



# The Israeli Experience in the Therapeutic use of Medical Cannabis



MK Dr. Rachel Adatto  
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# A few facts

<b>2009</b>	<b>1800 licensed users in Israel</b>
<b>7/2011</b>	<b>6619 licensed users in Israel</b>
<b>2/2012</b>	<b>9000 licensed users in Israel</b>
<b>12/2012</b>	<b>a predicted 11000 licensed users in Israel</b>

# Regulation of the therapeutic use of medical cannabis in Israel

<b>November 2009</b>	<b>Labour, Welfare and Health Committee</b>
<b>March 2010</b>	<b>Labour, Welfare and Health Committee</b>
<b>June 2010</b>	<b>Labour, Welfare and Health Committee</b>
<b>November 2010</b>	<b>Labour, Welfare and Health Committee</b>
<b>July 2011</b>	<b>Committee on Drug Abuse</b>
<b>February 2012</b>	<b>Government Resolution on the supervision and regulation of supply source of cannabis for therapeutic and research use</b>



# The need for regulation



- ⦿ Growing numbers of users
- ⦿ Increase in awareness by doctors and patients
- ⦿ Expansion of indications for treatment by cannabis
- ⦿ The cannabis plant, including all its components and derivatives, is defined by law as “a dangerous drug” so that its use, without a special license, is prohibited.
- ⦿ A rise in the number of growers who are demanding regulation
- ⦿ Involvement of the media

# Government Resolution 3609 – 7 August 2011



- ◎ The Ministry of Health, in consultation with the Ministry of Public Security and the Ministry of Agriculture, will take action to regulate a supervised supply source of cannabis for medicinal and research use.
- ◎ The Ministry of Health will serve as a Government Agency in accordance with the provisions of the Single Convention on Narcotic Drugs – 1961.

# Government Resolution 3609 – continued



- ◎ Role of the Government agency: regulation; supervision and control //inspection and supervision//; liaison with government and other agencies abroad regarding permits for import of cannabis for therapeutic use in accordance with the international Convention; liaison with parallel government agencies in other signatory countries to the Convention; reporting to United Nations authorities in accordance with the provisions of the Convention.



# Government Resolution 3609 – continued



- ◎ The Government Agency, itself or through other agencies, will procure and store imported cannabis or cannabis grown in Israel.
- ◎ Individual licenses for import and production will be issued by the Director General of the Ministry of Health after approval by the Israel Police (requirement for security and identification of applicants).
- ◎ An inter-ministerial steering committee will be set up for monitoring and coordination (Ministries of Health, Finance, Justice, and Public Security – Police, Agriculture; the Israel Tax Authority; the Israel Anti-Drug Authority).

# Government Resolution 3609 – continued



- Local production will continue for a period not exceeding two years (unless there is a different decision).
- Government commitment to allow an appropriate supply source through import (as far as this option is implementable and practicable).
- The Government Agency will report to the Government within a year on the detailed implications of importing versus local production (with verified data on costs).

## הכנסת השמונה-עשרה

הצעת חוק של חברי הכנסת

חיים כץ  
אריה אלדד  
עפו אנבאריה  
רחל אדטו  
אריה ביבי  
אילן גילאון  
שלי יחימוביץ'  
אורלי לוי אבקסיס  
משה (מוץ) מטלון  
חיים אמסלם  
סעיד נפאע

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### פקודת הסמים המסוכנים (טיפול באמצעות סם הקנבוס), התש"ע-2010

- תיקון סעיף 6 1. בפקודת הסמים המסוכנים [נוסח חדש], התשל"ג-1973<sup>1</sup> (להלן-הפקודה), בסעיף 6, האמור בו יסומן "(א)" ואחריו יבוא:
- "(ב) המנהל ייתן רישיון לפעולות בצמח הקנבוס כאמור בסעיף קטן (א), אם מצא כי הדבר דרוש לצורך ביצוע טיפול רפואי שנקבע על ידי רופא מומחה הפועל במוסד רפואי שנרשם ואשר פועל לפי הוראות פקודת בריאות העם, 1940<sup>2</sup>;
- (ג) שר המשפטים, בהתייעצות עם שר הבריאות, רשאי לקבוע בתקנת כללים לגבי הנסיבות שבהן יינתן רישיון לפעולות בצמח הקנבוס."
- תיקון סעיף 7 2. בסעיף 7 לפקודה אחרי סעיף קטן (א) יבוא:
- "(א1) המנהל ייתן רישיון להחזקה ולשימוש בצמח הקנבוס לצורך ביצוע טיפול רפואי שנקבע על ידי רופא כאמור בסעיף 6(ב)."

# The Government Agency



- ⦿ In preparation for establishing the Government Agency, the Ministry of Health published a tender for the position of Agency head in February 2012.
- ⦿ The tender was suspended due to reservations, including the minimal conditions set for the position.
- ⦿ Additional personnel will be required: a physician responsible for awarding permits to non-cancer patients; a logistics manager (supply and transportation); two administrators.
- ⦿ The Agency will issue permits, supervise distribution, be responsible for training, supervise quality, supervise correctness of procedure for production and distribution.

# Issues related to regulation of medical cannabis



## 1. Production in Israel versus import:

- 1.1 The initial decision of the Ministries of Health and Public Security to recommend importing arose from the desire to prevent or limit “leaks” of the substances during the production and distribution process.
- 1.2 The import of cannabis will hurt local growers and lead to price increase due to the high cost of import and higher prices abroad. (x4)
- 1.3 The Government Resolution allows local production for another two years.
- 1.4 The Ministry of Agriculture is working to amend the law so that local growers will come within the realm of responsibility of the Plants Production and Marketing Board.

# Issues related to regulation of medical cannabis



## 2. The Price of Cannabis to licensed users

2.1 The cost for licensed users using cannabis from local production – NIS 370 (US \$100) per month.

2.2 Currently this payment is not relative to the quantity actually used (on average 45 grams a month, costing \$2) – Payment according to quantity will ensure that patients who require only small quantities will not have to subsidize patients who need large quantities.



# Issues related to regulation of medical cannabis



## 3. Expansion of indications

3.1 There is currently public and scientific debate regarding the efficacy of treating certain diseases and medical conditions with cannabis.

3.2 For those conditions not predefined, research evidence regarding the efficacy of cannabis treatment must be presented.

# Summary and points for discussion

- Knesset committees became involved in the regulation of the therapeutic use of cannabis more than two years ago, but there has been no real progress in the process of regulation. On the other hand, the number of licensed users has increased significantly.
- We must consider the implication of expansion of the therapeutic use of cannabis. Does this increase in usage reflect an increase in therapeutic needs or is it due to “leaks” and inappropriate use.
- The attitude to cannabis as a drug, while medication containing opiates are considered normative.

# Summary and points for discussion

- The problematic link between licensed users and growers/producers. It is important to break the link between the production process, distribution, licensing and home delivery.
- It is not reasonable to impose a requirement for a security guard to accompany patients who require a quantity of over 50 grams.
- Import vs. local production.

