Home Office

Home Secretary
2 Marsham Street
London
SW1P 4DF

Rt Hon Yvette Cooper
Chair, Home Affairs Select Committee
House of Commons
London SW1A 0AA

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Dear Yvette,

RESCHEDULING CANNABIS-BASED PRODUCTS FOR MEDICINAL USE

I am pleased to be writing to you with an update on the Government's plan to reschedule cannabis-based products for medicinal use. This follows the joint letter that the Secretary of State for Health and Social Care and I sent to the Advisory Council on the Misuse of Drugs (ACMD) today, which set out the Government's plans to reschedule cannabis-based products for medicinal use by the autumn.

Last week, on 11 September, the ACMD published their advice on the Government's draft proposals. They set out eleven recommendations regarding the Government's preferred approach on rescheduling of *'cannabis-derived medicinal products'.* We have written today to the Chair of the ACMD to accept all the recommendations made. A copy of the full response is attached to this letter.

The next step is for the Government to make the necessary regulations to change the law in relation to scheduling cannabis-based products for medicinal use; this will be done shortly. When the regulations come into force, patients will be able to access appropriate medical treatment, and measures will be in place to ensure that the potential risks of diversion and misuse of controlled drugs are minimised. The Government recognises the particular challenges surrounding cannabis and, as such, we are taking a cautious approach to the way we are rescheduling cannabis-based products for medicinal use to provide the necessary protections and safeguards both the Government and ACMD feel are essential. The controls we have introduced are in two-parts and are set out below.

<u>Part one – The definition</u>

We are ensuring that only medicinal products (or ingredients of medicinal products) are rescheduled to Schedule 2 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations"). We have developed a purpose based definition which provides a three-limb requirement to constitute a cannabis-based product for medicinal use. These are as follows:

1. *It needs to be a preparation or product which contains cannabis, cannabis resin, cannabinol or a cannabinol derivative;*
2. *It is produced for medicinal use in humans and;*

3. *Is a medicinal product, or a substance or preparation for use as an ingredient of, or in the preparation or manufacture of an ingredient of, a medicinal product.*

All three limbs would need to be satisfied to constitute a cannabis-based product for medicinal use and thus be treated as a Schedule 2 drug. Any cannabis-based substances falling outside of the definition would remain a Schedule 1 drug and will not be able to be prescribed for medicinal use.

Part two – The limited access routes

To add an additional safeguard, products that satisfy the definition will not be available to be prescribed to humans in the same way as other Schedule 2 drugs. Instead, whilst the evidence develops, clinical expertise builds, and the ACMD consider whether the definition needs to be refined as part of their longer-term review, we have imposed special measures of control by limiting access to several routes to reduce risks of harm, misuse and diversion.

Firstly a person cannot **order** (whether by issuing a prescription or otherwise) a cannabis based product for medicinal use in humans for administration unless the product is:

1. *A special medicinal product that is for use in accordance with a prescription or direction of a specialist medical practitioner;*

Until these products have received marketing authorisation from the MHRA, they will not have been tested for quality, safety and efficacy. As a result, these products would be regulated as unlicensed medicines – commonly known as 'specials'. In line with other unlicensed medicinal products, practitioners will take on the responsibility for the quality and safety of the product. This is an established process that is already in place within the health system for prescribing novel drugs. It will be for prescribers to decide whether prescribing these products is in the best interest of the patient, taking into account a variety of factors, including consideration of using licensed products first. There is extant guidance from the GMC on prescribing specials and from the MHRA on their manufacture, including manufacturing site standards (Good Manufacturing Practice), import, supply, distribution, storage, labelling and pharmaco-vigilance. Further to this there is a legal requirement that unlicensed products are not advertised. The MHRA is currently updating the specials guidance to support the rescheduling of cannabis. The revised guidance will be available when the legislation is laid.

In addition, we have only permitted a 'specialist medicinal practitioner' (i.e. a doctor on the specialist register of the General Medicinal Council) to prescribe these products. This replicates the principle used in the interim Expert Panel on cannabis-based medicines and ensures patient safety is not compromised.

2. *An investigational medicinal product without marketing authorisation that is for use in a clinical trial or;*

This is in line with the advice from the Chief Medical Advisor to the UK Government and ACMD advice and ensures that clinical trials can be undertaken with these products, within the applicable safety framework, to ensure that the evidence base on cannabis-based products for medicinal use can be developed.

3. *A medicinal product with a marketing authorisation.*

Once products have received MHRA marketing authorisation and have been tested for quality, safety and efficacy they will no longer fall under the 'specials' regime and consequently will be available to the public in the same way as any other Schedule 2 drug (i.e. can be prescribed by a GP).

Secondly, a person cannot **supply** a cannabis based product for medicinal use in humans unless there has been a lawful order. This will have the practical effect that a pharmacy dispensing a cannabis-based products for medicinal benefits will need to be satisfied that one of the above three order routes has been followed before lawfully dispensing the product to a patient. This restriction on supply will act as a further barrier to individuals receiving such products inappropriately.

By placing these restrictions in the 2001 Regulations it will remain a criminal offence for a person to order or supply a cannabis-based product for medicinal use for administration outside of the 3 access routes, and so risks of harm, misuse and diversion will be mitigated.

Smoking

Both we and the ACMD have strong concerns regarding the potential smoking of these cannabis-based products for medicinal use, both from a health and enforcement perspective. This is why we have included a restriction within the 2001 Regulations which means that patients would not be able to administer cannabis-based products for medicinal use by smoking. We believe this will protect patients and help enforcement agencies to differentiate between legitimate and illegitimate use of these products. This will be critical in avoiding the unintended consequence of wider misuse of cannabis and associated social harm.

We want to take this opportunity to reiterate that the Government has no intention of legalising recreational cannabis. Our approach here has been guided by expert medical and scientific advice that there are potential medicinal benefits from these products. It remains the case, however, that there is clear evidence of the harms which cannabis can cause and, as with other schedule 2 drugs, such as diamorphine, the need to ensure there are in place strict controls as to its use and availability.

As we have indicated above, we intend to make the regulations shortly. This will fulfil our intention to make necessary changes to legislation by Autumn and ensure that clinically appropriate patients are able to lawfully access cannabis-based products for medicinal use. In the interim, the Expert Panel on cannabis-based medicines will continue to be in place. I hope you will understand our desire to work at pace to ensure that patients have access to the most appropriate form of medical treatment.

A copy of this letter will be placed in the House Library and will be shared with other interested MPs who have spoken in debates and have brought these matters to our attention.

Rt Hon Sajid Javid MP