



Medical Grade Cannabis - The Israeli Roadmap to Medicalization

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Medical use of Cannabis in ancient times

- 5000 years ago in Egyptian tombs
- 2700 years ago in India
- 2000 years ago in China for the treatment of pain

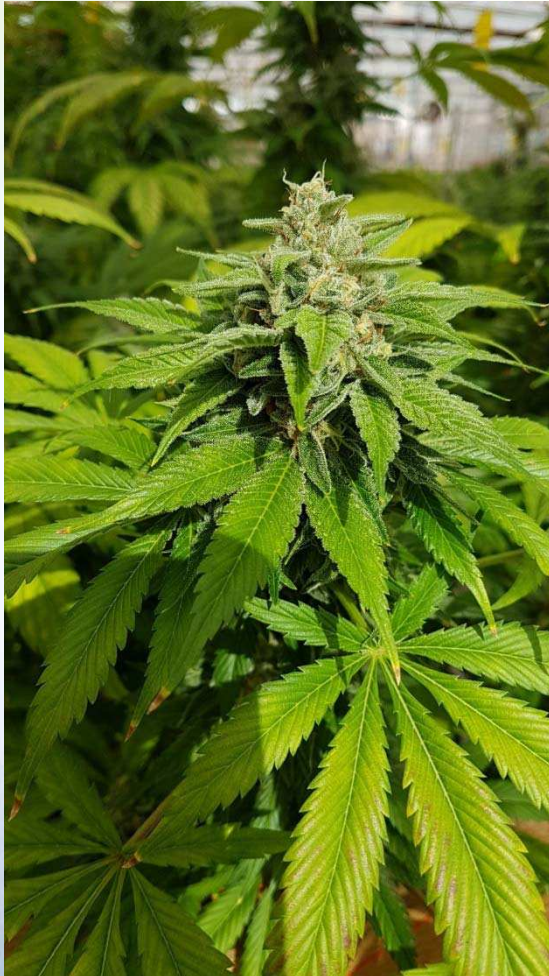




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International - Single Convention on Narcotic Drugs 1961

The Cannabis plant is subject to additional
measures of control

Israel - The Dangerous Drug Ordinance [New Version] - 1973

The Cannabis plant and its products are
defined as narcotic substances
They are not registered as medicinal
products



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The Government of Israel Resolutions

Government Resolution 3609 (7.8.2011)

- Establishes the obligation of the Ministry of Health to serve as “Government Agency” for Cannabis
- The multi-ministerial Stirring Committee
- The Israeli Medical Cannabis Agency (IMCA) is established

Government Resolution 1050 (15.12.2013)

- Improving efficiency of prescription, indication inspection, appointing of Physicians and accessibility to service.
- Search for feasibility of export
- Regulating research.



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**Government Resolution 1587 (26.6.2016) -
Cannabis for medical purpose and research**

The “Medicalization” of Cannabis





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The Vision of The Israeli Medical Cannabis Agency (IMCA)

**To support the use of Cannabis
for medical purposes exclusively,
while preventing misuse
and keeping public safety.**

Government Resolution 1587



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Professional infrastructure

Inter-ministerial Board of Directors of the IMCA

MOH (Chair), MOF, MOA, MOJ, MOHLS, Police, Customs



- Medical Indications Committee
- Security Measures Committee
- Quality Control Committee
- Research and Development Committee
- Appeal Committee





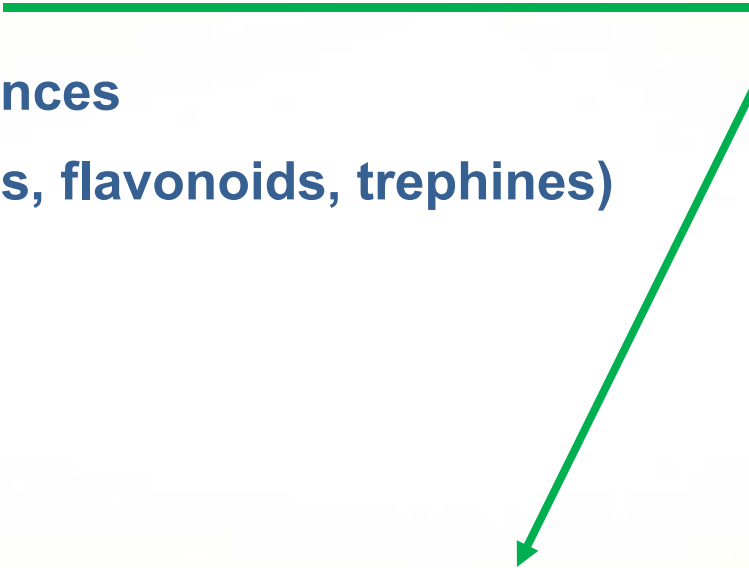
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The main challenges regarding the medical use of Cannabis

- EBM & Research are missing
 - Plant containing multiple substances
 - “Entourage” effect (cannabinoids, flavonoids, terpenes)
 - Recreational use
 - Smoking (decarboxylation)
 - An emotional issue: **Disagreements and fears among medical community**
- 



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The principles of the Policy on Cannabis for medical use

- 1. Medicalization – The use of Cannabis for medical purposes not legalization nor decriminalization.**
- 2. Standardization of Medicinal Cannabis products –** Medical Grade Cannabis (MGC) products, constant & controlled concentrations, practitioners safely prescription, sold in pharmacies.
- 3. Medical indications for prescribing Cannabis –** professional teams, IMA experts, supervision & learning from medical practice
- 4. Training of medical practitioners –** Physicians, pharmacists to treat with MGC using a systematic method of medical practice **IMC-GCP (the "green book")**.
- 5. Regulation of Research and Development**



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5. **Regulation of Research and Development**



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Procedures for Good Quality Practices

- **IMC-GAP** - Quality guideline for cultivation and multiplication of Cannabis strains, genetically defined.
Supervised range of concentrations of several active ingredients.
- **IMC-GMP** - Quality guideline for production of generic and uniform Medical Grade Cannabis (MGC) products.
- **IMC-GDP** - Quality guideline for distribution of MGC products.
- **IMC-GSP** - Guideline for ensuring the safety , security, prevention of diversion and supervision of adequacy of medical practice.

- **IMC-GCP**





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Standardization of 25 suggested cannabis products

EP	Exp.	CBN	CBD	THC	פריט	סוג
8	מנמסרצ שה	0% (Up to 1.5%)	24% (28% 20%)	0% (0.5% 00%)	"קובסרס אדא 10/24 CBD"	CBD Rich
7	מנמסרצ שה	0% (Up to 1.5%)	20% (24% 16%)	1% (2.5% 00%)	"קובסרס אדא 11/20 CBD"	
55	מנמסרצ שה	0% (Up to 1.5%)	15% (19% 11%)	3% (5.5% 0.5%)	"קובסרס אדא 13/15 CBD"	
5	מנמסרצ שה	0% (Up to 1.5%)	10% (14% 6%)	5% (7.5% 2.5%)	"קובסרס אדא 15/10 CBD"	
65	מנמסרצ שה	0% (Up to 1.5%)	10% (14% 6%)	10% (14% 6%)	"קובסרס אדא 10/10"	THC Rich
4	מנמסרצ שה	0% (Up to 1.5%)	2% (38% 0.2%)	10% (14% 6%)	"קובסרס אדא סטנד 10/2 Sativa שלזפ	
4	מנמסרצ שה	0% (Up to 1.5%)	2% (38% 0.2%)	10% (14% 6%)	"קובסרס אדא 10/2 Indica שלזפ	
6	מנמסרצ שה	0% (Up to 1.5%)	3% (5.5% 0.5%)	15% (19% 11%)	"קובסרס אדא סטנד 15/3 Sativa שלזפ	
6	מנמסרצ שה	0% (Up to 1.5%)	3% (5.5% 0.5%)	15% (19% 11%)	"קובסרס אדא 15/3 Indica שלזפ	
8	מנמסרצ שה	0% (Up to 1.5%)	4% (7% 1%)	20% (24% 16%)	"קובסרס אדא סטנד 20/4 Sativa שלזפ	
8	מנמסרצ שה	0% (Up to 1.5%)	4% (7% 1%)	20% (24% 16%)	"קובסרס אדא 20/4 Indica שלזפ	



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Cultivation

Cultivation farm for Medical Cannabis by **IMC-GAP** and
complying with security standards **IMC-GSP**





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Manufacturing

Produce generic and uniform Medicinal Cannabis products
IMC-GMP grade and complying with security standards **IMC-GSP**



GMP approved plants – BOL, Panaxia



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Storage and distribution

Storage and distribution by certified Cannabis wholesalers under **IMC-GDP** conditions and according to **IMC-GSP** security standards



מוצרי קנביס רפואי מובלים עי חברת סלא ממפעל BOL לבית המרקחת של סופרפארם בתלפיות ונשמרים בהתאם לנוהל הביטחון



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5. **Regulation of Research and Development**



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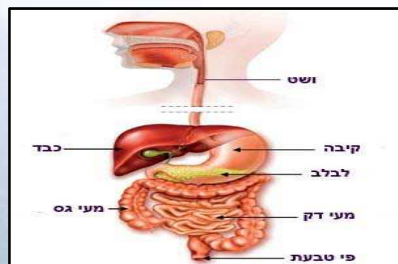
Administration of Medical Grade Cannabis Products



Cannabis cookies (for children only)



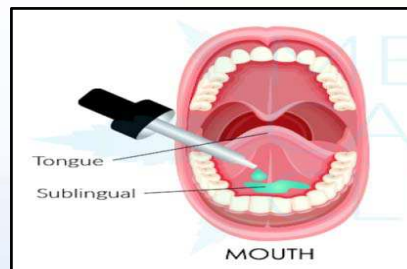
PO



Cannabis oil extracts



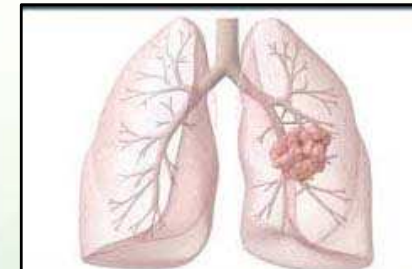
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Cannabis Flosses and Rollings



INH





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Prescription of Cannabis

Prescription of **Medical Grade Cannabis Products**
and a License issued by Trained Physician
according to the **Green Book – GCP standards**



המרשם הראשון לקנביס רפואי נרשם על ידי ד"ר דוד פרנקל מבי"ח
אלי"ן בירושלים, בוגר קורס הקנביס של היקר



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Dispensation in Pharmacies

Dispensation of Cannabis products to patients in pharmacies,
country-wide distribution.

According to the Narcotic Drug Ordinance and guidelines.
Pharmaceutical instruction of patients.



לראשונה, ניפוק קנביס הרפואי על ידי רוקח בסניף סופר פארם בתלפיות



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The old chain of supply of Cannabis

**Cultivation in old farms according to
“traditional” methods**

**Production of different “strains” of
products by the cultivators themselves**

**Transport to a distribution center (in
hospitals) or to patient’s home**

**Selling of Cannabis & training the patient
by the cultivator.**



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Implemented chain of supply of Cannabis

Cultivation in special cultivation farms
IMC-GAP grade.

Production of generic and uniform
Medicinal Cannabis products
IMC-GMP grade.

Distribution and storage of Cannabis
products **IMC-GDP grade**

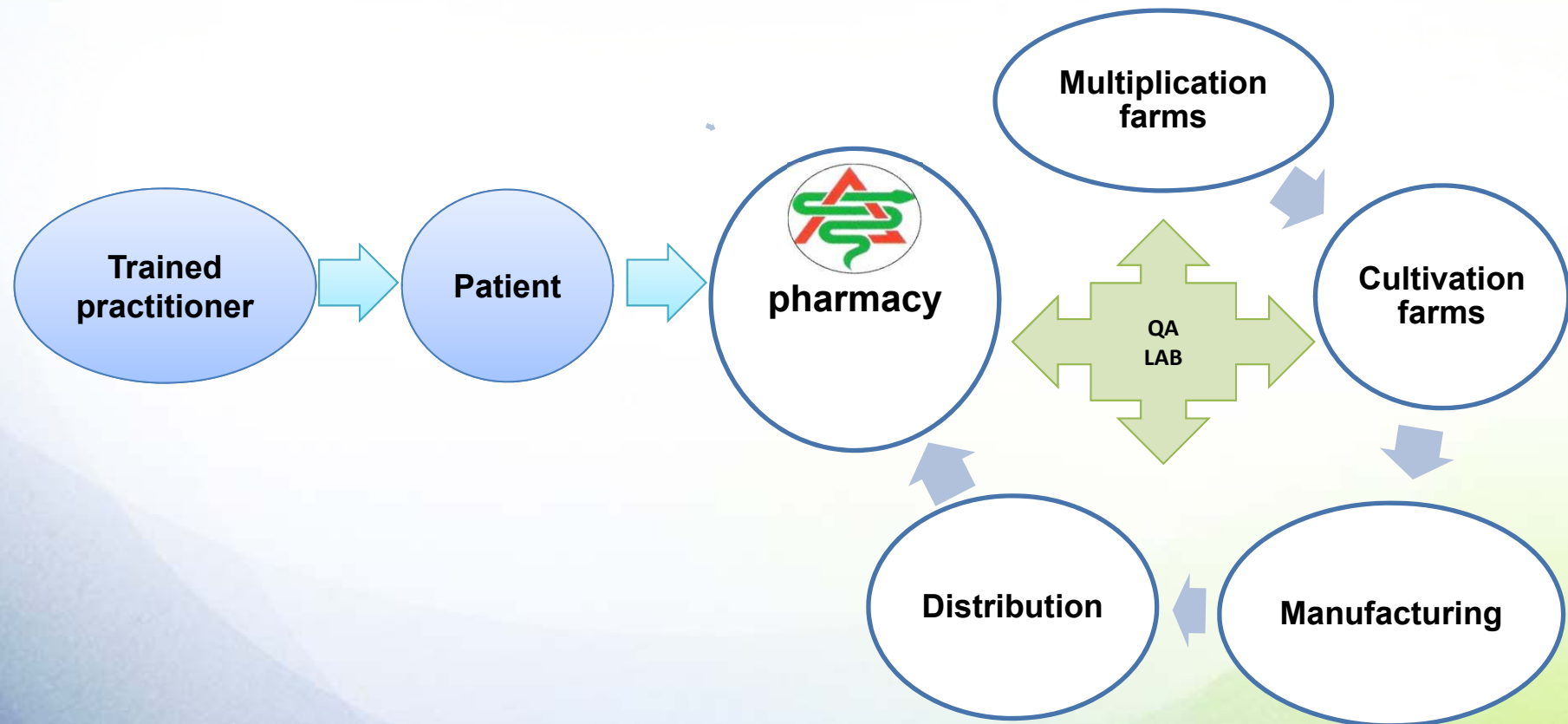
Drug Dispensation at pharmacies
according to narcotic products
regulation and training by registered
pharmacists.



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Summary - From concept to implementation of the Medicalization of Cannabis





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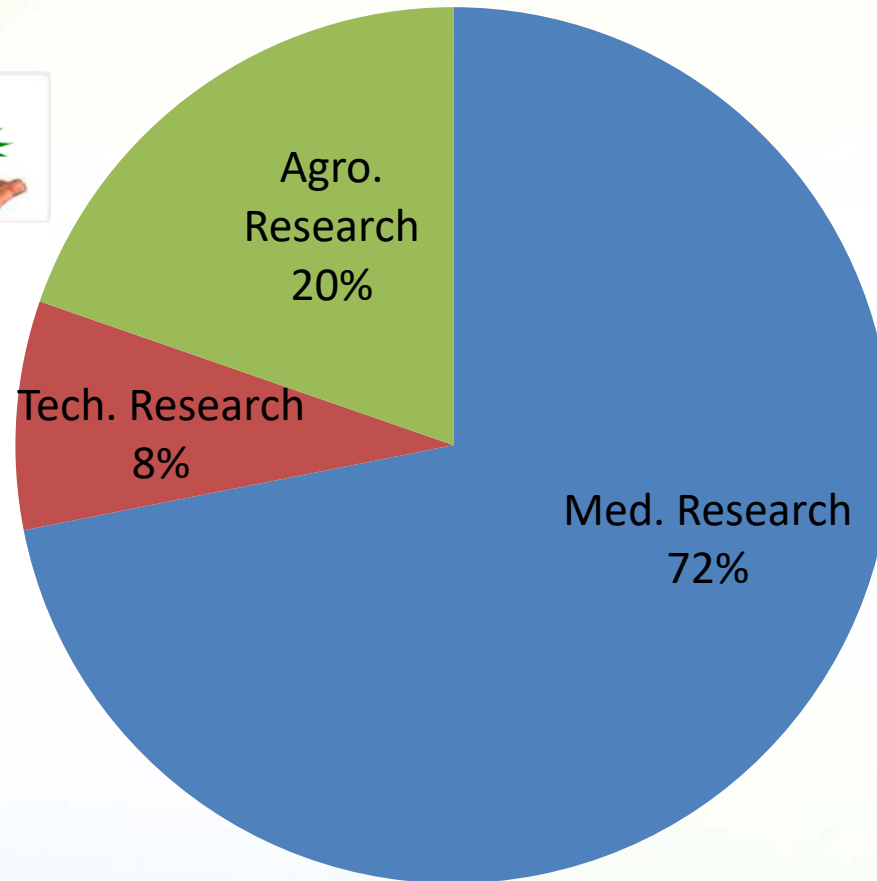


The regulation of Research and Development

- **Agricultural research**
Agronomic, agro technic, biochemical, physiologic and molecular aspects of the Cannabis plant.
- **Technological and medical device research**
Development of cannabis-based medical devices, smoking alternatives, etc.
- **Clinical research field - EBM**
Clinical, pre-clinical, pharmacologic, and molecular research on cannabis, cannabinoids and cannabis products



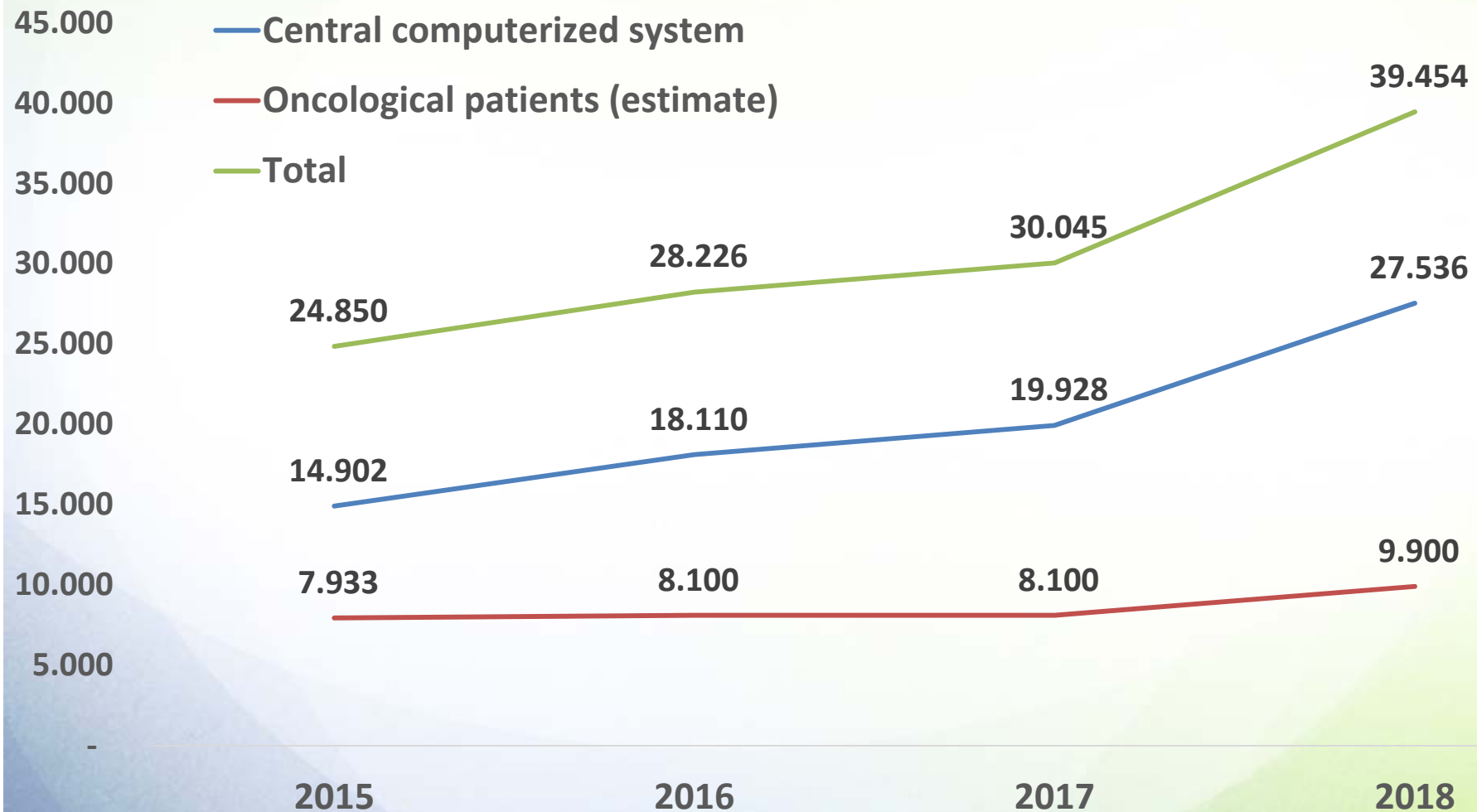
Cannabis Research & Development Categories (n=246)



Data on Usage of Medical Cannabis in Israel



Number of Patients with a Licenses to use Medical Cannabis (2015-2018)



Upward trend of number of licenses

פורטל BI - קנאביס רפואי



שלום דורית מוס

תאריך עדכון: לא ידוע

מגמות ברשיונות פעילים

אודותינו |

מספר רישיונות פעילים ל- 2017 30,603 מספר רישיונות פעילים ל- 2018 34,548



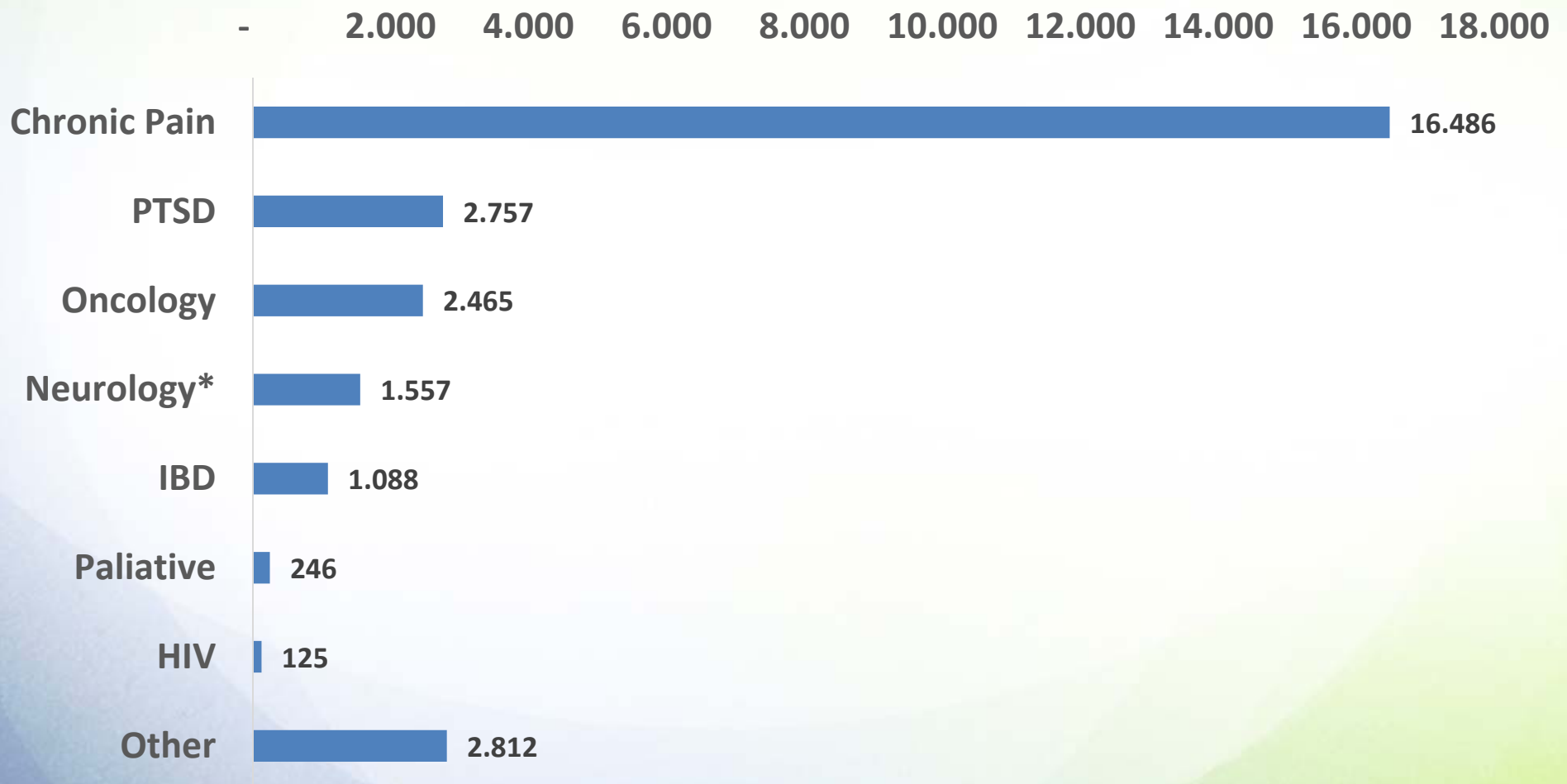
*רישיונות פעילים: מספר מטופלים אשר היה להם רישיון פעיל לפחות יום אחד בחודש הנבחר

מינון מצטבר בק"ג לפי צורת טיפול ברישיונות פעילים



*מינון מצטבר: סה"כ המינון בק"ג לימים בהם הרישיון היה בתוקף בחודש הנבחר

Number of Patients by Clinical Category




THE JERUSALEM POST

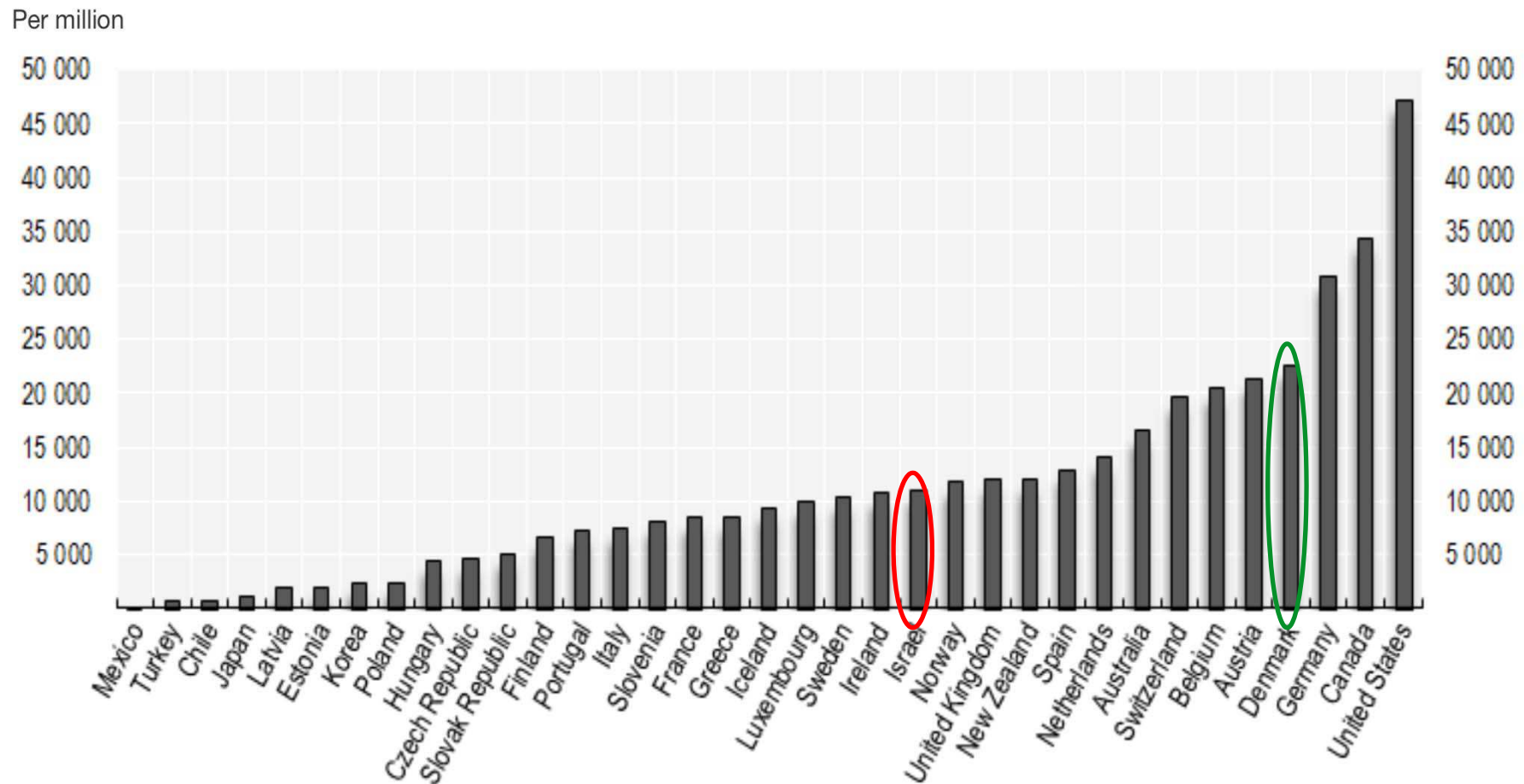
Jerusalem Post > HEALTH & SCIENCE >

WHY IS ISRAEL'S OPIOID DEATH RATE SO MUCH LOWER THAN IN THE U.S.?

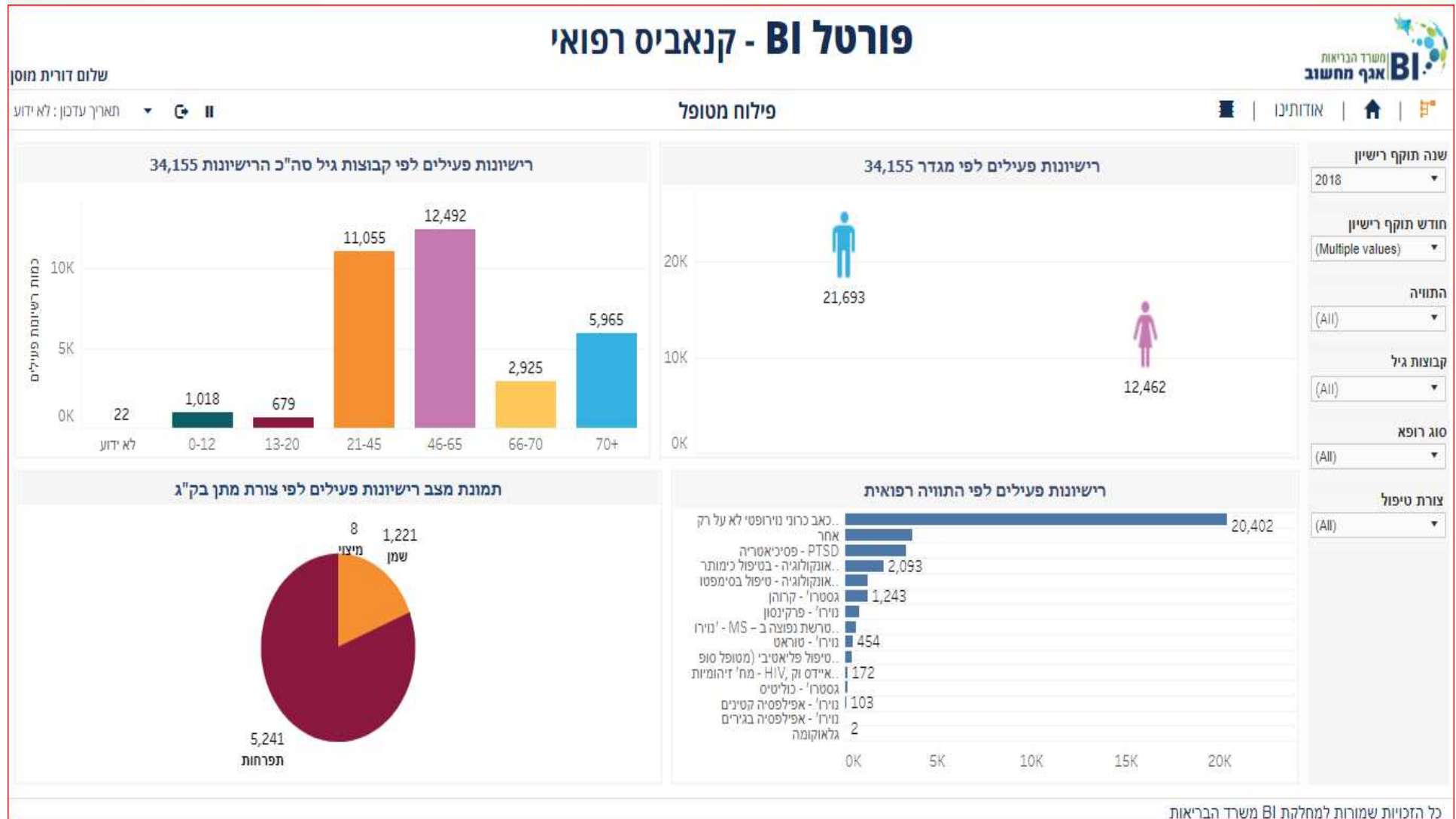
Since the late 1990s, more than 200,000 Americans have died as a result of using opioids.

BY JUDY SIEGEL-ITZKOVICH / JANUARY 12, 2018 06:25 

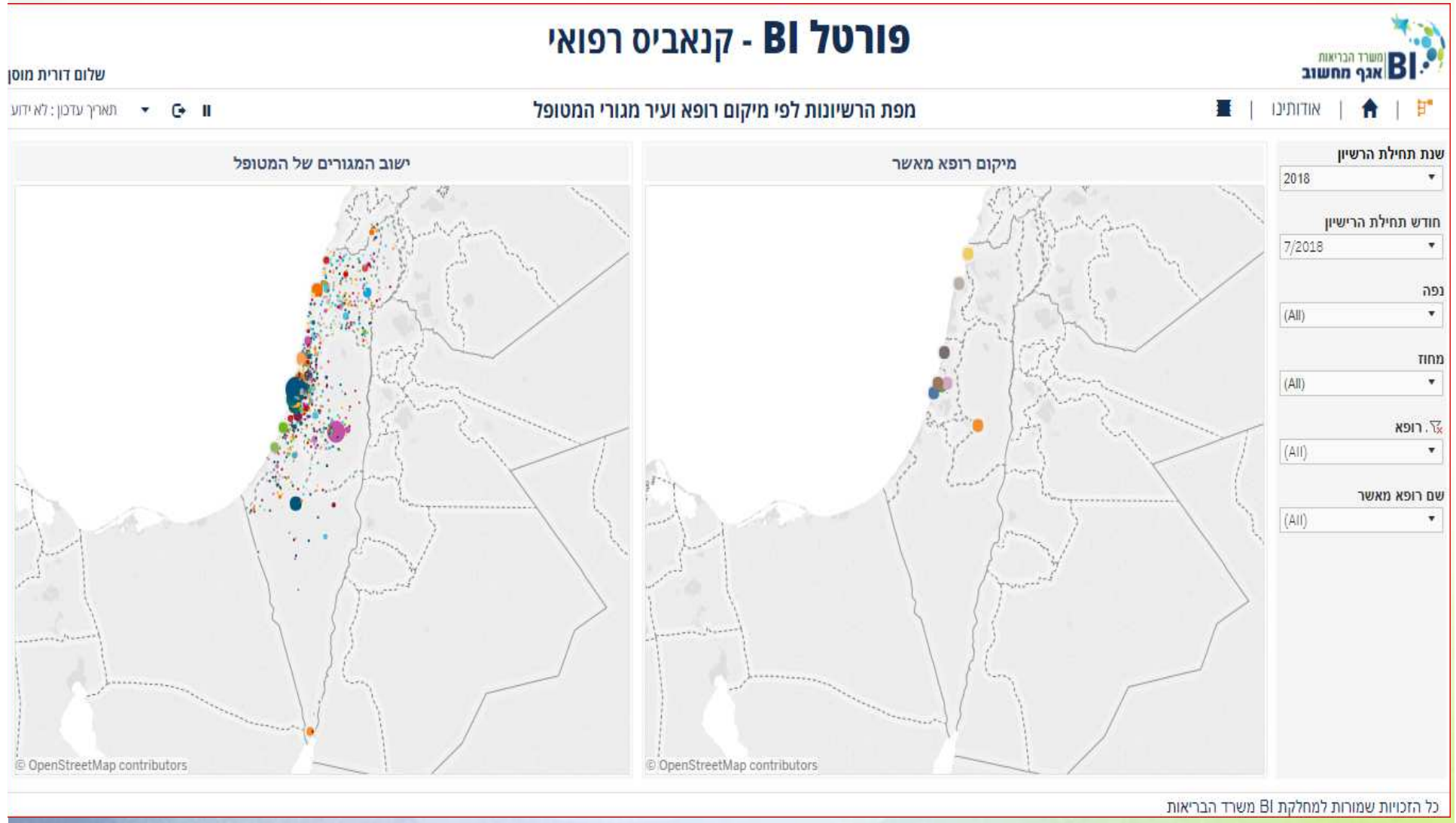
Opiates Use by Country (OECD – 2018)



Demographics of Patients with License



Geographic Distribution of Patients with License



Funding and financing

- Free market, but:
 - Prescribing physicians in the public service (or equivalent), limited visit's fee (\cong 50\$)
 - Ability to control the price (\cong 33\$ per 10g)
- Public resources:
 - Administration (will change with implementation of the “new” system)
 - Regulation and Control (MoH, Police)
 - Research and Development