



# Association of British Neurologists

## ABN statement on use of marijuana (cannabis) related products in the treatment of complex epilepsies

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The Association of British Neurologists (ABN) is the professional association that represents neurologists, whose roles including caring for adults with difficult epilepsies in the UK. The ABN actively supports scientific research in the area of epilepsy that leads to better understanding and treatment of the condition.

Epilepsy affects 1-2% of the population of the United Kingdom and one third of those will have seizures that are not controlled by currently prescribed medications. There is a legitimate interest amongst patients, families of people with epilepsy and medical professionals in any new therapies that may improve control of these difficult epilepsies.

Anecdotal reports regarding marijuana use for epilepsy have been around for over 150 years. Over 100 active compounds have been derived from the marijuana (cannabis) plant. Two of these compounds, cannabidiol (CBD) and tetrahydrocannabinol (THC), have been investigated the most for their possible therapeutic potential in medicine. THC is the major psychoactive component of marijuana that is responsible for giving so-called "highs" to recreational users of cannabis. CBD is not psychoactive in this way.

Both CBD and THC have been shown experimentally to have anti-epileptic effects. They act in different ways in the brain to achieve this effect. However, there is significant evidence that use of THC in the developing brain can cause damage to IQ, mental health and brain structure. These changes may be permanent. Consequently, doctors and scientists have concentrated instead on investigating the potentially less damaging cannabidiol (CBD) as a treatment for epilepsy, with studies having been carried out mainly in children.

One pharmaceutical company has produced a pure form of CBD (that contains less than 0.1% THC) and has rigorously investigated its use in two rare severe epilepsy syndromes: Dravet Syndrome and Lennox-Gastaut Syndrome. They have done this by conducting scientifically rigorous, double-blind, randomized controlled trials. This is the gold-standard method of investigating the efficacy of new drugs. These trials have shown that CBD is moderately but significantly more effective than a dummy treatment (placebo) in the control of seizures in these two conditions. However, the trials also showed that CBD had more side-effects than placebo and had interactions with other anti-epileptic drugs (eg clobazam and sodium valproate). The drug is also being evaluated as an add-on therapy for adults with poorly controlled focal seizures. The US Food and Drug Administration (FDA) has recently approved this purified form of CBD for use in Dravet Syndrome and Lennox-Gastaut Syndrome. The position for use in the UK for similar indications has recently changed<sup>1</sup>. It is not yet clear whether there will be any age restrictions in upcoming licencing.

There are pharmaceutical grade cannabis products produced in other countries that have higher concentrations of THC (ie greater than 0.2%). The efficacy of these products as a treatment for epilepsy in children or adults, their interactions with other drugs and their side-effects have not been assessed in scientifically rigorous double-blind randomized controlled trials. They are not licensed for use in the UK and are not currently legal in the UK.

There is a wide-range of other cannabis products ("artisanal cannabis oils") available on the internet, in some commercial outlets (eg health food shops) and from "marijuana

dispensaries” in some countries. These products will contain both CBD and THC in varying quantities and proportions. If the quantity of THC is less than 0.2% then they are legal in the UK. Products containing more than 0.2% can be purchased abroad and are currently not legal in the UK. Legal artisanal cannabis oils are not pharmaceutical grade products. As well as CBD and THC they may well contain other cannabinoids, pesticides and impurities. Independent laboratory testing of these products often reveals that they have different quantities of CBD and THC than is detailed on their label. It has also shown that different batches of the same product have different concentrations of constituents. Therefore, whilst individuals or their parents or carers may choose to use legal CBD-based oils, there are possible risks, including interactions with other antiepileptic drugs and worsening of seizure control. Patients and families should always discuss any such decision with their healthcare professional and should not stop taking their epilepsy medication without the supervision of their doctor.

The cannabis oils may have anti-epileptic effects and there are anecdotal reports of positive results in children with epilepsy. However, anecdotal reports should not determine treatment policy for the population as a whole and products with high concentrations of THC may cause significant damage to the developing brain. ABN does not support the use of street cannabis, which can be very dangerous and cause many mental health and respiratory problems.

In 2017, the UK's medicines regulator, Medical and Healthcare products Regulatory Agency (MHRA), said that all CBD products available via the internet and high street shops, should be classed as medicines. The MHRA has since been working with individual companies and trade bodies to make sure products containing CBD which can be classified as medicines, satisfy the legal requirements of the Human Medicines Regulations 2012.

On July 26th 2018, the Home Secretary rescheduled cannabis-derived medicinal products<sup>1</sup>. This means that senior doctors will be able to prescribe these medicines to patients with an exceptional clinical need. The Department for Health and Social Care and the MHRA are to develop a clear definition of what constitutes a cannabis-derived medicinal product so they can be rescheduled and prescribed. Only products meeting this definition will be rescheduled. Other forms of cannabis will remain under strict controls and will not be available on prescription. This change was made on advice from two sets of independent experts: the Advisory Council on the Misuse of Drugs (ACMD) agreed that there is evidence of medicinal benefits from some of these products in certain circumstances and clinicians in the UK should therefore have the option to prescribe cannabis-derived medicinal products for their patients.

The ABN is very sympathetic to the needs of people with epilepsy that is difficult to treat, and their families. Our members are devoted to improving the lives of people with epileptic seizures. We are keen to investigate the therapeutic potential of all new drugs coming to market, including pharmaceutical grade cannabis-related products, in robust scientific treatment trials and to support the use of scientifically tested and proven treatments in appropriate clinical circumstances. We encourage those with complex epilepsies to consult with their neurologist to explore the many treatment options that exist and to make informed decisions about the pros and cons of different treatments.

1. <https://www.gov.uk/government/news/cannabis-derived-medicinal-products-to-be-made-available-on-prescription>

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<https://www.bpna.org.uk/userfiles/file/BPNA%20Cannabis%20statement%2004072018.pdf>

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