College of Psychiatrists of Ireland

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Cannabidiol (CBD) and CBD products

Factsheet

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Content:

The College of Psychiatrists of Ireland

The College of Psychiatrists of Ireland, formed in 2009, is the professional and training body for psychiatrists in the Republic of Ireland. The Mission of the College is to promote excellence in the practice of psychiatry, and to advocate for the highest standards in our mental health services.

Prepared by a College Committee specifically set up to develop important information on the general risks of CBD and cannabis to mental health.

1. What is Cannabidiol (CBD)?

CBD is one of the more than 100 cannabinoids in cannabis. THC (delta-9-tetrahydrocannabinol) is another cannabinoid which is known to be associated with psychoactive properties.

2. How has it been possible for CBD and its products to be sold in Ireland?

In Ireland, CBD products are sold as food supplements and come under the regulation of Food Safety Authority of Ireland (FSAI). According to FSAI [1], no health or medicinal claims for hemp or CBD products (currently sold in shops) has been authorised in the sale of these CBD products under Regulation (EC) No. 1924/2006. Furthermore, after a recent national survey, FSAI have published a warning to the general public that the majority of the CBD products analysed by them significantly exceed the safety limits for THC set by European Food Safety Authority (EFSAI) and also that the content of CBD varies significantly in these products sold as food supplements [2]. According to the EFSAI [3], the maximum amount of THC should not exceed 0.2% in hemp (containing CBD). Similar issues with levels exceeding 0.2% of THC have been reported in other countries with varying amounts of CBD.

3. Are there exceptions in Ireland?

Under the Medical Cannabis Access Programme (MCAP) [4] which was established by law in June 2019, on a pilot basis for five years, medical consultants will be able to prescribe a cannabis based product (which are different to cannabis based medicines) for three medical conditions under specific requirements as set out in the law. The person must have failed to respond to standard treatments for three conditions:

- spasticity associated with multiple sclerosis
- intractable nausea and vomiting associated with chemotherapy and
- severe and treatment-resistant refractory seizures.

In addition to that, the Minister of Health has the authority to license use of cannabis associated product on individual application and this license has reportedly been granted in individual cases.

Cannabis based products are often from extracts of cannabis plant or material from dried cannabis plant which have not been assessed by regulatory authorities for its efficacy, quality and safety in addition to lack of clinical trials and assessment of their risk/benefit profile [5]. Until now, three cannabis based products have been approved for use under the Medical Cannabis Access Programme (MCAP) by the Minister of Health [6].

4. Can a person access (authorised) cannabis based medicine in Ireland (which do not come under the MCAP)?

Cannabis based medicines (which are different to cannabis based products described as above) are medicines which are subject to ongoing monitoring by regulatory authorities such as the Health Products Regulatory Authority (HPRA). These cannabis based medicines are obtained from synthetic or

standardised extract of cannabis plant and are approved for use as a medicine based on clinical trial data [5].

In Ireland:
Sativex oromucosal spray (generic name-Nabiximols) is authorised as a medicinal product for use in spasticity associated with multiple sclerosis, resistant to other treatments. Sativex contains both CBD and THC. It is currently not available under the reimbursement scheme in Ireland although this is being reviewed at present.

Marinol (generic name-Dronabinol) which contains synthetic THC requires the Minister's license before it is prescribed for nausea and vomiting associated with chemotherapy.

Epidyolex, which is reported to contain only CBD, is licensed for use by European Medicines Agency (EMA) since 2019 for two severe and rare forms of epilepsy namely Lennox-Gastaut Syndrome and Dravet syndrome. The HPRA (Health Products Regulatory Authority) has approved use of it in Ireland based on the license by EMA. It has not yet been actively marketed in Ireland by the manufacturers of Epidyolex but this may change in the future.

5. Is CBD known to cause adverse effects?

Most of the studies examining the adverse effects of CBD and its products sold through health food shops are very limited, leading to claims that CBD has no adverse effects. However there are common side effects reported by the European Medicines Agency (EMA).

Epidyolex
The most common side effects (as reported by the EMA) of Epidyolex which contains CBD include reduced appetite, urinary tract infection, increased body temperature, irritability, poor sleep, aggression, abnormal behaviour and agitation. *Of note*, Epidyolex has been shown to increase liver enzymes in a dose dependent pattern in clinical trials. This has led to Epidyolex being discontinued for affected patients. Hence, liver enzymes [alanine aminotransferase (ALT), aspartate aminotransferase (AST) and bilirubin] should be measured at one, three and six months after Epidyolex is commenced and periodically thereafter or as required clinically [7].

Sativex (Generic name -Nabiximols)
Sativex oromucosal spray (generic name-Nabiximols) is contraindicated in those with severe personality disorders, known family history or suspected or known history of schizophrenia or other psychotic disorders and other significant psychiatric conditions other than depression associated with their underlying condition. It is also not recommended in those with serious cardiovascular conditions.

Adverse effects reported with Sativex include changes in mood, anxiety, paranoid ideas, hallucinations, confusion. It has also been reported to cause loss of consciousness in a few cases, and, hence, caution with driving and heavy machinery after using Sativex is recommended. Manufacturers of Sativex recommend immediate discontinuation if the user of Sativex experiences psychotic symptoms or starts having suicidal ideation [8].

6. Does CBD interact with prescribed medications?

Limited studies analysing the interaction of CBD (from places like health food shops) with prescribed medications have suggested CBD when combined with prescribed medications results in adverse effects due to increased levels of the prescribed medication, or the prescribed medications being less effective due to lower levels. Similar findings have been reported for Epidyolex when combined with other prescribed medications [7]. Manufacturers of Sativex recommend care when using it with sedatives or medications with psychotropic effects. In addition, caution is suggested when using Sativex with some prescribed medications due to the possibility of interaction with them [8].

7. Does CBD help with anxiety, post-traumatic stress disorder (PTSD), psychosis, depression, and insomnia?

There have been widespread advertisements and claims in the media that CBD helps with various conditions such as anxiety, PTSD, psychosis, depression, insomnia. However, there is very little if any, large scale controlled trials examining the role of CBD in managing these conditions. The evidence until now does not support the use or prescribing of CBD or associated products for these psychiatric conditions including a study, published by the Lancet Psychiatry journal, stating that there is insufficient evidence to provide guidance on the use of CBD in mental disorders at present [9]. There are ongoing research studies on this issue in some countries and the outcome of such studies and further future large scale clinical trials may guide future role of CBD in certain psychiatric illnesses.

8. Is it safe to use CBD or its products in pregnancy and in breastfeeding?

No, there is inadequate evidence to suggest the safety of CBD and its products in pregnancy and in breastfeeding. Use of CBD in animal studies have suggested risk to the foetus and it is also expected that CBD would be passed on to the baby through the breast milk. Hence, regulatory bodies including FDA [10] advise against the use of CBD or its products during pregnancy or while breastfeeding.

Please note:

Evidence on cannabidiol (CBD) is a rapidly evolving subject and we will endeavour to update this fact sheet as further evidence becomes available. (March 2021)

References:

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