

# Cannabidiol (CBD)

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*Working with people affected by a brain tumour, healthcare professionals, policy makers and politicians, we will deliver equal access to the best treatment and care.*

## Key points

Cannabidiol (CBD) is a naturally occurring cannabinoid found in cannabis plants. This paper refers primarily to those CBD-based products which may be obtained legally and do not contain the illegal psychoactive ingredient tetrahydrocannabinol (THC).

- The charity's position on cannabis and other cannabis based products (including cannabis oil) is explained in a separate statement.
- There is no evidence that CBD can treat brain tumours, however it may be used by people affected by a brain tumour for a variety of reasons including the management of neuropathic pain or epilepsy.
- The Medicines and Healthcare products Regulatory Agency (MHRA) stated that CBD-based products cannot be marketed for medicinal purposes without a marketing authorisation (medicines licence). It is not clear to what extent this will affect the availability of those CBD-based products currently used by people affected by a brain tumour



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## Introduction

People affected by a brain tumour may see radical and long-term changes in quality of life as a result of the condition and treatment. It is essential that they can manage their symptoms and that products designed to improve quality of life are safe.

Products containing CBD come in a variety of forms including oil, shampoo and skin cream. We recognise that many people affected by brain tumours are using CBD oil and other CBD-based products for side-effects that they experience.

Sativex is the only licensed medicine in the UK which contains CBD, in addition to THC<sup>1</sup>. It is licensed for people with multiple sclerosis and doctors can prescribe it off label for people with other diseases<sup>2</sup>. However, it is only currently available on the NHS in Wales and doctors take personal responsibility for giving medicines off-label so may be hesitant to do so. Medical products must be issued a license before they can be legally sold, supplied or advertised (including for prescription) as medicine.

Studies suggest that CBD may alleviate chemotherapy-induced neuropathic pain<sup>3</sup> and epilepsy<sup>4</sup> and that CBD has relatively few side-effects compared to other medications used to alleviate symptoms<sup>5</sup>. There is no evidence that CBD-based products have a curative effect on brain tumours. However there is an

<sup>1</sup> <https://www.gwpharm.com/products-pipeline/sativex-delta-9-tetrahydrocannabinol-and-cannabidiol>

<sup>2</sup> <https://www.gov.uk/government/publications/scheduling-of-the-cannabis-based-medicine-sativex>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pubmed/24117398>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189631/>

<sup>5</sup> <http://europepmc.org/abstract/med/26976797>

ongoing clinical trial to investigate if Sativex is an effective treatment for recurrent glioblastomas when paired with the chemotherapy drug temozolomide.<sup>6</sup>

## The issue

The majority of CBD-based products cannot be marketed as a medicine (a medicinal license is granted only after a period of research to evaluate safety and efficacy)<sup>7</sup>. Sativex is the only CBD-based product with a medicinal license in the UK. In spite of this, some CBD-based products may be marketed with an implicit reference to medicinal qualities.

In 2016 the MHRA came to the opinion that products containing CBD and used for medical purposes are a medicine<sup>8</sup>. The body recognised that CBD has a *restoring, correcting or modifying effect* on physiological functions when administered to humans.

It is not clear the extent to which the MHRA opinion will affect the availability of CBD-based products. The award of a license requires research which can take years. The MHRA has stated that Sativex is the only CBD oil with the correct product license. The MHRA ordered relevant products to be removed from the market or manufacturers to work with the MHRA to satisfy existing legal requirements. However, they accept that CBD oil is still on the market and readily available to consumers and there are criteria which make some CBD-based products exempt from the decision, such as strain of hemp.

In the longer term, the reclassification of some CBD-based products by the MHRA could be beneficial. The award of a license will ensure that a CBD-based product has robust evidence for safety and efficacy. This means that consumers can be assured that a product is more likely to work as advertised.

In the short term, in light of the WHO's acknowledgement that there is no evidence of abuse or dependency relating to the use of CBD-based products, we are concerned that the MHRA's opinion might make it more difficult for people affected to acquire CBD.

## Recommendations

We will follow developments on the availability of CBD-based products which people affected by a brain tumour may use to manage symptoms. Our information and support team will continue to provide information on the current evidence for and availability of CBD.

- The MHRA should clarify which CBD-based products remain legal to obtain, in particular CBD oil, which is widely used by people affected by a brain tumour.
- The MHRA should work with patient advocacy groups to provide timely information and updates on the availability of CBD-based products.

<sup>6</sup> <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-sativex-temozolomide-glioblastoma-multiforme-brain-tumour-gwca1208>

<sup>7</sup> <https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device>

<sup>8</sup> <https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd>