

## **Dronabinol Evidence**

**By Joanne Griffiths & Lara Smith**

The EMCDDA states that,

“The major active principle in all cannabis products is  $\Delta$ 9- tetrahydrocannabinol ( $\Delta$ 9-THC or simply THC), also known by its International Non-Proprietary Name (INN) as dronabinol.

[Cannabis drug profile | www.emcdda.europa.eu](http://www.emcdda.europa.eu)

The World Health Organisation states that,

“ International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.”

### **Assessment of dronabinol and its stereo-isomers - World Health Organization**

The primary psychoactive compound in botanical cannabis (*Cannabis sativa* L.) is dronabinol ( (-)-trans-delta-9-tetrahydrocannabinol,  $\Delta$ 9-THC) (Gaoni and Mechoulam, 1964; ElSohly, 2002). Other cannabinoids present in the cannabis plant modulate the pharmacological effects of dronabinol.

Dronabinol is frequently referred to as synthetic, but as can be seen on the EMCDDA website and World Health Organisation documents, that this is not the case.

Page 12 of the 2016 [Drug Science report](#) prepared for WHO, reports that several medicinal cannabis preparations come under the INN name is dronabinol.

Dronabinol was rescheduled in 1995 from schedule 1 to schedule 2 via Statutory Instruments 2047 and 2048, to allow for medical use.

Additionally, a 1995 Home Office Document confirms that dronabinol was rescheduled to allow for prescription- without the need for a Home Office Licence. It also notes that dronabinol is the active constituent of cannabis.

Please see Home office document if you click onto the PDF version-

[Annex disclosed records on dronabinol scheduling.pdf \(whatdotheyknow.com\)](#)

[Annex disclosed records on dronabinol scheduling.pdf](#)

We have in writing from [Raphael Mechoulam](#) before he died information about THC/ dronabinol. According to his statement, THC and dronabinol are the same molecule, with dronabinol being the name given to delta-9-THC for legal reasons. Mechoulam confirms that there is no scientific or medical difference between the two. He also states that THC can be extracted from cannabis, synthesized, or prepared from CBD, and when pure, it is exactly the same.

### **Real-World Prescribing Example**

In 2015, cannabis flower was prescribed by a UK doctor under the name dronabinol, as shown in the photo below. This prescription label demonstrates that dronabinol terminology was actively used in clinical practice, even for whole-plant cannabis. It directly supports the argument that dronabinol is not limited to synthetic formulations but is also applied to naturally occurring THC in medical cannabis products.

This real-world example aligns with the WHO's definition of dronabinol as the primary psychoactive compound in botanical cannabis, and with UK-authorized medicines like Sativex that contain plant-derived dronabinol.



## **UK Medicines Confirm Plant-Derived Dronabinol**

Before Lara Smith's correspondence to the ACMD, it is important to highlight two authoritative sources that directly support her concerns:

- The [RxReasoner drug profile](#) for Sativex lists dronabinol and cannabidiol as active ingredients, stating that "dronabinol is an active ingredient of cannabis."
- The [British National Formulary \(BNF\)](#) confirms that Sativex contains naturally occurring delta-9-THC (dronabinol) extracted from cannabis.

These sources affirm that UK-authorized cannabis medicines contain plant-derived dronabinol, contradicting the 2018 Misuse of Drugs Regulations which exclude cannabis-derived dronabinol from the definition. This contradiction is central to Lara's submission below.

## **2024 Correspondence to the ACMD from Lara Smith**

Why therefore, is medical cannabis prescribed as THC and not as Dronabinol?

As I understand the law was amended in 1995, by Statutory Instrument Number 2047 and 2048 to allow for the prescription of Dronabinol.

In the book Cannabis: [The Genus Cannabis](#): Medicinal and Aromatic Plants (2003) it states that,

"With similar intent, in 1995 the UK amended their Misuse of Drugs Regulations 1985, specifically naming "Dronabinol" in S2 of the regulations and concomitantly removing it and its stereoisomers from the list of drugs designated under s7 (4) of the MDA 1971 as having no therapeutic value. These two changes enable any stereoisomer of delta 9 THC to be used in medical practice in the UK."

It also states in the book Forensic Chemistry of Substance Misuse: A guide for forensic scientists by Leslie A King (2009) that,

"The major active principle in all cannabis products is delta 9 - tetrahydrocannabinol (delta 9-THC) also known by its international Non-proprietary Name (INN) as dronabinol."

So I find myself rather perplexed at the 2018 misuse of drugs regulations which states that,

"dronabinol does not include any substance which

a) has the international non-proprietary name dronabinol (recommended by the world health organisation); and

b) is derived from cannabis, cannabis resin or their constituents”,

It does not seem to make any sense that dronabinol does not include any substance which is derived from cannabis, when dronabinol is defined as being the primary psychoactive in botanical cannabis according to the WHO.

As documented in the EMCDDA (2002) although dronabinol can be "chemically synthesized", which is marketed as Marinol, it is nevertheless the active compound which occurs naturally in the cannabis plant.

The World Health Organisation (2014), in the document Cannabis and Cannabis Resin, states that,

"The United Kingdom produces cannabis for the production of a **dronabinol-cannabidiol** combination preparation for the treatment of spasticity due to multiple sclerosis (Sativex) that is prepared using cannabinoids extracted from plant material."

The WHO (2014) document also refers to the constant strength of **dronabinol** in Dutch medical cannabis...

"An example of production with good quality assurance is the Dutch medicinal cannabis. This is produced under responsibility of the Ministry of Health and meets a number of quality requirements: constant strength on **dronabinol** and constant composition of secondary cannabinoids..."

It further states in the WHO (2014) document that,

"Where there is a norm provided in the European Pharmacopoea, this norm is followed".

Thus, I would like to ask, why is this norm not being followed?

A doctor could not prescribe heroin but would prescribe diamorphine. So why is medical cannabis being prescribed as THC instead of Dronabinol?

In the Statutory Instrument of 2018, has the Government defined Dronabinol as being chemically synthesised?

If so why, as dronabinol is clearly the active compound, as evidenced above, in botanical cannabis?