BMJ 2016;355:i5556 doi: 10.1136/bmj.i5556 (Published 14 October 2016)

NEWS

"Muddled thinking" over cannabis leaves patients in limbo, warn campaigners

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London

Companies selling cannabis based products have been told to remove them from the market within 28 days, after a review by the Medicines and Healthcare Products Regulatory Agency (MHRA) determined that they were medicinal products.

Campaigners for cannabis law reform welcomed the recognition that cannabidiol (CBD) had medicinal properties but warned that the MHRA's action would deprive thousands of users of a product they relied on. They said that it was impossible to obtain marketing authorisation in the timescale given and may never be possible given the high costs of clinical trials and lack of patent protection for a product that contained many components.

"In the long term, it's a good thing," said Peter Reynolds of the pressure group CLEAR (Cannabis Law Reform). "But my immediate concern is for the tens of thousands of people who use CBD and have become reliant on it. We urgently need interim measures so that supplies can continue."

The MHRA sent letters on 3 October to 18 companies that sold CBD, saying that it had concluded that CBD met the definition of a medicinal product as defined in the Human Medicines Regulations as "any substance or combination of substances which may be used or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action or to making a medical diagnosis."

This meant, the letter said, that CBD products required a marketing authorisation before they could be sold. Marketing authorisation for drugs requires lengthy clinical trials, only justifiable if the product has patent protection. An alternative route is under the traditional herbal medicines regulations, but that requires evidence that the product has 30 years of use and applies only to minor conditions, where medical supervision is not required. Reynolds said that he thought it unlikely that CBD could qualify by this route.

Mike Barnes, a neurologist and former NHS consultant and chief executive, is clinical adviser to CLEAR. He said, "The decision by the MRHA to treat CBD products as medicines has also been done without thought to the consequences for many thousands of people in the UK who currently benefit from the products. It will have very significant, and in many cases terminal, impact on the many legitimate businesses that provide high quality products.

"The government must now act to sort out their muddled thinking and try to help those people with long term and often painful conditions who benefit from the ready and hitherto legal availability of natural cannabis products. It is ironic that in acknowledging the therapeutic benefits of CBD, the MRHA is effectively suspending access to a product that has enhanced the lives of thousands for many years."

Crispin Blunt, an MP and CLEAR supporter, has written to the MHRA saying that the decision to designate CBD as a medicine is directly contradicted by the Home Office's position that cannabis has no medicinal value.

"It is vital that we do not let this anomaly in government policy cause harm to people's health," his letter said. He asked for details of how the decision was reached, the consultations undertaken, which specific regulatory regime MHRA proposed for these products, and whether the continued supply of these products, regulated as food supplements, could be ensured until such time that medicinal marketing authorisations could be obtained.

The MHRA has not yet posted details on its website about the decision. In a statement it said that people who used CBD should speak to their GP or other healthcare professional. "We can provide regulatory guidance to any company who may wish to apply for a licence," the statement added.

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