



Integrating Cannabidiol in pharmaceutical grade herbal cannabis

May 22, 2014

**Tjalling Erkelens
CEO Bedrocan BV
The Netherlands**



Integrating Cannabidiol in pharmaceutical grade herbal



- Cannabis as herbal medicine
(history and cannabis as medicine)
- Standardization & quality control
(tour the facility)
- About THC, CBD and more
- Problems & Solutions

May 22, 2014

Tjalling Erkelens
CEO Bedrocan BV
The Netherlands

Short history

Before 1937:

Cannabis extracts are regular

Since 1937:

1937: Cannabis prohibition starts in USA

1961: UN drug treaties prohibit cannabis unless when used as medicine

All cannabis medicines taken from the market globally

1963: Discovery of CBD

1964: Discovery of THC

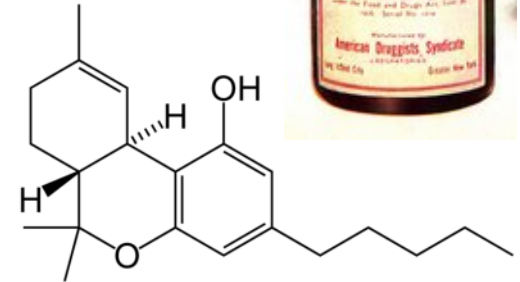
1988: Discovery of cannabinoid receptor in humans

2000: OMC's established in Canada and The Netherlands

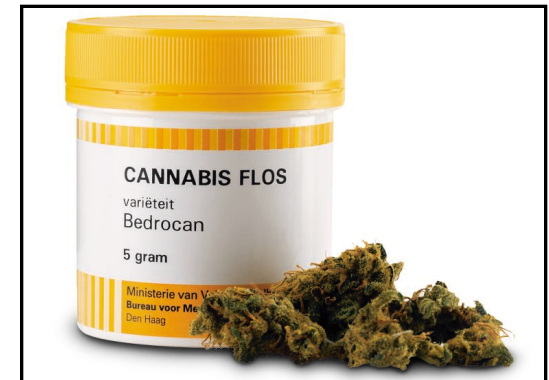
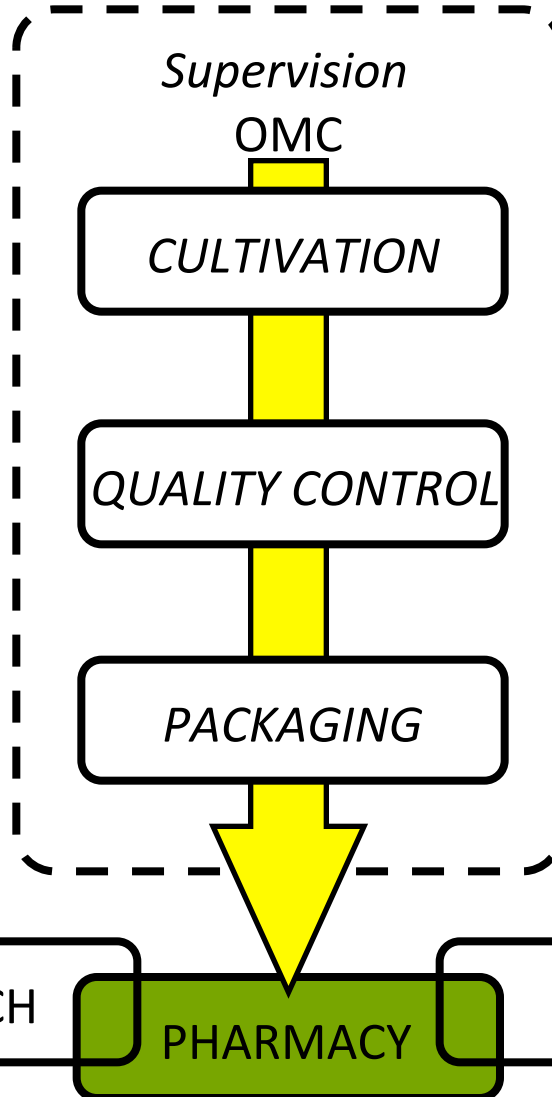
2005: First CBD variety: Bediol (6,5% THC/8 % CBD)

2014: First full CBD variety: Bedrolite in Canada and NL
9 % CBD < 1 % THC

medicine



Dutch model



Cannabis as a medicine



Heating Cannabis :

CO₂



THC-acid -----> THC

CBD-acid -----> CBD



-Tea

-Vaporizer

-smoking

-cake

} not advised

Cannabis as a medicine



Most important indications:

- Cancer (chemotherapie)
- HIV/Aids (appetite/nausea)
- Multiple Scleroses
- Neural pain (neural damage)
- Spasmes (Tourette syndrome)
- Glaucoma

In research:

- Psychological disorders
(ADHD/ bipolair/ PTSS)
- Inhibiting cancer cell growth

Active ingredients

THC: Nausea – pain – appetite – sleep

CBD: Psychosis – inflammation – anxiety – cancer

CBG: Pain – inflammation – antibiotic

Terpenes: Infection – inflammation – depression

Beta-caryophyllene
Humulene
Myrcene



Standardized production

1. Using genetic stable varieties
2. Only indoor production
3. Fixed schedules for growing
4. Fixed schedules for processing
5. Modular system
6. Active substances within standard limits
7. Science driven



Let's take a tour



Our collection of varieties



Starting the next generation



A cultivation room



Our CBD-variety Bedrolite



Harvest time



The drying room



Dried flowers



Processing of the buds



Samples for quality control



Ready for the pharmacy



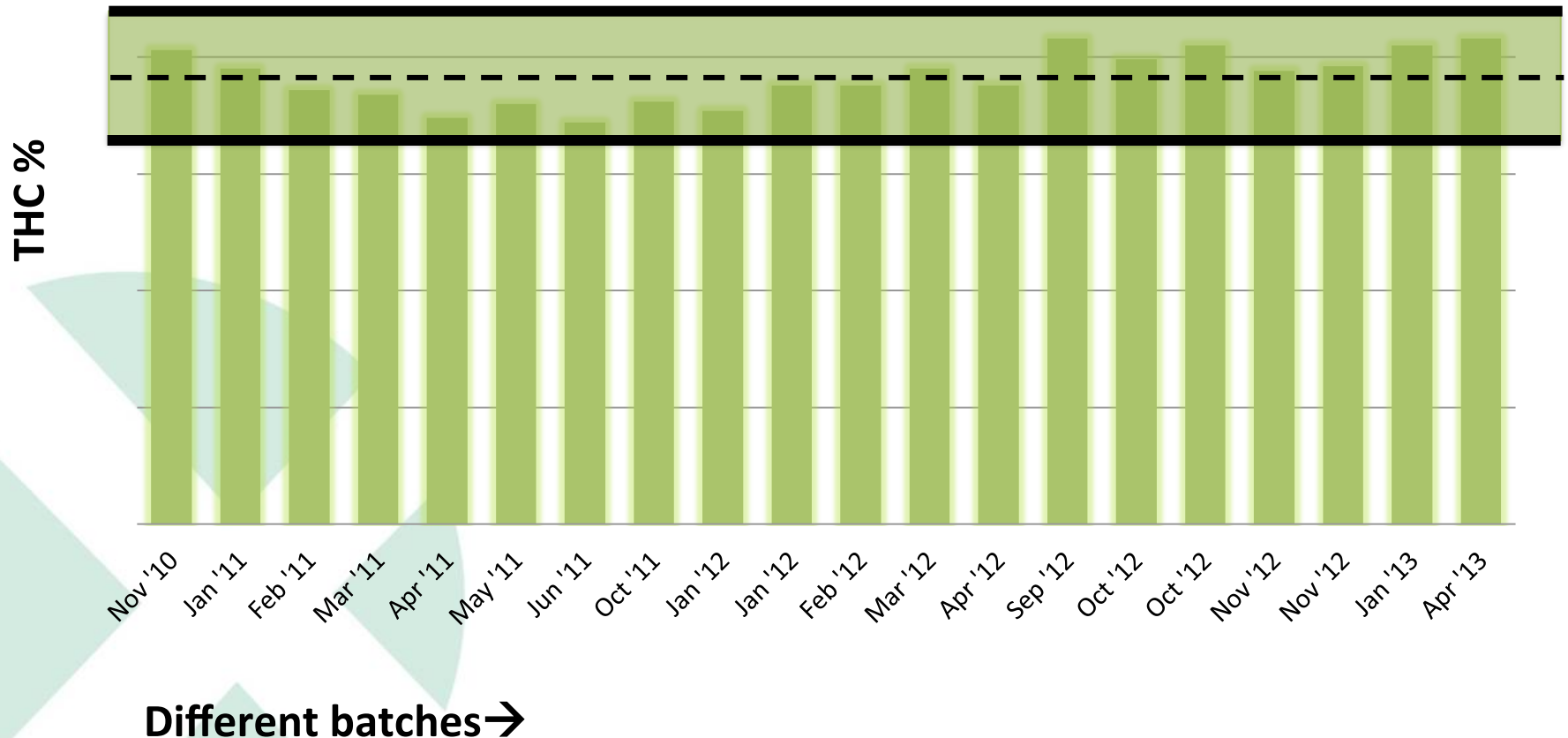
Available varieties

Variety	THC	CBD	Terpenes
Bedrocan [®]	22	-	sativa
Bedrobinol [®]	14	-	sativa
Bediol [®]	6	8	sativa
Bedrolite [®]	< 1	9	sativa
Bedropuur	23	-	indica
Bedica [®]	14	-	indica

In % of dry weight

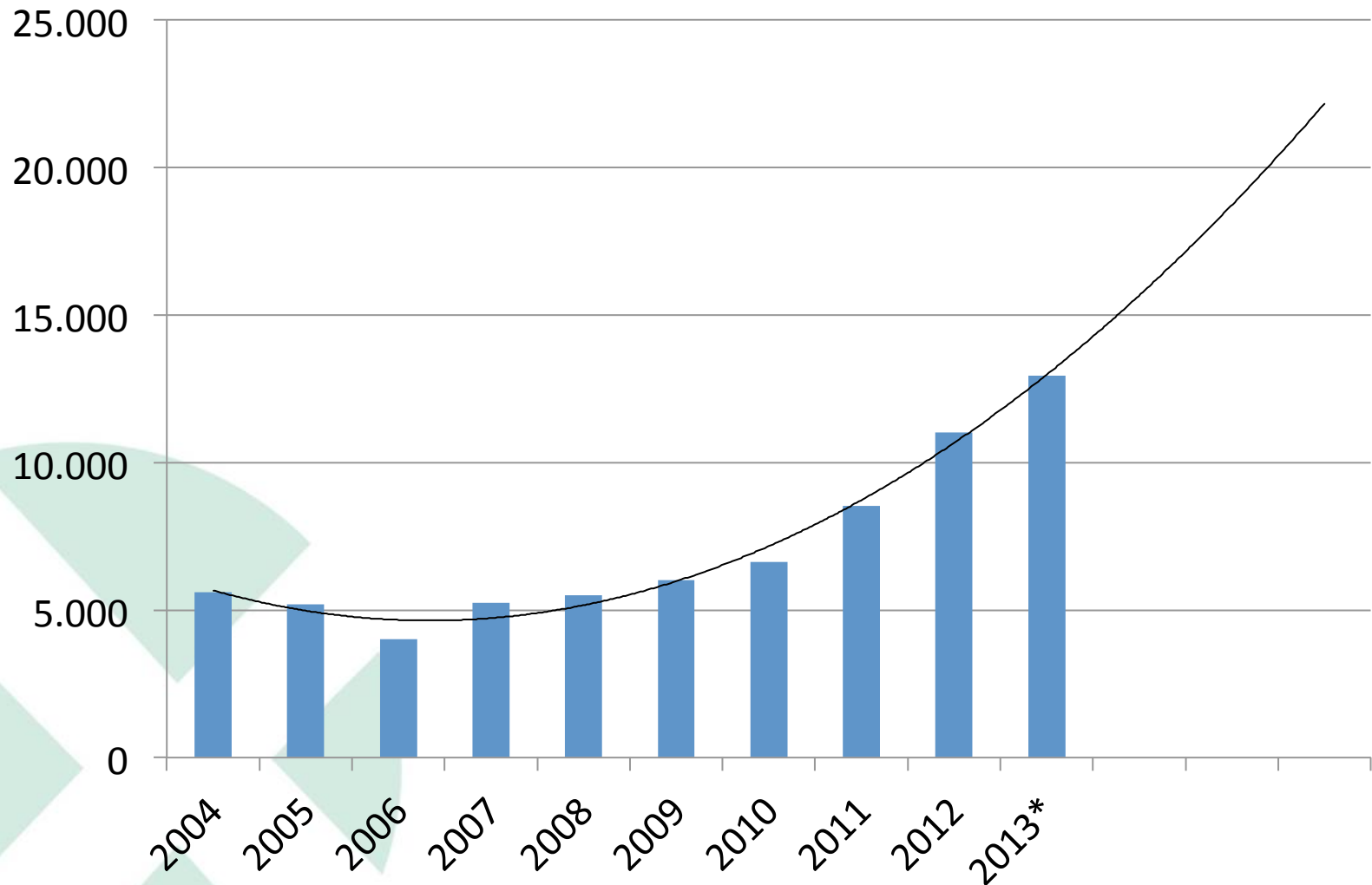
Always the same content

- Variety BEDROCAN: 22% THC
- Allowed deviation (*EU regulations for botanical drugs*)



Growing demand

Prescriptions per year in The Netherlands



Cost of treatment

- Per mg THC and per day

	Contnt	Price	Euro / mg	Use / day	Euro / day	Source
Bedrocan	22 %	8.67 €/gr	0.039	0.7 gr	6.07	OMC
US street cannabis	14 %	5.33 €/gr (200 \$/OZ.)	0.038	3 gr	15.99	www. priceofweed. com
Sativex	90 sprays x 2.7 mg	147 €/10ml (125 £/10ml)	0.60	8 sprays	13.07	GW - UK
Marinol	20 capsules x 2.5 mg	37.82 € (50 \$)	0.76	30 mg	22.69	www. Goodrx. com

Psychology claims(CBD !)

Depression

Anxiety

PTSD

- War veterans

Schizophrenia

Psychosis

- Chicken/egg

Results of 3 different varieties

Brunt et al

Journal of Clinical Psychopharmacology • Volume 34, Number 3, June 2014

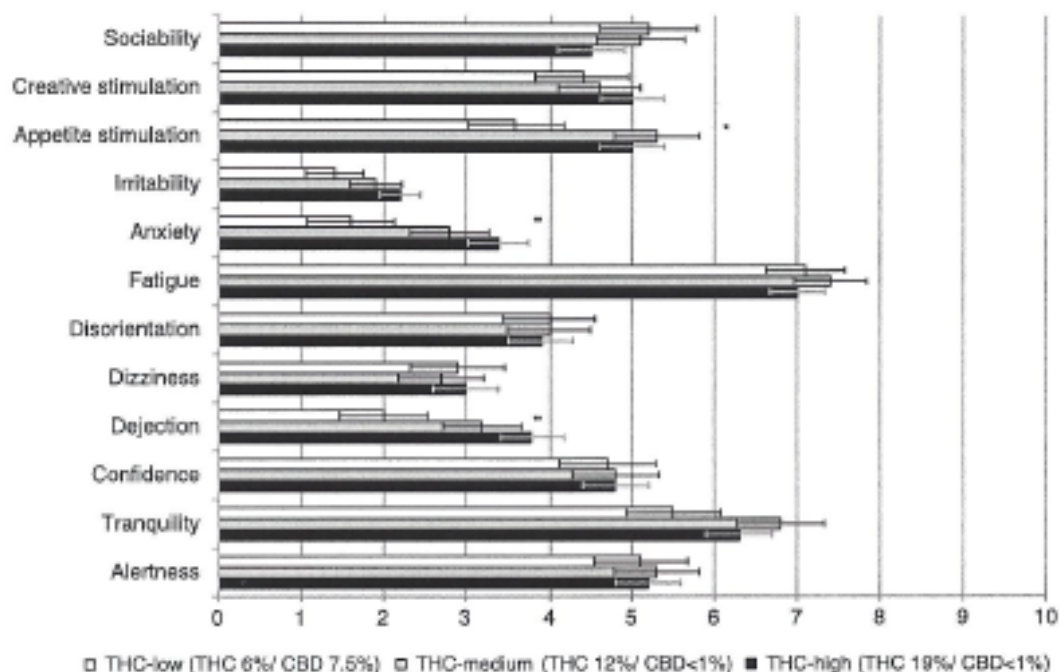


FIGURE 3. Mean VAS scores for 12 subjective effects of medicinal cannabis across the 3 cannabis strains. *Significant differences among the variants as determined with post hoc Bonferroni multiple comparisons.

Physical claims(CBD !)

Anti convulsant in rats (Chiu 1979)

Epileptic seizures in humans (Fernandez-Ruiz 2013; Jones 2012 and 2010; Carlini 1981; Karler 1981; Cunha 1980; Turkanis 1979)

Anti cancer (breast cancer) (McAllister 2011)

Child epilepsy (Pelliccia 2005)

“Baby Kaitlyn” (news paper story on Dravet Syndrome Canada 2013;)

CBD Problems

- No regulatory framework:
- Cannabidiol is not a pharmaceutical substance like THC (*safety and efficacy*)
- No proper dosaging
- No proper administration form



CBD Problems and solutions

- No regulatory framework:
- Cannabidiol is not a pharmaceutical substance like THC *(safety and efficacy)*
- No proper dosaging
- No proper administration form
- Dutch government wants to regulate CBD-extracts
- New administration forms in development
- Epidiolex[®] *(pure CBD extract GW Pharma received FDA Orphan Drug Designation)*
- Clinical trials needed

**So while more research is needed
Herbal cannabis as medicine needs to be
of pharmaceutical quality by default**



Thank you for your attention