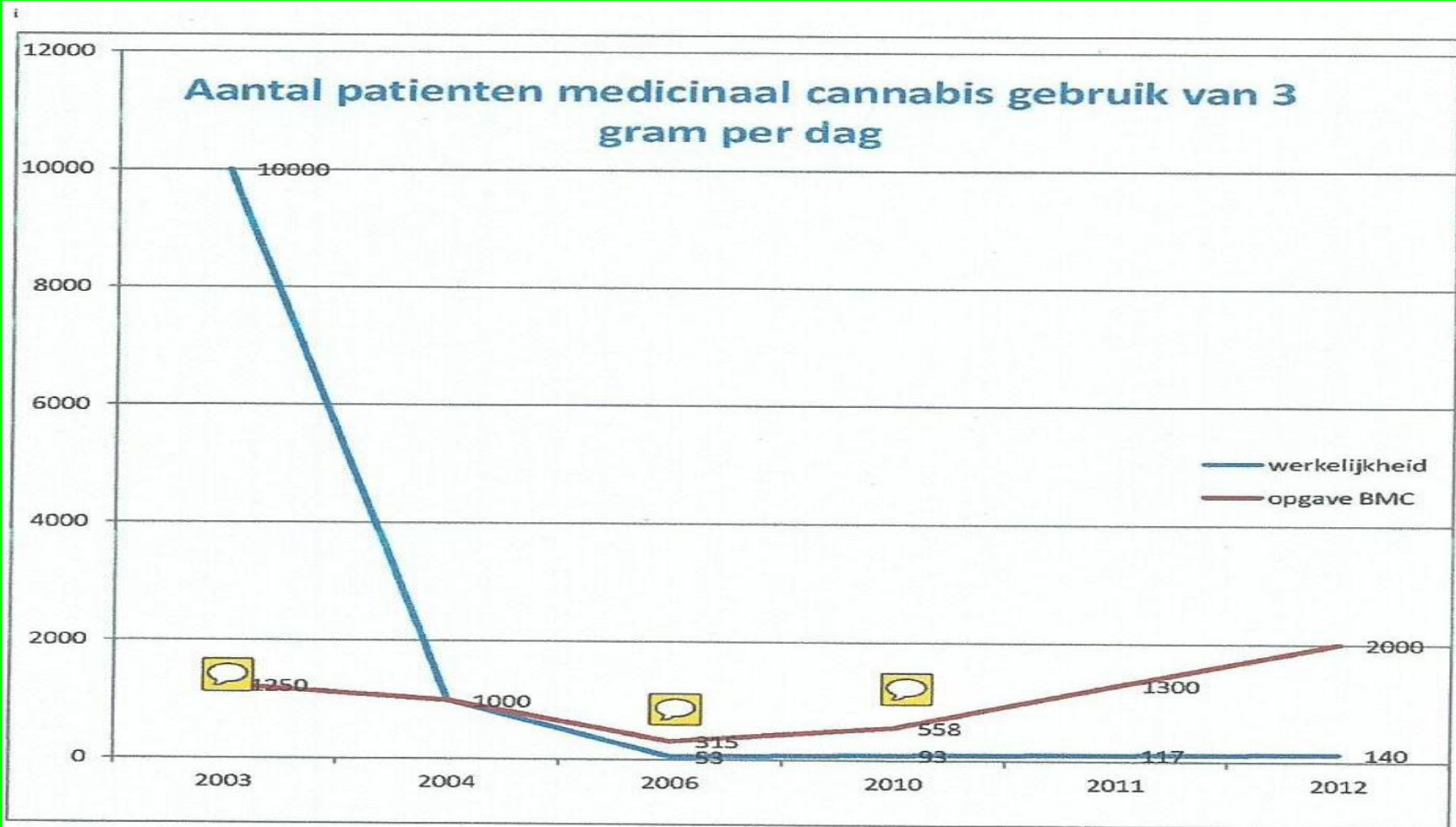
Office of Medical Cannabis Netherlands – info. for patients

- **There are different types of medicinal cannabis varieties available.**
- **These varieties differ from each other in composition, and strength, and therefore also in operation.**
- **In the pharmacy are three varieties available: Bedrocan, Bedrobinol and Bediol (see table).**
- **The variety that is most suitable to a patient depends on the symptoms and reaction differs from person to person. In consultation with the doctor determine which variety is the best choice for you.**
- **There is evidence that cannabis with a combination of a high content of THC and CBD (such as Bediol) provides MS patients good relief from the pain.**

Dutch MC Varieties – THC & CBD content



variety	THC content	CBD content
Bedrocan	19%	<1%
Bedrobinol	12%	<1%
Bediol	6%	About 7.5%

Number of patients in Holland
Blue line – Source: Dutch patient groups
Brown line – Source: Office of MC - Holland



Cost of medical cannabis (& extract/synthetic medications) in various countries

(1 gram and 30 grams – in US Dollars)

CANADA	Holland	Israel	Approved cannabis extract medications
<p>\$7 per gram (appr.) \$210 for 30 grams</p>	<p>USD \$ 10 gr. variety SIMM 18 per gr. (2005) \$ 11 + per gr. for variety Bedrocan</p> <p>The prices are built up as follows:</p> <ol style="list-style-type: none"> the OMC's selling price per gram SIMM 18: \$ 8.68 Bedrocan: \$ 10.07 the pharmacy's fee: \$ 7.44 per prescription +3.6% tax <p>Exported: in Germany \$ 23.3 gr. \$ 700 for 30 gr.</p>	<p>\$ 3.3 gr. \$ 100 per 30-100 Gr.</p> <div style="text-align: center;">  </div>	<p>Sativax spray (UK) cost per patient per month – 500 UK pounds = <u>803 USD per month.</u></p> <p>Marinol/ Dronabinol (synthetic THC pills) The average dose is 12.5mg per day = \$1.81 per milligram X 30 days= \$ 678 per month</p> <div style="text-align: center;">  </div>

Sativax: Now approved in the UK, Spain, Germany, Denmark, the Czech Republic, Sweden, New Zealand and Canada and a few other countries

CANADA

Proposed Improvements to Health Canada's Marihuana Medical Access Program

- **June 17, 2011**
- **Introduction**
- **The Marihuana Medical Access Program (the Program) provides seriously ill Canadians with access to marihuana for medical purposes . In recent years, a wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, have identified concerns with the current program.**

Production facility in the underground mine in Fling Flong

- **Cost of Cannabis to Patients**
- ***Health Canada is passing on the inflated cost of the contract to patients.***
- **• Health Canada pays PPS \$328.75/kg and charges patients \$5000/kg. This**
- **constitutes a 1500% mark-up.**



Marijuana production in a Copper/Zinc mine in Flin Flon by Prairie Plant Systems

- Flin Flon gained international notoriety in 2002 when the Government of Canada awarded a four-year contract to a [Saskatoon](#)-based company for the production of [medicinal marijuana](#). [Prairie Plant Systems](#), based in Saskatoon, **used an inactive underground copper/zinc drift** owned by the Hudson Bay Mining and Smelting Company to produce approximately 400 kilograms of medicinal marijuana annually.
- The entire operation was situated several hundred meters under Flin Flon for security and climate control reasons.
- Since the original stock of marijuana seeds were obtained from [Royal Canadian Mounted Police](#) drug raids, there was some lack of consistency in the early crops of medicinal marijuana.
- After selective use of seeds from the first crop, subsequent generations have shown to have a more consistent quality.
- In 2009, Prairie Plant Systems discontinued operation at the mine due to the ending of their lease and the uncertainty regarding the pending closure of the Trout Lake mine
- http://en.wikipedia.org/wiki/Flin_Flon

A Review of the Cannabis Cultivation Contract between Health Canada and Prairie Plant Systems

- Prairie Plant Systems Inc. entered into a joint venture with Hudson Bay Mining & Smelting Co. Ltd. of Flin Flon, Manitoba, in 1990 to establish a growth chamber 365 meters below the surface of the earth. The success of this project and the media coverage resulted in international recognition and provided further opportunities for diversification and expansion of services; especially toward plant-made pharmaceuticals. See the Biosecure Underground Growth Chambers page for more information. (from the company's website)
- The total cost of the contract, at this point in time, for six years and 9 months is \$10,278,276.
- (http://safeaccess.ca/research/pdf/hc_pps_contract_report.pdf)

:Some of the key concerns raised include

- **the complexity and length of the application process** for individuals who wish to obtain an authorization to possess and/or a license to produce marihuana ;
- **the impact of increasing participation in the Program on the efficiency and timeliness of the application and review process ;**
- **the fact that Health Canada only supplies one strain of dried marihuana;** and ,
- **the need for more current medical information pertaining to the risks and benefits** associated with the use of marihuana for medical purposes, as a means of **supporting discussions between physicians and their patients as to whether such treatment is appropriate.**
- **the potential for diversion of marihuana produced for medical purposes to the illicit market ;**
- **the risk of home invasion due to the presence of large quantities of dried marihuana or marihuana plants ;**
- **public safety risks,** including electrical and fire hazards, stemming from the cultivation of marihuana in homes ;
- **public health risks due to the presence of excess mould and poor air quality** associated with the cultivation of marihuana plants in homes ;

The Improvements under Consideration

- The improvements being considered would not alter the Program's intent to provide seriously ill Canadians with reasonable access to a legal source of marihuana for medical purposes, where conventional treatments are not appropriate and/or have failed to provide necessary relief.
- The core of the redesigned Program would be:
- A new, simplified process in which Health Canada no longer receives applications from program participants.
- A new supply and distribution system for dried marihuana that relies on licensed commercial producers would be established.
- These licensed commercial producers, who would be inspected and audited by Health Canada so as to ensure that they comply with all applicable regulatory requirements, would be able to cultivate any strain(s) of marihuana they choose.
- Finally, the production of marihuana for medical purposes by individuals in homes and communities would be phased out.
- Individuals wishing to use marihuana for medical purposes would still be required to consult a physician who is licensed to practice medicine in Canada.

How the Proposed Redesigned Program Would Work

- **4.1 Physician-Patient Interaction**
- Health Canada maintains that the determination as to whether the use of marihuana for medical purposes is appropriate for a particular individual is best made through a discussion with their physician. In this regard, Health Canada is proposing to eliminate the categories of conditions or symptoms for which an individual may possess marihuana for medical purposes under the MMAR.
- Individuals would continue to be required to consult a physician to obtain access to marihuana for medical purposes. Since categories would be eliminated, there would no longer be a requirement for some individuals to obtain the support of a specialist in addition to their primary care physician in order to access marihuana for medical purposes.
- The existing medical declaration would be replaced by a new document provided by the physician to the individual. Health Canada will consult the medical community on the form this document will take.

- Individuals would no longer be required to submit information to Health Canada to be authorized to possess dried marihuana. Instead, they would submit their physician's document directly to a licensed commercial producer.
- Health Canada will establish an Expert Advisory Committee to improve physician access to comprehensive, accurate and up-to-date information on the use of marihuana for medical purposes, thereby facilitating informed decision-making with respect to the use of marihuana for medical purposes.
- Health Canada would work with the medical community, their provincial/territorial licensing authorities and their associations on the proposed improvements to the program.

Dried Marihuana Production and Distribution

- Under the proposed redesigned program, Health Canada would no longer enter into a contract with a commercial entity to supply and distribute dried marihuana and marihuana seeds .
- The only legal source of dried marihuana would be commercial producers, who would be licensed by Health Canada to produce and distribute dried marihuana. Individuals would purchase their supply of dried marihuana from one of these licensed commercial producers .
- Personal and designated production would be phased out .
- In order to be licensed by Health Canada, licensed commercial producers would have to demonstrate compliance with requirements related to, for example, product quality, personnel, record-keeping, safety and security, disposal and reporting, as set out in new proposed regulations. These controls would aim to ensure the quality of the product being purchased by program participants, as well as the security of production sites.

- Health Canada would establish a comprehensive compliance and enforcement regime for licensed commercial producers, centered on regular audits and inspections.
- Licensed commercial producers would be required to comply with specific product labeling and packaging requirements. The label and/or the package itself could be one way by which a program participant could demonstrate that their supply of marihuana is legal.
- Licensed commercial producers would only be permitted to produce marihuana indoors.
- Licensed commercial producers would be able to produce any strain(s) of marihuana, thus giving individuals greater choice as to which strain(s) they wish to use.
- Licensed commercial producers would set the price for marihuana for medical purpose.
- Licensed commercial producers would only be able to send the dried marihuana they cultivate to individuals by registered mail or bonded courier.

Marihuana Medical Access Program (MMAR) Statistics 2013

Source: Health Canada

- **December 31, 2013**
- Number of persons who hold an Authorization to Possess Dried Marihuana in Canada: 37,884
- Number of persons who hold a Personal-Use Production License in Canada: 24,990
- Number of persons who hold a Designated-Person Production License in Canada: 3,896
- Number of persons in Canada who have indicated they will access dried marihuana and/or marihuana seeds from Health Canada for medical purposes: 8,165

What is missing from the Canadian NMCP

- Significant research funding
- Patient education
- Physician and Nurse education
- Guidelines for use in Hospitals and Old patient homes.
- Subsidies for the poor or health insurance coverage
- Price cap on “price per gram”

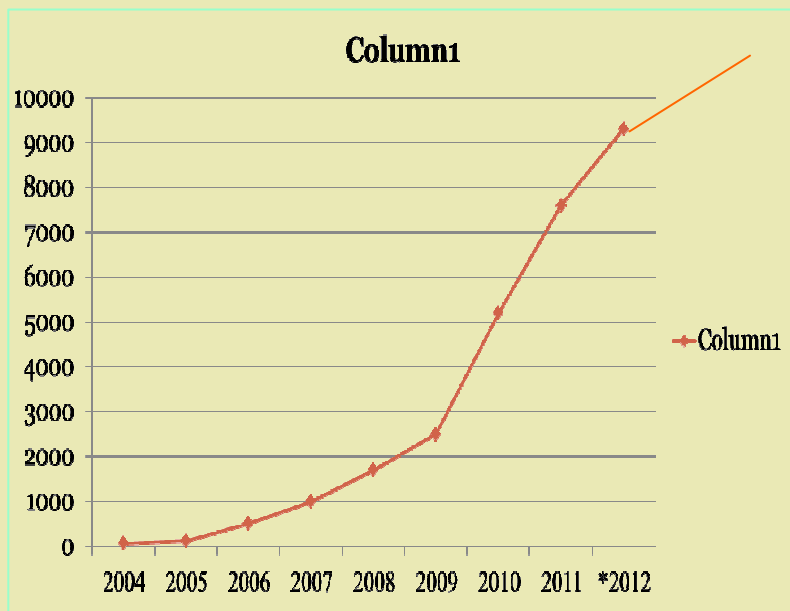
ISRAEL

Israel's National Medical Cannabis program: a model to follow?

- **Israel's national Medical Cannabis program evolved in the last 15 years from an activist's efforts to a full fledged National medical Cannabis program serving over 13,000 patients with cannabis grown by 8 growing groups.**
- **Israel is the third country in the world to establish a National Medical Cannabis Program/Agency, after Holland and Canada.**

Medical Cannabis (MC) program

14,000 + patients with permits
served by 8 licensed growers



Physician Perspective (Dr. Y Baruch – former head of MC program)

On one side:

- A lot of patients benefit greatly from the use.
- Another medicine in the pharmacopeia.
- Higher safety than opioids (no death due to OD).

On the other side:

- Mainly in chronic pain Clinique – fear of becoming a cannabis Clinic

Patient's Perspective

- Cannabis is better tolerated than opioids.
- No risk of Overdose and death.
- A different mechanism of work – can help where other medications did not.
- A social trend.
- What strain to use? Who decides?
- Should self growing be allowed?

After the establishment of the National MC Agency

- Sarel – the monopolistic arm of the agency.
- Sarel will buy all the crop (through tenders among growers).
- Distribution to pharmacies already licensed to handle control substances.
- Option of home delivery (additional fee).
- Option of trial and error to try and decide which strain (among different growers) gives the best result to the specific patient.
- (Source – Dr. Y Baruch – former Director of the MC program)

Patients pay 110 \$ per month regardless of the quantity (30-100 grams) of dried flowers or extract they receive

Consumption options for patients (Israel)

1. Cleaned & dried Cannabis flowers
 2. Oil – in small bottles with peptide
- A trade off exists between the number of bottles and the weight of dried flowers a patient receives
3. Cannabis lased brownies
 4. Cannabis Salve (ointment)
 5. Cannabis lased brownies
 6. Ready made joints

Vaporizers (rent or sale – are approved for use in oncology wards in hospitals)



Various cannabis products at the MECHKAR distribution and training center available to Israeli medicinal cannabis patients. From top, a cannabis tincture, baked cannabis cookies, cannabis salve, and cannabis cigarettes rolled with organic paper.
Photo ©2013 Moish Yarel

Patients' Intake questions – Israel



Intake Interview – Israel

- What are you suffering from?
- How bad is it (1-10)?
- For how long?
- What kind of medications have you been using?
- Do you have experience with cannabis? Do you know how to roll joints?
- Have you ever smoked cigarettes?
- Do you have kids or minors in your house?
- Do you have someone to take your cannabis from the distribution center?
- Do you have someone to be with you in the house while you smoke the MC?
- These are the possible side effects (*)
- **Psychotic episodes**
- **Panic attacks**
- **Generalized Anxiety Disorder**
- **A-motivational Disorder**
- (*)The side effects are quoted from a presentation of Dr. Y. Baruch, the director of the MC program and a psychiatrist

How to improve the MC program in Israel?

- Every doctor should be allowed to give a prescription for MC and not just a few specialists . (They are allowed to prescribe morphine so why not cannabis?)
- Better quality control in real time before the MC reaches patients
- Grow under GMP (Good Manufacturing Practice) and the guidelines for cannabis cultivation, derived from the general rules for Good Agricultural Practice (GAP) of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMA).
- Reduce THC levels and increase CBD levels
- Have the national medical insurance companies pay for the MC (some do partially already – as well the Ministry of Defense to PTSD and wounded soldiers)
- Improve MC education for doctors, nurses and patients.
- Prepare MC curriculum to be taught in medical and nurse schools
- Allow for distribution through pharmacies and not in a few limited locations
- Increase government funding for MC research

Comparative view

	Holland	Canada	Israel	remarks
Number of patients	3000	Dried Marihuana: 37,884 # of persons who hold a Personal-Use Production License: 24,990 (*)	14,000	(*)Canada: Transition period between old and new programs
Model	UN strict adherence	Commercial – medium adherence	UN – Strict adherence	Different interpretation to the model by countries
Number of suppliers	1 now (2 suppliers were initially chosen – one became bankrupt)	20+	8	
Sale	Pharmacies	New program - Direct from suppliers via mail	now secured home delivery Soon – Pharmacies & HD	
Patient education	On line – very limited	On line - extensive	Half an hour instruction with nurses	Doctor’s education lacking in all programs
Number of strains	5	unlimited	Now many – soon 12	Large number of strains - essential for success of program
Research 32	Very, very limited	Gaining momentum	Extensive – funded by the state and private sector	



REUTERS

TOP NEWS

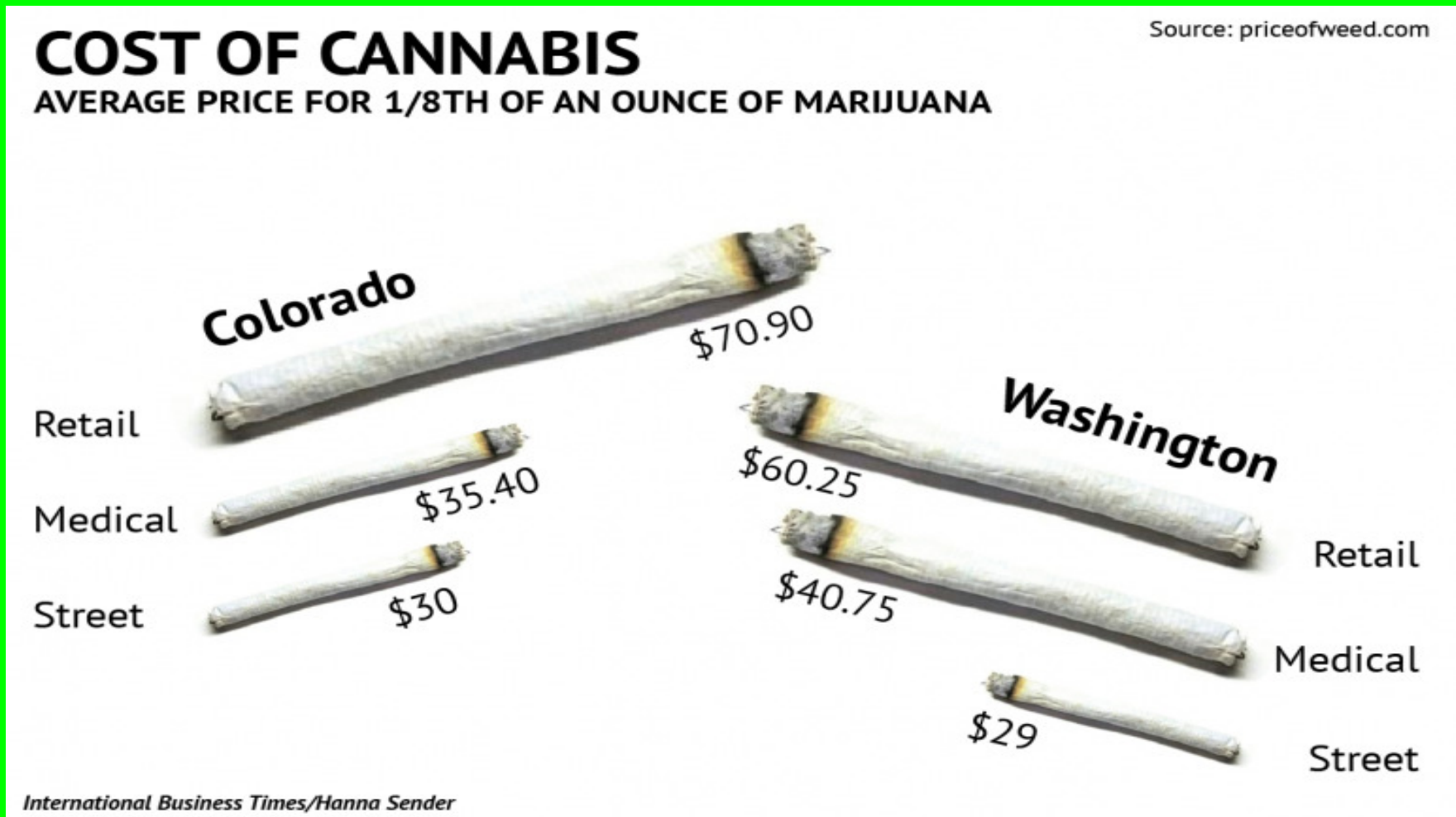
FEATURE-

To grow cheap marijuana, Italy calls in the army

- Sun, Oct 12
- *Imported medical marijuana now costs about 38 Euros per gram
- *Military compound to start growing cannabis next year
- *Drug stigma in Catholic country may keep number of users low

FREE POT

- Because of the bureaucracy of obtaining import permission, ensuring purity and overseeing sale, legal cannabis from Holland now costs about **38 Euros** a gram in Italian pharmacies, compared to as low as 5 Euros for illegal pot on the street.
- Even when a doctor prescribes it, the state does not cover the cost, which could run to around 1,000 Euros (\$1,200) a month for a typical patient. As a result, when legalized medical marijuana arrived last year, only a few dozen people signed up.
- Health Minister Beatrice Lorenzin said that should change once the military production begins. The army should be able to produce marijuana at a high enough standard to satisfy regulators for less than half the cost of importing it, allowing the government to offer it to patients at subsidised prices.



So the average retail price for MC in Washington and Colorado is 37 dollars for 3.53 grams – about 10 dollars a gram

Estimated whole Sale price of MGC in Uruguay and for Exports

- **Cultivation**

- 1] *Indoor*: 1000-1500 m2, MGC,
Export quality **\$ 4**
- 2] *Greenhouse*: 5000-10,000 m2 Medical
and recreational **Local and export** **\$ 2**
- 3] *Outdoor*: 10.000-20.000 m2
Medical and recreational
Local and export **\$ 1**

- Thank You good folks!