Breaking the Embargo: A Proposal to Break UK Public Health Medicinal Cannabis Impasse

Friday 28 June, 2019

LONDON -- Friday, 28 June 2019 -- The Centre For Medicinal Cannabis has today set out a proposal to create a new government body - the **Cannabinoid Clinical Trials Authority** to enable the **Department of Health and Social Care** (DHSC) to prescribe and commission national clinical assessments of Cannabis Based Medicinal Products (CBMP) to manage the symptoms of a wide range of chronic healthcare conditions.

Designed specifically for the UK, but drawing on evidence from Denmark, Australia and New York State, the proposal creates a simultaneous pathway for patients to access CBMPs on the NHS within a structured national trial environment. This promotes clinical competence and the collection of *'real world data*' whilst safeguarding against any diversion of products into the recreational market. This policy, over a short implementation period, will place the UK as a world leader in safe, knowledge based cannabinoid prescribing practice.

Key points from the proposal are:

- An increasing number of patients are turning to street cannabis for therapeutic use. Despite a change in the scheduling of CBMPs, a limited number of prescriptions have been issued, due to a weak evidence base.
- High profile calls for access to cannabis-based medicines have placed CBMPs on the national agenda.
- It's now tacitly accepted by key policy makers in the UK that current policy will not adequately deliver patient access to CBMPs within an acceptable time frame.
- CMC is urging the DHSC to embrace these proposals as a pragmatic, efficacious solution to current policy failures.
- The CMC engaged with all CBMP stakeholders, including those with international experiences, to design, propose and conceptually test an enhanced CBMP development draft policy at their annual cannabis policy summit.
- CMC draft policy intends, through the creation of a new government body to:
    - Drive the rapid acquisition of clinical data and knowledge regarding the use of CBMPs.
    - Provide immediate access to safe, regulated CBMPs for those currently resorting to medical tourism or street cannabis alternatives.
- Over a 5 year period this would generate world-leading data through modern clinical trials recruiting tens of thousands of patients, providing evidence for the future generation of clinical guidelines by the **National Institute for Health and Care Excellence** (NICE) and regulation by the **Medicines and Healthcare products Regulatory Agency** (MHRA).
- Commissioned trials will be university centred with national reach and capacity, involving 21st century approach (Real World Data and apps driven data collection) to mass trials surveillance where appropriate, validated by randomised control trials (RCTs).
- Establishment of UK centres of excellence, which will host trials to nurture existing CBMP clinical expertise, with eventual growth to both tertiary and primary care.
- Funding will be partially met through involvement of industry partners, in addition to deployment of existing CCG, NHS and NIHR budgets.
- Thereby, all patients who might wish access to CBMPs, and for whom it is appropriate, will obtain access through clinical trials.

Policy interventions from other countries have shown that change in clinical attitudes and access is possible. Lessons from Denmark, Australia and New York State have proved that rapid change, delivering realistic access to pharmaceutical grade CBMPs, is feasible and effective. Rather than copy these blueprints, patients and doctors in the UK require their own tailored policy to bring about safe access to these medicines. This proposal outlines how.

The proposal was co-authored by **Dr. Daniel Couch,** CMC Council of Clinicians and Scientists, **Dr. David Horn**, CMC Medical Lead, and **Dr. Charles Akle,** CMC Council of Clinicians and Scientists.

CMC Expert Quotes

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The Centre For Medicinal Cannabis :: CMC :: DHSC :: Cannabis Based Medicinal Products :: CBMP :: NHS :: NICE :: Cannabis :: Medicinal Cannabis :: Medical Cannabis ::

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Dr. Daniel Couch, CMC Council of Clinicians and Scientists

“It is clear that we need a new approach within the NHS to enable access to medicinal cannabis. This must be in keeping with the UK’s reputation for high quality research and medicines safety. These proposals should be central to the new debate about creating a medicinal cannabis regime in the UK.”

Dr. David Horn, CMC Medical Lead

“The medicinal cannabis policy put in place on 1 November 2019 raised expectations that have not been met. Whilst no country has yet been able to permit access to CBMPs without establishing a new regulatory framework, our proposals offer a safe, measured and accelerated approach within existing NHS paradigm.”

Dr. Charles Akle, CMC Council of Clinicians and Scientists

“It is clear that a new authority now needs to be established which has the power to set standards and advance access, and so balance the demands of the public with the needs of society.”

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About the Authors

Dr. Daniel Couch, CMC Council of Clinicians and Scientists

Daniel Couch, MB ChB MBA PhD MRCS, completed his medical degree in 2007, graduating from the University of Leicester, and has worked internationally in General Surgery after achieving membership of the Royal College of Surgeons in 2011. Daniel completed his PhD in 2018 from the University of Nottingham on cannabinoid pharmacology, focussing on the medical use of CBD in humans, and has 11 internationally published scientific papers. Daniel also recently completed his MBA from the University of Nottingham, with a focus on healthcare development and policy.

Dr David Horn, CMC Medical Lead

David is formerly a UK surgeon, now for 15 years a senior Business Management Consultant operating within the medical sector. He is exceptionally qualified and has wide experience within both clinical and management settings across the UK NHS, including NHS Acute Trusts and NHS Commissioners (CCG). His expertise spans medical business start-ups, business case development, Transformational Change, Clinical Process Redesign, and performance management within the NHS.

Dr. Charles Akle, CMC Council of Clinicians and Scientists

Charles Akle is a Fellow of the Royal College of Surgeons and was awarded the prestigious Hallett Prize, in addition to a number of awards and prizes in his undergraduate career. He trained in Medicine at Guy’s Hospital in London and researched into transplantation and immunology early in his career, obtaining his Master of Surgery degree. This set the scene for his return to active medical research after retirement. He was a prominent London-based surgeon and a pioneer in the development of laparoscopic surgery, helping to train many of today’s excellent surgeons in Europe. He was also active in establishing and promoting a better relationship between the private and public health sectors in the UK, building on the fact that many new developments in medicine, such as In vitro Fertilisation and laparoscopic surgery, began in the private sector.

About Centre for Medicinal Cannabis

The Centre for Medicinal Cannabis (CMC) is the UK’s first and only industry membership body for stakeholders operating in Cannabis Based Medicinal Products (CBMPs) and cannabidiol (CBD) wellness markets. We have a unique capability to engage intelligently and strategically with all influential political and public policy stakeholders, as well as relevant regulatory bodies, drawing on the experience from our global membership base. More information about The CMC can be found at www.thecmcuk.org.

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