Pharmacy Update

Regional SpR Teaching 28 February 2019

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Delving into the Weed(s)

Medical cannabis products available on prescription

1 November 2018 | Share

REUTERS

Charlotte Caldwell previously said the law change would mean her son, Billy, would be able to live a "normal life"

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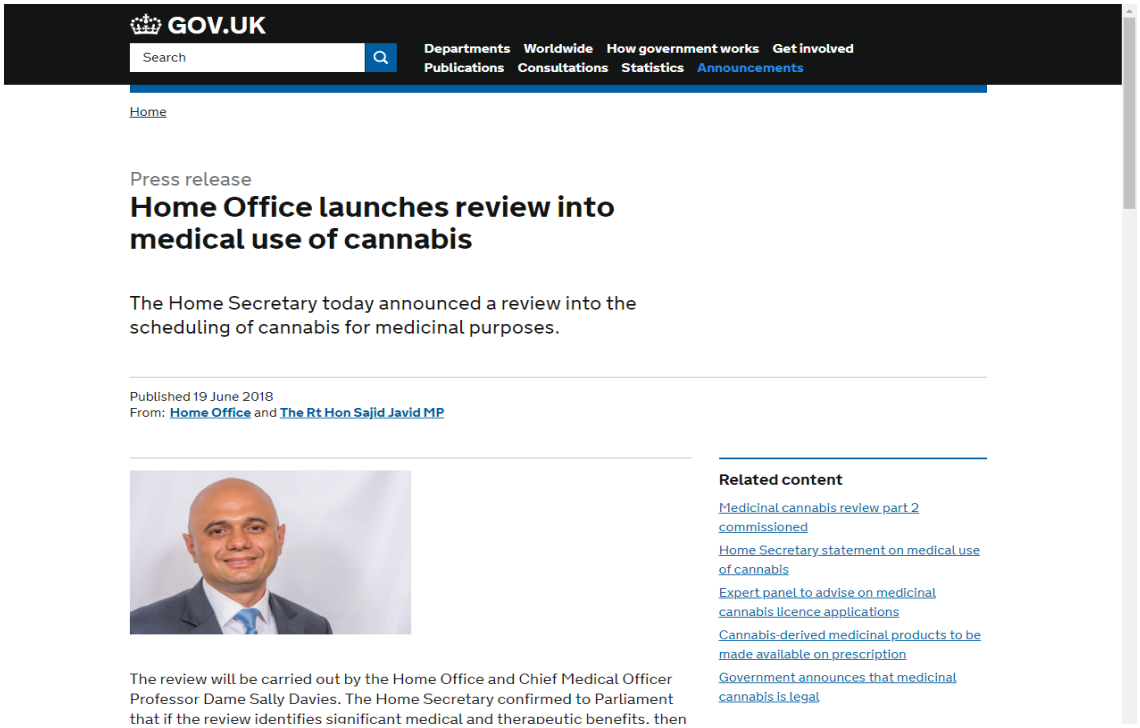
Features

The Review

- A review was launched by the Home Office 19 June 2018



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Press release

Home Office launches review into medical use of cannabis

The Home Secretary today announced a review into the scheduling of cannabis for medicinal purposes.

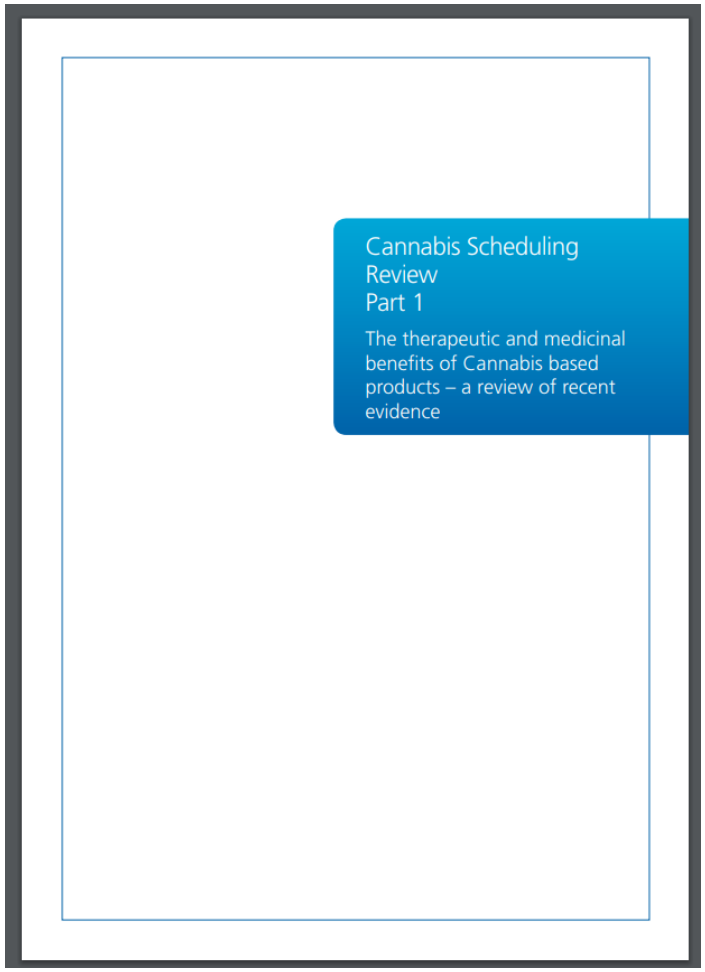
Published 19 June 2018
From: Home Office and The Rt Hon Sajid Javid MP

The review will be carried out by the Home Office and Chief Medical Officer Professor Dame Sally Davies. The Home Secretary confirmed to Parliament that if the review identifies significant medical and therapeutic benefits, then

Related content

Medicinal cannabis review part 2 commissioned
Home Secretary statement on medical use of cannabis
Expert panel to advise on medicinal cannabis licence applications
Cannabis-derived medicinal products to be made available on prescription
Government announces that medicinal cannabis is legal

The Review: Part 1



The CMO recommended that,

"…the whole class of cannabis based medicinal products be moved out of Schedule 1."

The Review: Part 2

ACMD

Advisory Council on the Misuse of Drugs

Chair: Dr Owen Bowden-Jones
Secretary: Zahi Sulaiman
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Rt. Hon. Sajid Javid MP
Home Secretary
2 Marsham Street
London, SW1P 4DF

19 July 2018

Dear Home Secretary,

RE: Scheduling of *Cannabis*-derived medicinal products

Thank you for your commission of 3 July 2018, which the Advisory Council on the Misuse of Drugs (ACMD) has accepted. This report presents our short-term advice on the scheduling of *Cannabis*-derived medicinal products.

1. *Cannabis*-derived medicinal products

The ACMD agrees with the Chief Medical Officer for England (CMO) that there is now evidence of medicinal benefit for some *Cannabis*-derived products in certain medical conditions for some patients.[1,2,3,4,5,6,7]

The ACMD advises that clinicians in the UK should have the option to prescribe *Cannabis*-derived medicinal products that meet the requirements for medicinal standards to patients with certain medical conditions. It is therefore appropriate for

[1] Thiele EA, Marsh ED, French JA et al. Cannabidiol in patients with seizures associated with Lennox Gastaut syndrome (GWPCARE4): a randomised, double blind, placebo-controlled phase 3 trial. Lancet 2018;Jan 25. pii: S0140-6736(18)30136-3.

[2] Devinsky O, Cross JH, Laux L et al. Trial of cannabidiol for drug resistant seizures in the Dravet syndrome. New Eng J Med 2017;376:2011-20.

[3] Devinsky O, Patel A, Cross JH et al. Effect of cannabidiol on drop seizures in the Lennox Gastaut Syndrome. New Eng J Med 2018;378:1888-97.

[4] Rice J, Cameron M. (2018) Cannabinoids for Treatment of MS Symptoms: State of the Evidence. Curr Neurol Neurosci Rep. 18(8):50.

[5] Tzadok M, Uliel-Siboni S, Linder I, Kramer U, Epstein O, Menascu S, Nissenkorn A, Yosef OB, Hyman E, Granot D, Dor M, Lerman-Sagie T, Ben-Zeev B.(2016). CBD-enriched medical *Cannabis* for intractable pediatric epilepsy: The current Israeli experience. Seizure. 35:41-4.

[6] Mücke M, Phillips T, Radbruch L, Petzke F, Häuser W. (2018) *Cannabis*-based medicines for chronic neuropathic pain in adults. Cochrane Database of Systematic Reviews 2018, Issue 3. Art. No.: CD012182.

[7] Whiting PF, Wolff RF, Deshpande S, et al. (2015). Cannabinoids for Medical Use. A Systematic Review and Meta-analysis. *JAMA*. 313(24):2456–2473.

Recommended:

- Cannabis-derived medicinal products of the appropriate medicinal standard should not be subjected to Schedule 1 requirements
- Once defined, cannabis-derived medicinal products be moved into Schedule 2

‘cannabis-based product’ for medicinal use

“a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which:

a) Is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);
b) Is produced for medicinal use in humans; and
c) Is
    I. A medicinal product, or
    II. A substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product”

The regulations

Cannabis-based products (CBP) are:

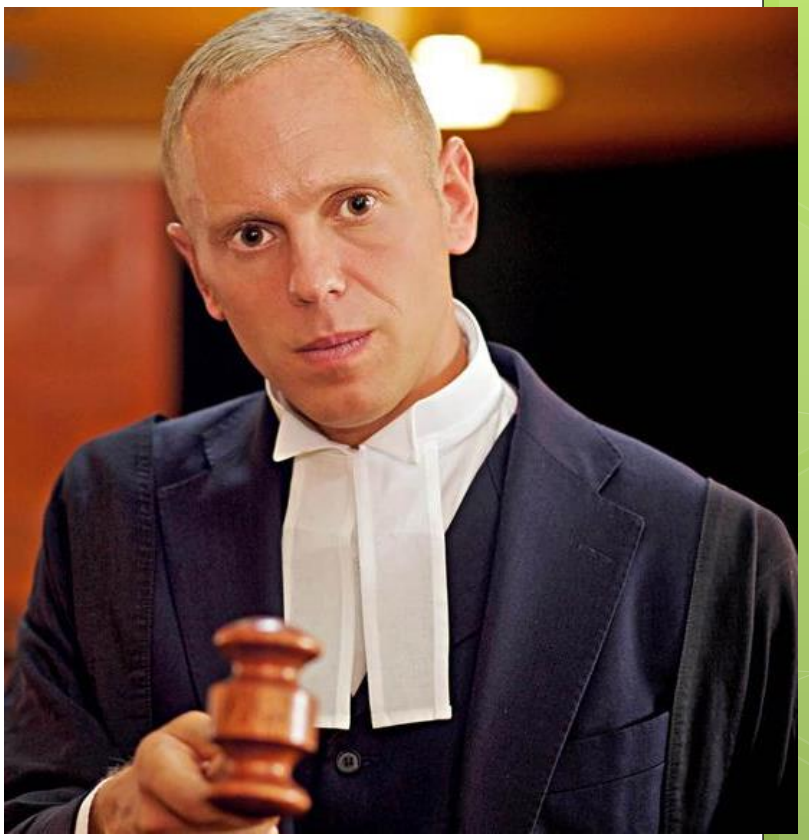
- Scheduled 2* controlled drugs
- Unlicensed medicines*
- Restricted to use by clinicians listed on the Specialist Register of the GMC*

*except Sativex, which is a licensed product already listed in Schedule 4

Controlled drugs

Relevant legislation:

- The Misuse of Drugs Act 1971 as amended
- The Health Act 2006
- The Misuse of Drugs Regulations (Safe Custody) 2001 as amended
  - Schedule 1-5



Schedule 2 CDs

- Prescriptions valid for 28days
- No emergency supplies
- Prescription requirements apply…

Prescription requirements for Schedule 2 and 3 CDs

1. Signature of prescriber
2. Date
3. Address of prescriber (must be in UK)
4. Dose
5. Formulation
6. Strength
7. Total quantity requested in words
8. Total quantity requested in figures
9. Patient name
10. Patient address

- As directed
- When required
- PRN
- As per chart
- Titration dose
- Weekly

- One as directed
- 5ml when required
- Two PRN
- Three ampoules to be given as directed

~~Un~~licensed medicines

- Process of licensing
- Marketing authorisation (MA) = product licence
- MA defines a medicine's terms of use
- Outlined in its summary of product characteristics (SPC/SmPC)
  - See www.medicines.org.uk
- A licensed medicine has been assessed for efficacy, safety and quality, and manufactured to appropriate quality standards

Off-label vs. unlicensed meds

- Off-label is the use of a licensed medicine outside of its MA
  - Common in certain specialties
  - May be indication/dose/route
- Unlicensed meds are those that do not have a MA
  - Oxetacaine and antacid suspension
  - Lutrol 24% with lidocaine 2% gel
  - Levomepromazine 6mg tablets
  - Spironolactone 25mg/ml suspension
  - Many examples during manufacturing problems

Unlicensed medicines

Prescribers should:

- be satisfied that an alternative, licensed medicine would not meet the patient's needs before prescribing an unlicensed medicine
- be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up
- record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine; you may wish to record that you have discussed the issue with the patient
- Further info:
- "Off-label or unlicensed use of medicines: prescribers' responsibilities available" via www.gov.uk

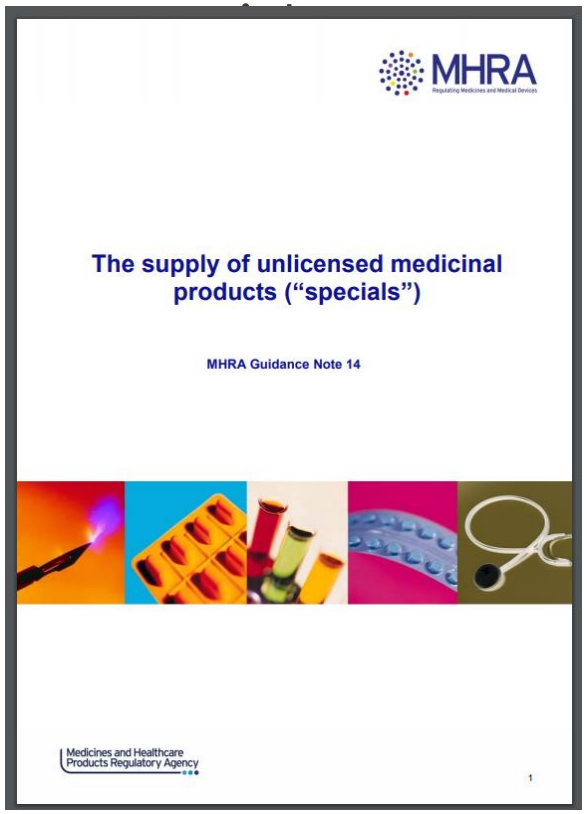
Restricted to use by clinicians listed on the Specialist Register of the GMC

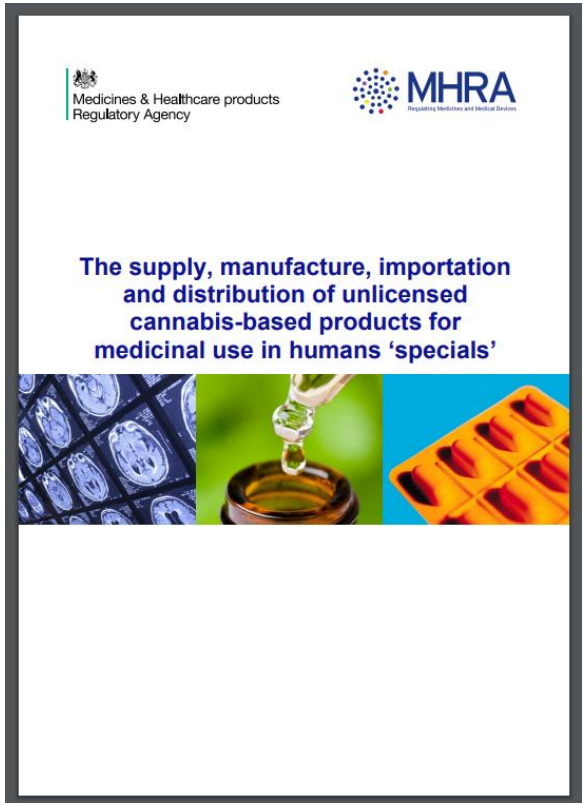
The regulations also lay out some best practice principles:

- CBP should only be used where there is clear published evidence of benefit or UK guidelines
- In patients where there is a clinical need which cannot be met by a licensed medicine
- Established treatment options have been exhausted
- Only prescribe within your area of practice and training
- Decision should be agreed by the MDT
- Only prescribe a product where you are certain of its content and quality

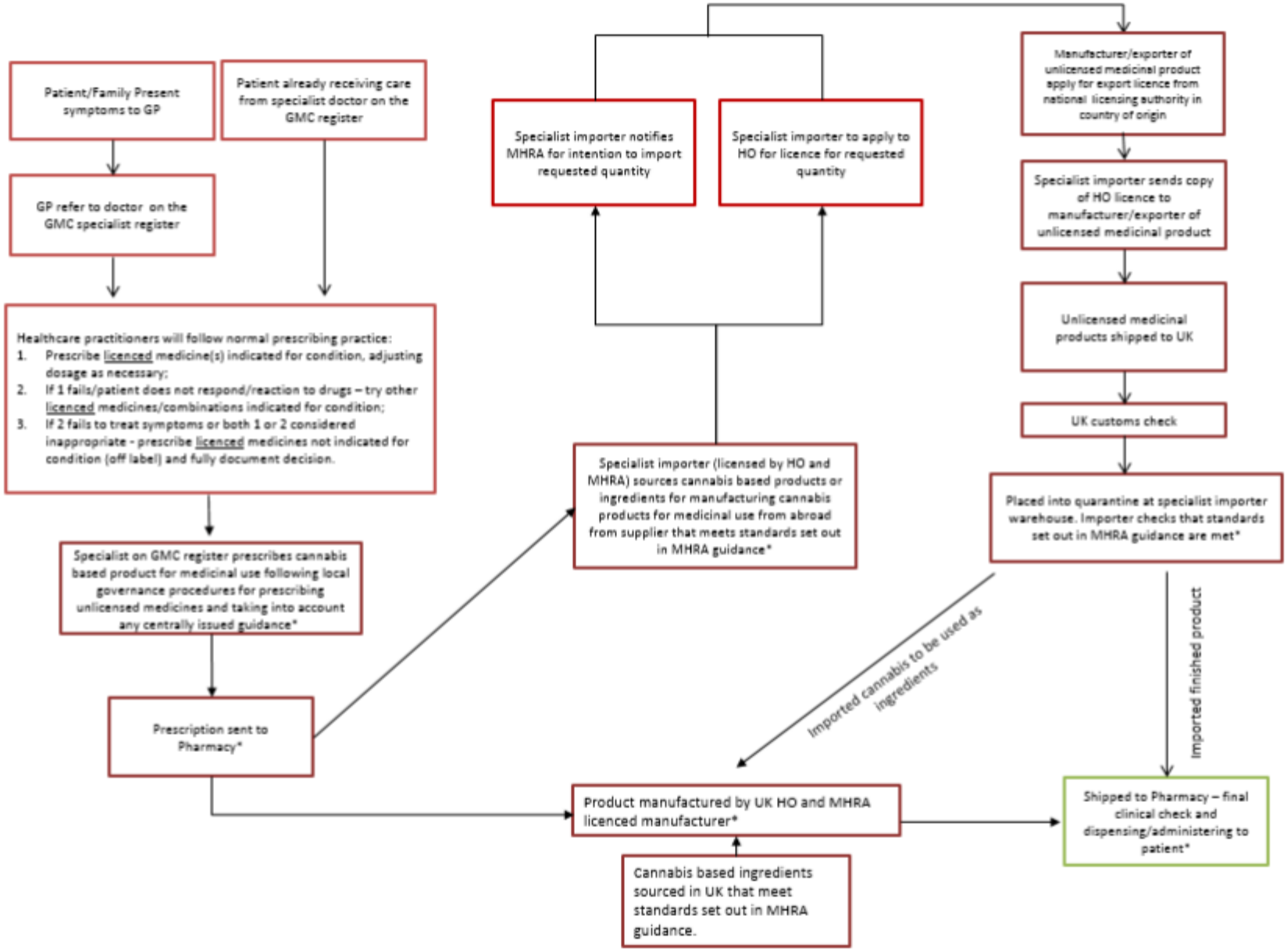
Assuring quality

- Products are expected to fulfil the requirements of the MHRA's specials





Process for prescribing, supplying & importing unlicensed cannabis-based medicinal produ



Notes:

* Refer to the Quality Checklist in this guidance which details what checks should be made at each stage to ensure that the prescription/direction of the specialist doctor is fulfilled.

Further considerations

- Unlicensed medicines and CBP are not eligible for shared-care agreements so prescription would remain under specialist supervision