



CIBG
Ministry of Health, Welfare and Sport

The Dutch Medicinal Cannabis Program

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Ministry of Health, Welfare & Sport
The Netherlands

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Overview

- Policy and legislation
- Responsibilities
- Production and distribution
- Quality control



Multiple sclerosis: chronic disease with high impact on quality of life





Reasons for a new policy

From 1993 onward:

- Increasing pressure from society against prohibition of medicinal use;

Health Council advised (1996):

- insufficient evidence of efficacy;
- trials done with ill-defined products.

Existing practice of illegal medical use

- No quality control;
- No medical coaching of patients;
- Patients at the mercy of illicit trade.



Microbiology: *recreational* cannabis coffee shop

(Source: A. Hazekamp et al; University of Leiden, the Netherlands)

Cannabis sample	aerobic bacteria (cfu/gram) ¹⁾	aerobic fungi (cfu/gram) ¹⁾	Identified pathogens
Bedrocan ²⁾	<10	< 100	
Bedrobinol ²⁾	<10	< 100	
A	<10	480000	
B	4500	900	
C	<10	1000	
D	70	120	
E	13000	6500	
F	80000	4800	
G	180	350	
H	27000	1300	
I	350	4200	
J	23000	91000	
K	5900	3600	<i>E. coli</i> <i>Penicilium</i> <i>Cladosporium</i> <i>Aspergillus</i>

1) : CFU = colony forming units

2) : limit: total aerobic bacteria and fungi <100 cfu



Illegal cannabis

- Heavily contaminated with fungi
 - Up to 600.000 colony forming units/gram
(source: Hazekamp);
- 50% of samples contaminated with pesticides
(source: Rikilt, The Netherlands);
- Heavy metals;
- No constant content (st dev: 15%).



Foundation of OMC

- In 1998 the Dutch government decided to establish an agency as regulator for medicinal cannabis according to art. 28 of Single Convention (UN);
- Foundation of the Office of Medicinal Cannabis (OMC) (1 March 2000);
- Office of Medicinal Cannabis empowered as national agency (1 January 2001);



National legislation

Amendment to the Opium Act (2002-2003)

- With respect to hemp, hashish and hemp oil Our Minister is, to the exclusion of others, authorized:
 - › to bring it inside or outside the Netherlands;
 - › to sell and deliver it;
 - › to have it available, with the exception of stocks maintained by those who have a license to cultivate, work up and convert.

Amendment to the Royal Decree (2002)

Royal Decree on prescribable and dispensable controlled substances.



Main responsibilities of the OMC

- Ensure constant quality of medicinal cannabis produced which meets pharmaceutical standards;
- Establish an effective procedure for distribution;
- Prevent leakage to the criminal circuit (tracking procedure / recordkeeping);
- Ensure availability of medicinal cannabis;



Organisational aspects



Policy within the Ministry of Health

Part of pharmaceutical affairs policy

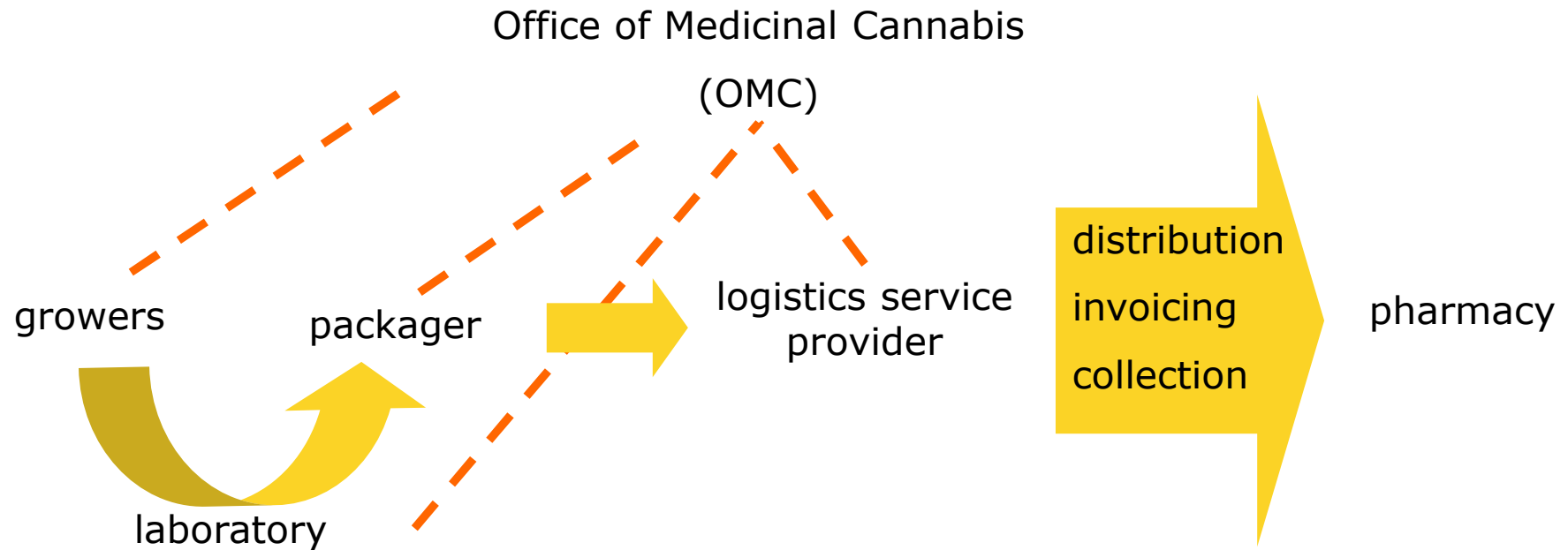
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Part of addiction care policy because:

1. Patients using cannabis as a medicine should not be stigmatised as drug abusers.
2. Cannabis as a medicine should meet all pharmaceutical requirements.



Production and distribution model





Contracted third parties:

Cultivation (Bedrocan BV)



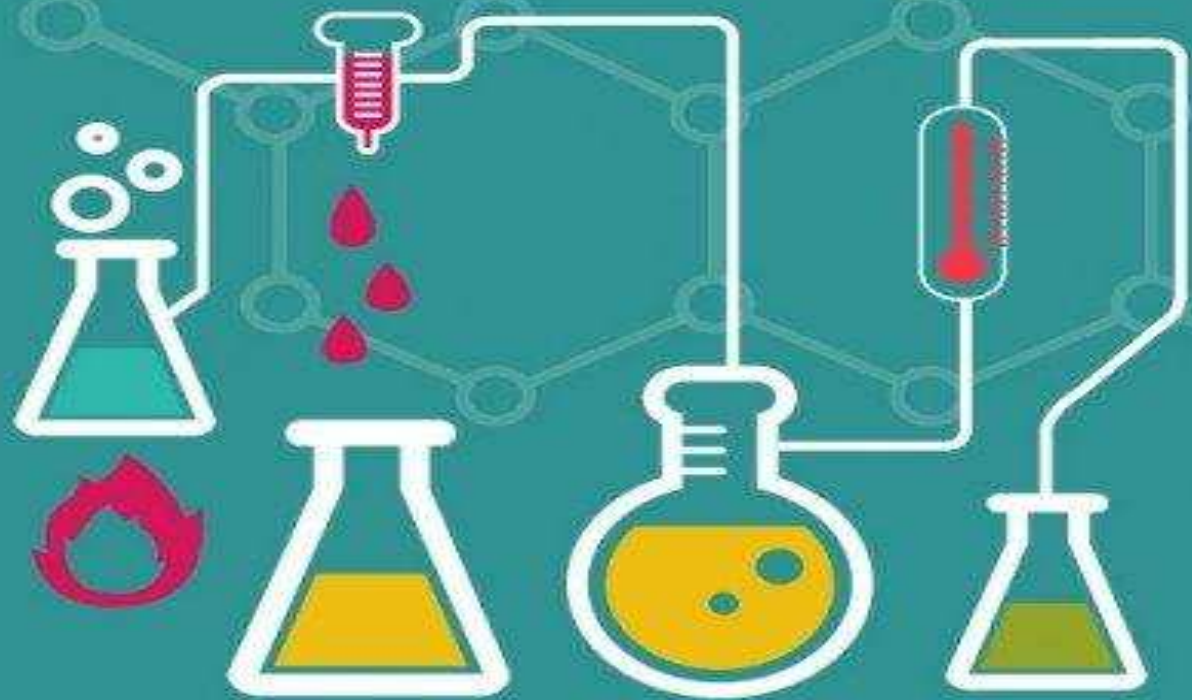
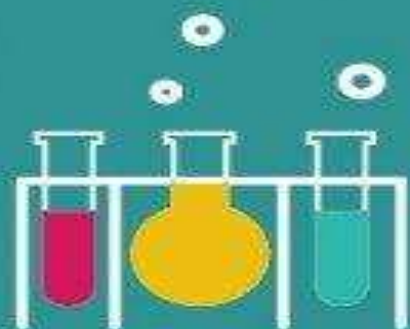
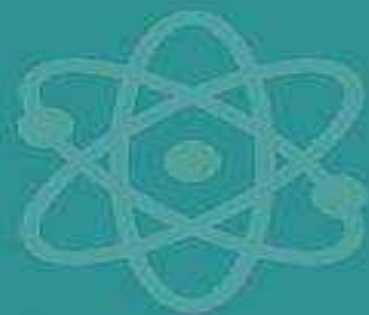
Quality control (Sinensis - Farmalyse BV)



Packaging and distribution (Fagron BV)



Pharmacy/Research/Product development




CHEMISTRY LAB

designed by  freepik.com



Laboratory analysis

- › Monography available;
- › Validated testing methods;
- › Every batch tested;
- › Approval by OMC;
- › Certificate of analysis for pharmacists.

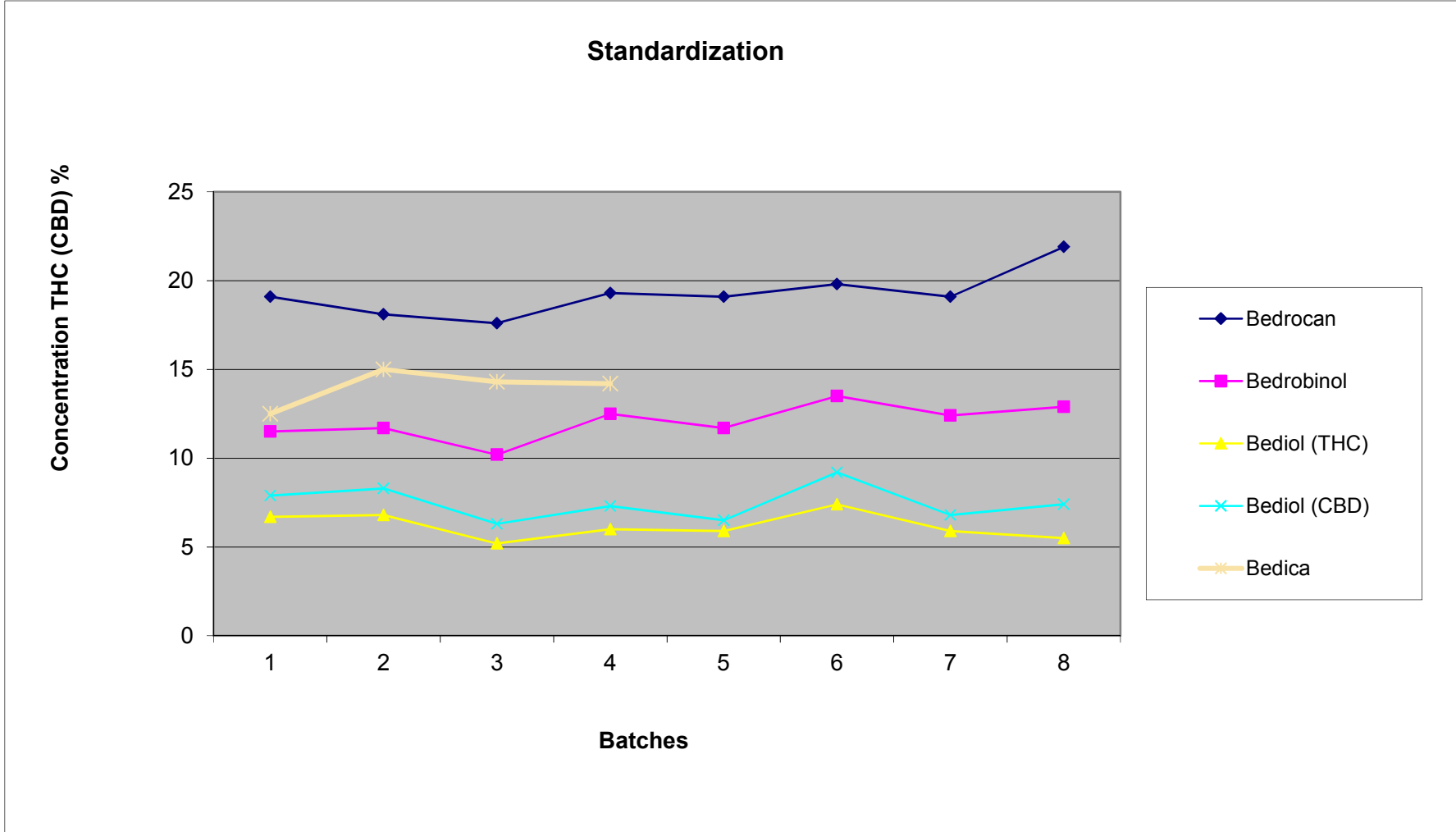


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Medicinal cannabis complies with pharmaceutical quality guidelines

- Standardized product with constant content (dronabinol, cannabidiol and other)
 - Within ranges of regulatory authorities
- Very low concentration of degradation compounds (e.g. CBN)
- Free of contamination
 - Micro-organisms
 - Pesticides
 - Heavy metals





Products

- Cannabis flos, variety Bedrocan: 22% THC, <1% CBD
- Cannabis flos, variety Bedrobinol: 13,5% THC, <1% CBD
- Cannabis flos, variety Bedica granulated: 14% THC, <1% CBD
- Cannabis flos, variety Bediol, granulated: 6,3% THC, 8% CBD
- Cannabis flos, variety Bedrolite granulated: <1% THC, 10% CBD









Pharmaceutical characteristics:

- Pharmaceutical raw material;
- Standardised herbal medicinal product;
- Not registered as a medicine;
- Opium Act.



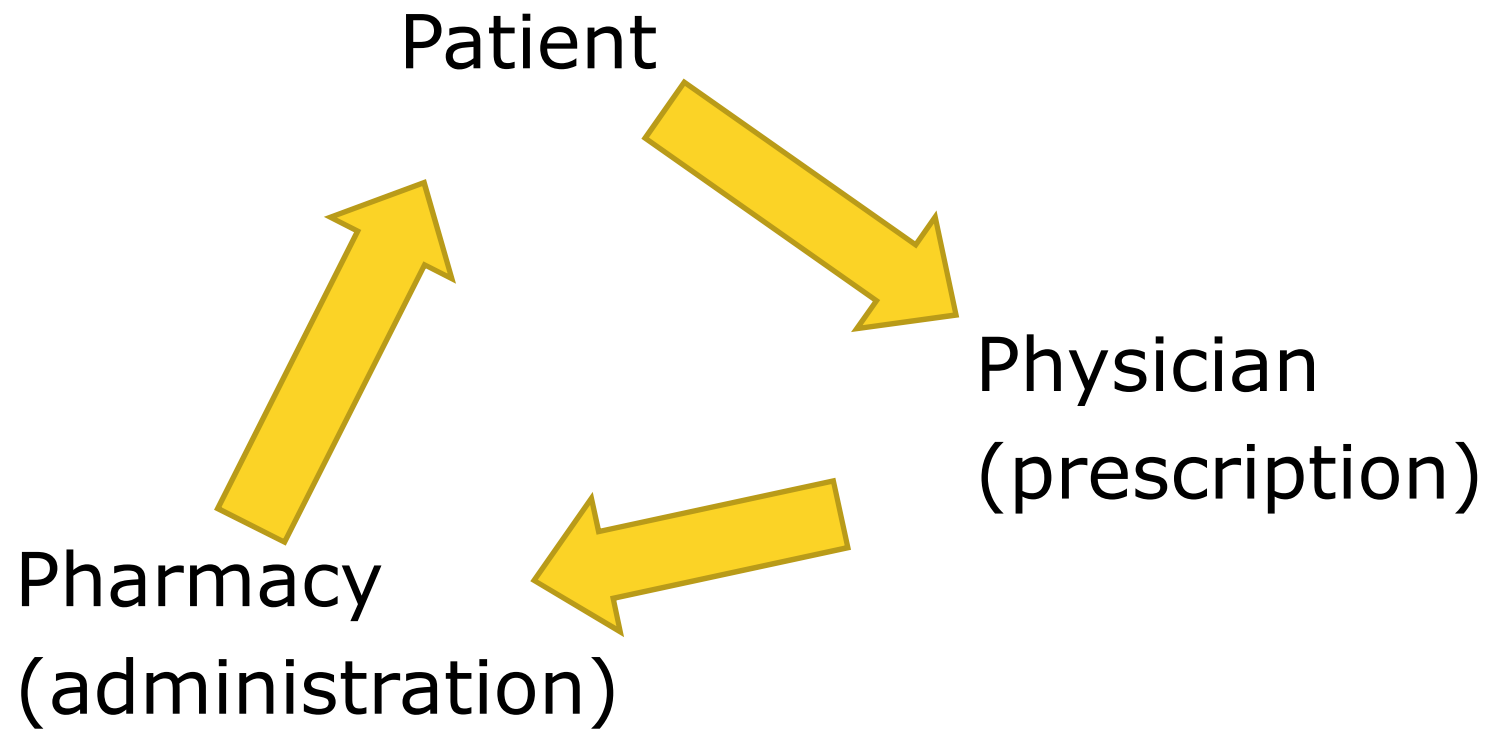
Indications

- Spasticity: multiple sclerosis, spinal cord injury, etc;
- Anti-emetic: chemotherapy, radiotherapy, etc;
- Appetite loss: HIV/AIDS, cancer, etc;
- Chronic pain / neuropathic pain: multiple sclerosis;
- Gilles de la Tourette syndrome;
- Glaucoma.



Prescription behaviour of physicians

- ***Only if treatment in conformity with guidelines or protocols does not work sufficiently or gives too many side effects.***
- ***A Dutch physician is free to prescribe medicinal cannabis for every indication***





Patient characteristics	N	Percentage
Age	53,1 ^	(24-81) ^
Sex		
Mail	35	(45,5%)
Female	42	(54,5%)
Variety		
Bedrocan	38	(49,4%)
Bedrobinol	19	(24,7%)
Bediol	16	(20,8%)
Bedica	4	(5,2%)
Therapeutic indication		
Multiple Sclerose	16	(20,8%)
Chronic pain	51	(66,2%)
Nausea / vomiting	7	(9,1%)
Cancer of AIDS	5	(6,5%)
Mental disorders	10	(13,0%)
Others	18	(23,4%)
Therapeutic use		
Decreased spasticity	37	(48,1%)
Pain relieve	63	(81,8%)
Anxiety	8	(10,4%)
Decreased drowsiness	42	(54,5%)
Appetite stimulation	10	(13,0)
Improvement daily functioning	26	(33,8)
Improvement state of mind	15	(20,8%)
Others	7	(9,1%)



	Bedrocan	Bedrobinol	Bediol	Bedica
Route of administration				
Tea	11 (29,7%)	3 (15,8%)	3 (18,8%)	1 (25,0%)
Inhalation	25 (67,6%)	15 (78,9%)	13 (81,3%)	3 (75,0%)
Vaporiser	9*	5*	4*	2
Smoking	23*	11*	10*	1
Others	2 (2,7%)	1 (5,3%)	0 (0%)	0 (0%)



Retrospective study 2003-2010 (Hazekamp et al, 2012)

	N= (%)	Average duration of use (days)	Average number of dispensations	Average daily use (grams)	
Study population	5,540 (100)	251	6.43	0.68	
<i>Age</i>					
≤ 20	93 (1.7)	181	5.57	0.82	
21-40	846 (15.3)	316	8.73	0.72	
41-60	2,551 (46.0)	304	7.44	0.66	
61-80	1,722 (31.1)	174	4.51	0.67	
> 80	303 (5.5)	99	3.01	0.74	
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Dependency - Tolerance

- Low average daily dosage points to a low potential of misuse;
- Absence of widespread development of tolerance;
- No signs that use of medicinal cannabis by Dutch patients may increase recreational use;



Study on (co)medication

Observations:

- 40,4 % decrease of comedication;
- 48,6 % unchanged;
- 0,9 % increase of comedication;
- 10,1% of patients did not use other medication

(PHARMO Institute, april 2004)



Need for information and (education)

Healthcare providers / health insurers:

- Lack of information;
- No guidelines available;
- Limited scientific evidence about efficacy;
- Difficult to determine therapeutic value;
- Lack of well-designed clinical trials / studies.



Guidelines: evidence-based

Example: Guideline 'Treatment of cancer pain'

<2008: 'oral cannabinoids **may not be used** for treatment of cancer pain'

>2008: 'oral cannabinoids **are not recommended** for treatment of cancer pain'

Argumentation:

Therapeutic value of cannabinoids for the treatment of cancer pain is not evidence-based;

Clinical experience is insufficient.



Supply of information in the Netherlands

- Leaflets for physicians, pharmacists and patients;
- Presentations for organizations involved;
- Direct contact with patients, general practitioners and specialists;
- Website and call center OMC;





Thank you for your attention.



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