European Monitoring Centre
for Drugs and Drug Addiction

European observations on regulating cannabis-based medicines

Cannabis: Myths & Facts

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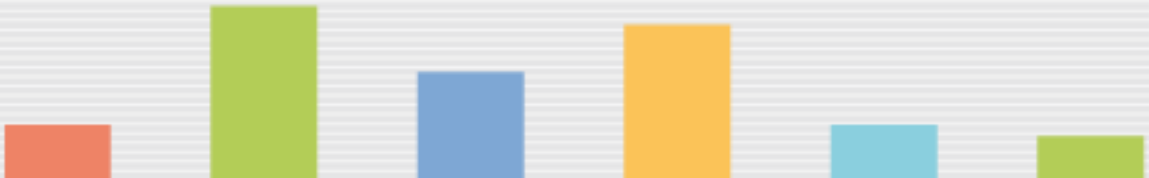


What is a medicinal product?

EU Directive 2001/83, Art 1(2)

Any substance or combination of substances presented for treating or preventing disease in human beings; or

bet kuri vaistinė medžiaga ar vaistinių medžiagų derinys, vartojamas žmonėms gydyti arba ligų profilaktikai; arba

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

bet kuri vaistinė medžiaga ar vaistinių medžiagų derinys, kuris gali būti skiriamas arba duodamas žmonėms jų fiziologinėms funkcijoms atkurti, koreguoti ar pakeisti farmakologiniu, imunologiniu arba metabolitiniu būdu arba nustatyti diagnozę.

A simple typology:

Medicinal products with marketing authorisation	Cesamet and Canemes Nabilone Synthetic cannabinoid similar to THC	Marinol and Syndros Dronabinol Synthetic THC	Sativex Nabiximols Plant-based: approx. equal quantities THC/CBD	Epidiolex Cannabidiol Plant-based CBD

Cannabis preparations (varied THC / CBD)	Raw cannabis	Magistral preparations	Standardised cannabis preparations

The medical use of cannabis and cannabinoids in the EU – medicinal products

- **Nabiximols (Sativex)** – available in most EU countries
- **Dronabinol and nabilone** (various medicinal products) – available in 1/3 of EU countries
- **Epidiolex** - under review at EMA, approved by FDA

- Sometimes, in some countries – costs are reimbursed by national health insurance systems

The medical use of cannabis and cannabinoids in the EU – cannabis preparations

- Increasing number of countries
- Policies and practice are evolving rapidly; dynamic
- Variety of approaches
- Standardised or magistral preparations?
- Different routes of administration
- Different indications and applications
- Prescription by?
- Reimbursement?

Availability of cannabis preparations for medical use in the European Union and Norway

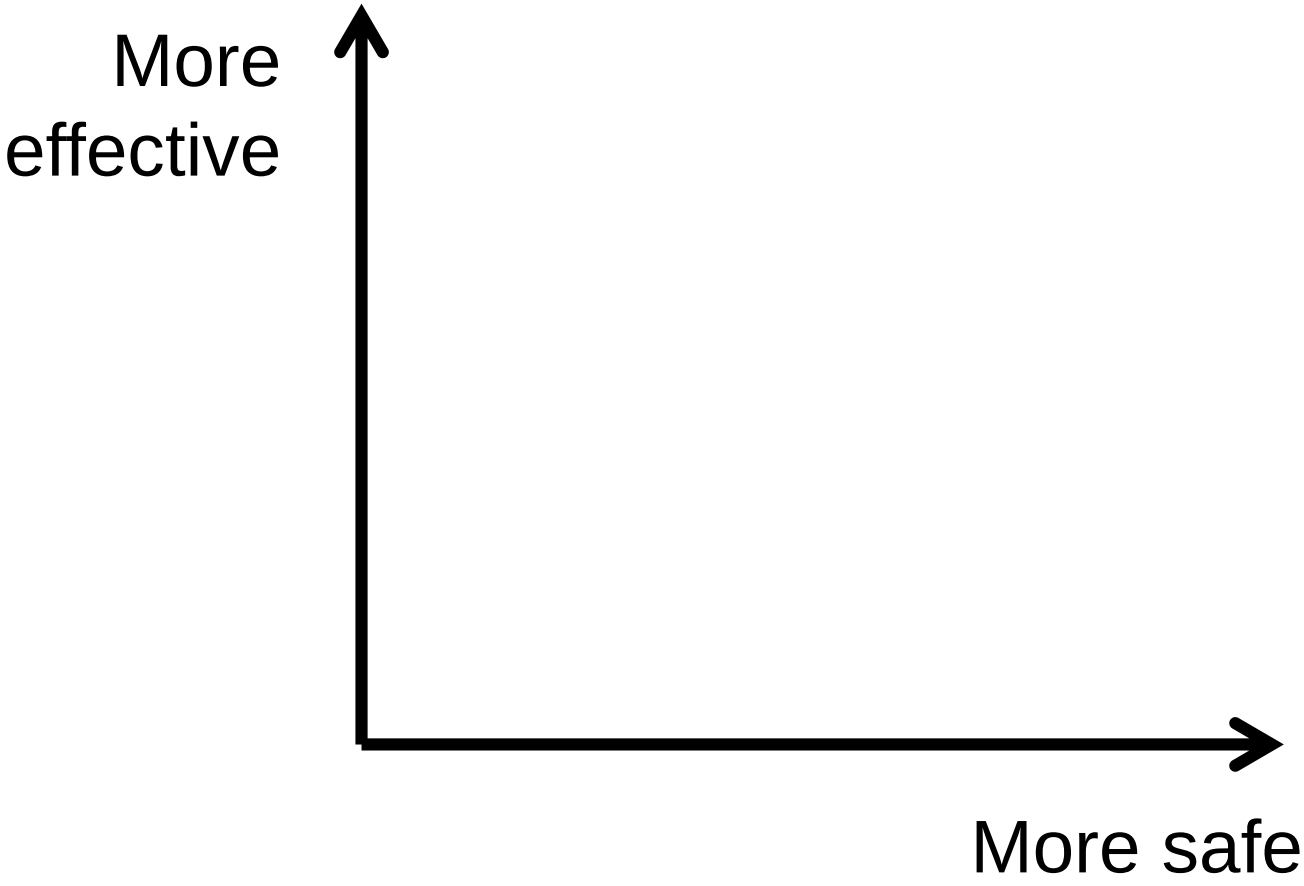
The current evidence - summary

- Cannabinoids relieve the symptoms of some illnesses
- In these cases, they are often added to other medical treatments rather than used on their own.
- They are also typically used only after a patient has failed to respond to recommended treatments for these conditions
- Need for additional research and clinical studies (including larger trials, studies looking at dosage and interactions, and studies with longer follow-up)
- Harms are similar to those of other commonly used medicines and serious adverse events are rare.

Limitations: evidence base is evolving rapidly, but currently quite limited and fragmented; in addition, often different cannabis products and preparations have been used.

Additional details in the background paper.

Is it better than existing medicines?



Regulatory frameworks

International Drug Control Law

- UN Single Convention 1961: Cannabis included in (Schedule I and) Schedule IV; 'serious risk of abuse' + 'no medical value'
- BUT January 2019: WHO-ECDD recommendations:

  - Remove cannabis from Schedule IV ('serious harm and no medical value');

  - CBD with less than 0.2% THC should be excluded from international drug control.

European (EU) medicines authorisation:

Centralised / decentralised / mutual recognition procedures.

To date, no EU-wide marketing authorisation for cannabinoid-containing medicinal products.

National regulation without formal marketing authorisation in Europe

- Early access (for medicines not yet approved, still in trial) using specialised prescriber and named patient: CZ, HR…

- Expanded access (using national regulations): NL, IT, DE…

Could cannabis be sold and marketed as a herbal medicine?

UN drugs Convention / no prescription

Indications and applications

Country	Indications	Route of Administration
Netherlands	MS, HIV, cancer, pain, Tourette's	Vaporising or infusion
UK+ / EMA	MS	Spray under tongue
Czech Republic	Cancer, Parkinson's disease, MS or psoriasis	
Croatia	MS, cancer, epilepsy, AIDS	Infusion, ointment, galenical: Not smoking or vaporising
Italy	Supporting standard treatments: MS, pain, chemo or HIV, appetite from cancer or AIDS, glaucoma, Tourette's	Vaporising or infusion
Germany	life-threatening illness, or one that will affect quality of life permanently because of severe health problems.	
Denmark	MS, central nervous pain, spinal cord injury, chronic pain where other treatments are inadequate, nausea and vomiting after chemotherapy	

North America or Europe - comparable?

	Colorado	California	Canada	Netherlands
Year Started	2001	1996	2001	2003
Population (approx)	5m	39m	36m	17m
Registered users	11 000 (pre commerc.) 100 000 (post commerc.)	800 000 (est)	140 000	1 200
Approx Users/ M. Pop.	20 000	20 500	3 900	71

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Challenges for Regulation

- ✓ Type of products? Medicinal, or preparations?
- ✓ Raw cannabis, magistral preparations, other preparations?
- ✓ Routes of administration?
- ✓ For which medical conditions?
- ✓ Who manufactures?
- ✓ Who can prescribe?
- ✓ Training and guidelines for prescribers?
- ✓ Who pays?
- ✓ How to monitor outcomes?
- ✓ Quality standards?

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Thank you for listening