

ACMD

Advisory Council on the Misuse of Drugs

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Rt. Hon. Priti Patel MP
Home Secretary
2 Marsham Street
London, SW1P 4DF

Monday, 23rd December 2019

Dear Home Secretary,

RE: Commission to the ACMD – Framework for the assessment of the impact of rescheduling cannabis-based products for medicinal use (CBPMs)

In February 2019, the then-Home Secretary commissioned the Advisory Council on the Misuse of Drugs (ACMD) to conduct a longer-term review of cannabis-based products for medicinal use (CBPMs) in humans.¹

That commission was split into three components. I am writing to you with respect to the first component. The first component asked the ACMD to:

“provide an outline for an assessment framework. This should set out how the ACMD will assess the various impacts of rescheduling cannabis-based products for medicinal use to Schedule 2 under the 2001 Regulations, and the data sources (including those provided by the Home Office and DHSC) the ACMD will use by November 2019?”

The ACMD has carefully considered this request and I am pleased to enclose our outline for an assessment framework. This outline framework has taken into account guidance and documentation issued by a number of bodies, including the National Institute for Health and Care Excellence (NICE), NHS-England and the UK Chief Medical Officers (CMOs), the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA).

¹ <https://www.gov.uk/government/publications/cannabis-based-products-for-medicinal-use-in-humans-commission-to-the-acmd>

We look forward to providing a full report using this outline assessment framework in November 2020.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Owen Bowden-Jones". The signature is written in a cursive style with a large initial 'O' and a long, sweeping tail.

Dr Owen Bowden-Jones
Chair of the ACMD

ACMD

Advisory Council on the Misuse of Drugs

ACMD framework for the assessment of the various impacts of rescheduling Cannabis-based Products for Medicinal use in humans (CBPMs) to Schedule 2 under the Misuse of Drugs Regulations 2001

Introduction

Objectives

The ACMD outline assessment for cannabis-based products for medicinal use (CBPM) framework has the following objectives:

- To set out how the ACMD will assess the various impacts of rescheduling CBPMs to Schedule 2 under the Misuse of Drugs Regulations 2001 (MDR);
- To set out the data sources that might be used in an assessment.

Sources of Guidance

This outline framework has taken into account guidance and documentation issued by bodies including the UK Chief Medical Officers (CMOs), the National Institute for Health and Care Excellence (NICE), NHS England, the Department of Health and Social Care (DHSC), and the Medicines and Healthcare products Regulatory Agency (MHRA).

Limitations

There are a number of factors which may limit the comprehensive assessment of the impact of the rescheduling. These include: the availability of relevant data, mechanisms to successfully collect data; the interpretation of multiple data sources and; the difficulty in assessing the impact of the rescheduling after only a relatively short amount of time following the legislative change occurred in November 2018.

Logic model

A logic model is a graphic which represents the theory of how an intervention (an “input”) produces an impact. It represents a simplified hypothesis about how an intervention is expected to work.

The critical aspects of an intervention are identified, described and arranged in a logic model to represent how the intervention produces change, with arrows indicating causal relationships between those aspects.

The ACMD used a logic model to outline a flexible assessment framework which may develop over time to help prioritise and structure the data collection and analysis that will be necessary for that assessment. The impact assessment may then in turn be used to test and refine the hypothesis represented by the logic model.

The logic model can be found in Annex 1.

Using the ACMD CBPM outline assessment framework

The outline assessment framework sets out a number of the potential intended and unintended impacts identified from the ACMD logic model as 'Policy objectives/elements' – factors that the ACMD considered might potentially have resulted from the CBPM rescheduling. Alongside those impacts is a 'description' which expands on how they might look like in practice.

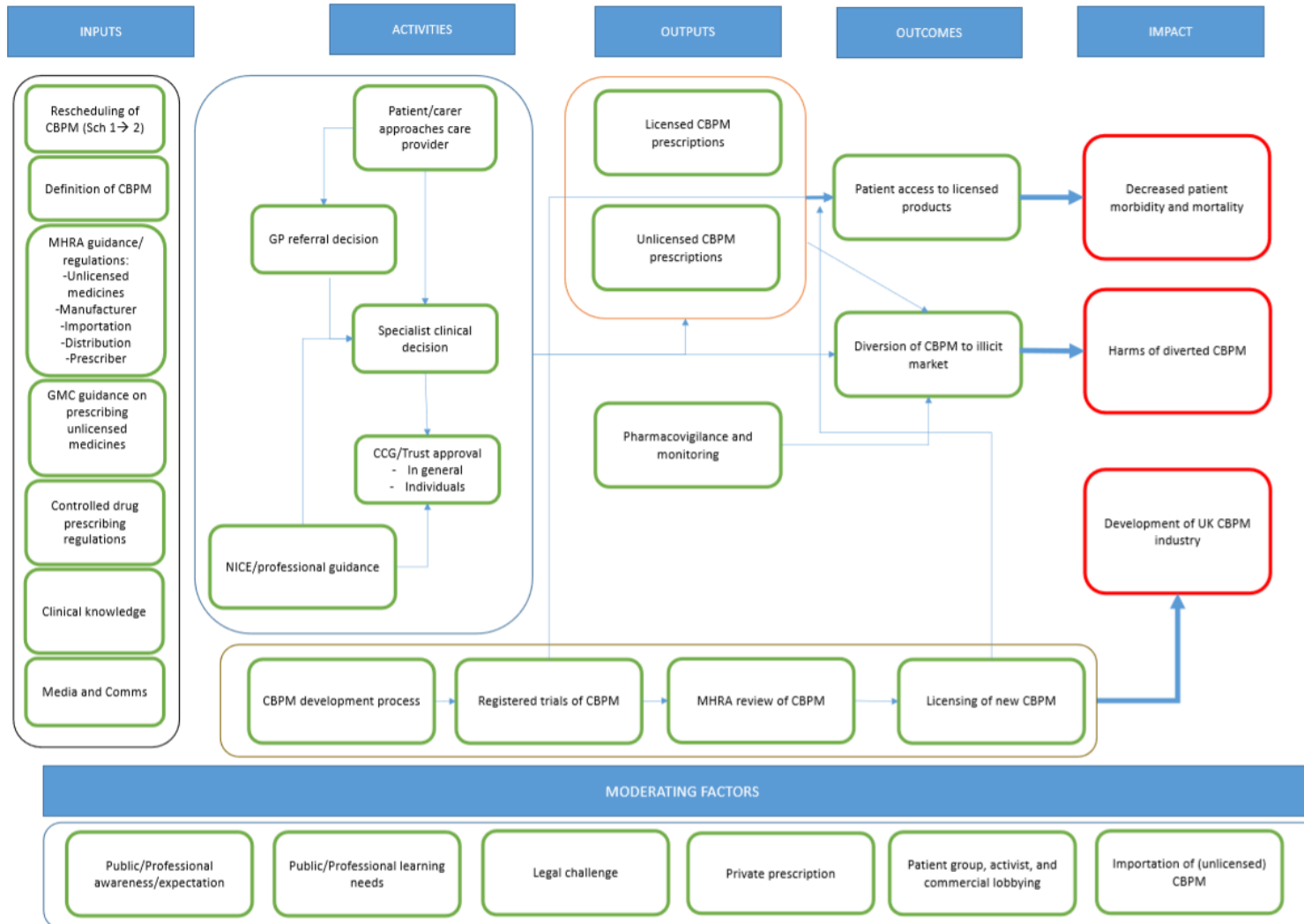
A 'justification' has been included to illustrate why the ACMD have chosen these policy objectives/elements as potential impacts to assess.

The framework then sets out 'indicators', potential datasets which would allow the ACMD to assess the extent to which the suggested impact has been realised, and 'sources/responsible bodies' – to explain who the ACMD may approach (for example, various Government Departments) to collate these datasets.

For example, one intended impact of the CBPM rescheduling was to facilitate the prescription of unlicensed CBPMs where patients' conditions are not managed by licensed medicines. This was justified as a potential impact because of the legislative amendments made by 'The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018'. In order to assess the extent to which this impact has been realised, the ACMD have suggested collecting the following datasets (from before, and after the legislative change) from DHSC, NHS/HSC Business Services Authority, and NHS Scotland: the 'number of patients in receipt of special CBPM prescriptions' and the 'number of prescribed unlicensed CBPMs'.

The ACMD CBPM outline assessment framework can be found in Annex 2.

Annex 1: ACMD logic model – CBPM rescheduling



Annex 2: ACMD outline assessment framework – CBPM rescheduling

Policy objective/elements	Description	Justification	Indicator(s)	Sources/responsible bodies
Clinical practice				
Prescriptions of licensed CBPM	Prescription of CBPM as preferred treatment	The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 [Rescheduling of CBPM]	Number of patients with prescriptions of licensed CBPM Number of prescribed licensed CBPM items	DHSC; NHS/HSC Business Services Authority; NHS Scotland
Special prescriptions of unlicensed CBPM	Prescription of unlicensed CBPM where patients' conditions are not managed by licensed medicines	Rescheduling of CBPM	Number of patients in receipt of special CBPM prescriptions Number of prescribed unlicensed CBPM	DHSC; NHS/HSC Business Services Authority; NHS Scotland
Legislation/licensing/regulation				
Definition of CBPM	The current definition of CBPM covers an appropriate range of products to meet clinical need Products either rescheduled back into Schedule 1, or into other Schedules, as appropriate	Rescheduling of CBPM Commissioning letter to ACMD 15/2/19	Number of compounds rescheduled under the Misuse of Drugs Regulations 2001	ACMD Home Office Industry Research
Markets, monitoring & pharmacovigilance	Updated MHRA guidance on CBPM	Government response to ACMD: cannabis-	Number of licensed specialist importers	MHRA

	facilitates access to medicines (importations, domestic); reduces risks to prescribers, patient, and public	derived medicinal products, 21 September 2018 Updated MHRA guidance on CBPM manufacture, supply and distribution GMC guidance on prescribing specials	Number of imports of CBPMs Number of licensed domestic manufacturers Number of sanctions for regulatory breaches Number of reported adverse drug reactions on UK Yellow Card Scheme Costs of licensed and unlicensed CBPMs	DHSC/NHS-England
Research				
Improvements to the CBPM evidence base	Rescheduling and associated actions led to an increase in the number of registered trials being undertaken NICE guidelines and NIHR CBPM themed call led to an increase in the number of publicly funded trials Rescheduling CBPM encouraged research organisations to undertake work in this area Increased availability of improved patient outcomes	Rescheduling of CBPM Underdeveloped evidence base for effectiveness Underdeveloped evidence base for effectiveness Understanding effectiveness of CBPM in routine clinical practice; Response to ACMD: cannabis-	Number of trials registered Number of completed trials Number of trials reporting Amount of funding involved with trials Number of patients involved in trials NIHR funding portfolio Number of Home Office controlled drug licence renewals and new awards for universities	EMA EU Clinical trials Registry; ClinicalTrials.gov; International Standard Randomised Controlled Trials Number (ISRCTN) Registry NIHR DHSC; NIHR Home Office

	Patient registry and uniform dataset enacted	<p>derived medicinal products, 21 September 2018</p> <p>Recommendation from NHS England and NHS Improvement (2019)</p>	<p>Condition/disease specific outcomes</p> <p>Introduction of patient registry, collection of patient outcome data for a range of conditions</p>	NHS England and NHS Improvement, DHSC and Devolved Administrations
New CBPM development	Rescheduling of CBPM encouraged industry/research organisations to undertake work in this area	Number of CBPM on the market is low in contrast to unlicensed products available internationally	Number of CBPM clinical and non-clinical trials	Industry Universities
Awareness/Education				
Patient demand – education, expectations	<p>Public informed which products are likely to be prescribed, for which conditions, and the route by which they can be prescribed</p> <p>Public informed about legal restrictions, and clinical and safety implications of self-treatment with illicit cannabis</p> <p>Public informed of legal restrictions of self-</p>	<p>Human Medicines Regulations 2012</p> <p>Misuse of Drugs Regulations 2001</p> <p>Response to ACMD: cannabis-derived medicinal products, 21 September 2018</p> <p>Populous poll 24/25 October 2018</p> <p>The Misuse of Drugs (Amendments) (Cannabis and Licence</p>	<p>Self-reported knowledge</p> <p>How frequently patient information pages/websites are being accessed</p>	<p>DHSC; Papers/reports published by Universities and other research organisations</p> <p>NICE</p> <p>NHS-England</p>

	treatment with CBPM not prescribed to them	Fees) (England, Wales and Scotland) Regulations 2018		
Prescriber and healthcare professional education	Additional training/competence is required to develop understanding of CBPM and support safe and effective prescribing	<p>CBPM are currently an unfamiliar category of drugs for most clinicians</p> <p>GPs and other healthcare workers may be unfamiliar with processes</p> <p>Response to ACMD: cannabis-derived medicinal products, 21 September 2018</p> <p>Recommendation from NHS England and NHS Improvement (2019)</p>	<p>How many accredited learning modules/courses are being provided by recognised national training organisations and professional bodies</p> <p>Number of successful completions of accredited learning modules</p>	Health Education England; Professional Bodies (e.g. RCGP; GPC; GMC; RCPC; RPS; RSM); NHS England and NHS Improvement and DHSC
<i>Illicit and non-medical use</i>				
Diversion of prescribed CBPM into the illicit market	Increased number of CBPM prescriptions, poor prescription practices, and failure of monitoring of prescribing, supply and administration leads to an increase in products diverted to the illicit market	<p>Response to ACMD: cannabis-derived medicinal products, 21 September 2018</p> <p>International literature</p>	<p>Number of reports to MHRA notifying counterfeits being seized</p> <p>Number of reports to MHRA notifying diversion</p> <p>Reports of illicit cannabis being misrepresented as CBPMs</p>	<p>Crime Survey for England & Wales (CSEW) - new question; police seizure data</p> <p>MHRA</p> <p>National Crime Agency (NCA)</p>

General population use of cannabis	<p>Availability of CBPM promotes positive social norms towards cannabis more generally, leading to an increase in recent illicit cannabis use</p> <p>Legislative change is (partly) a response to changing social norms on cannabis</p>	International literature	Changes in use indicated by existing measures/surveys	<p>CSEW and equivalents (existing cannabis measures – Last Year Prevalence (LYP); Last Month Prevalence (LMP))</p> <p>Smoking, drinking and drug use among young people in England (SDD) and equivalents (cannabis measures – LYP; LMP; attitudes to cannabis use; awareness of cannabis; descriptive norms; new measures around CBPM)</p> <p>British Social Attitudes survey Papers/reports published by Universities and other research organisations</p>

Annex 3: ACMD CBPM Working Group Membership

Dr Owen Bowden-Jones – Chair of the ACMD CBPM working group, ACMD member and Chair of the ACMD

Dr Anne Campbell – ACMD Member

Annette Dale-Perera – ADP Consulting

Dr Cathy Stannard – Consultant in Pain Medicine

Professor David Taylor – ACMD Member

Dr Derek Tracy – ACMD Member

Dr Emily Finch – ACMD Member

Gillian Arr-Jones – Chief Pharmacist at the Care Quality Commission

Professor Harry Sumnall - Professor In Substance Use, Liverpool John Moores University

Professor Helen Cross - The Prince of Wales's Chair of Childhood Epilepsy and Head of the Developmental Neuroscience Programme at UCL-Great Ormond Street Institute of Child Health

Dr Mike White – Former Forensic Intelligence Adviser

Professor Raymond Hill – Professor of Pharmacology, Imperial College London

Ric Treble – retired Laboratory of the Government Chemist (LGC) Expert

Dr Richard Stevenson – ACMD Member

Professor Robin Murray - Professor of Psychiatric Research Professor of Psychiatric Research, King's College London

Professor Roger Knaggs – ACMD Member

Professor Simon Gibbons - Professor of Medicinal Phytochemistry, UCL

Professor Steve Alexander - Associate Professor of Molecular Pharmacology, University of Nottingham

Annex 4: ACMD Membership

Dr Kostas Agath - Consultant Psychiatrist (Addictions), CGL Southwark

Dr Owen Bowden-Jones - Consultant Psychiatrist, Central North West London NHS Foundation Trust

Dr Anne Campbell - Senior Lecturer in social work at Queens University Belfast (QUB) and co-director of the Drug and Alcohol Research Network Northern Ireland based at QUB.

Mohammed Fessal - Chief Pharmacist for Change, Grow, Live

Dr Emily Finch - Consultant Psychiatrist and Clinical Director, Addictions Clinical Academic Group, South London and Maudsley NHS Trust

Lawrence Gibbons - Head of Drug Threat, NCA Intelligence Directorate, Commodities

Dr Hilary Hamnett - Senior Lecturer in Forensic Science, University of Lincoln

Professor Graeme Henderson - Professor of Pharmacology at the University of Bristol

Dr Carole Hunter - Lead Pharmacist at the Alcohol and Drug Recovery Services at NHS Greater Glasgow and Clyde

Professor Roger Knaggs - Associate Professor in Clinical Pharmacy practice at the University of Nottingham

Dr Tim Millar - Senior Research Fellow and Addiction Research Strategy Lead, University of Manchester

Rob Phipps - retired Head of Health Development Policy Branch, Department of Health, Social Services and Public Safety (Northern Ireland)

Harry Shapiro - Director, DrugWise

Dr Richard Stevenson - Emergency Medicine Consultant, Glasgow Royal Infirmary

Dr Paul Stokes - Clinical Senior Lecturer in Mood Disorders at King's College London

Dr Ann Sullivan - Consultant Physician in HIV and Sexual Health

Professor Matthew Sutton - Professor of Health Economics at the University of Manchester

Professor David Taylor - Director of Pharmacy and Pathology at the Maudsley Hospital, and Professor of Psychopharmacology at Kings College London

Professor Simon Thomas - Consultant Physician and Clinical Pharmacologist, Newcastle Hospitals NHS Foundation Trust

Dr Derek Tracy - Consultant Psychiatrist and Clinical Director, Oxleas NHS Foundation Trust, London

Rosalie Weetman - Senior Commissioning Manager of Substance Misuse

Annex 5: Special Acknowledgement

The ACMD and ACMD Secretariat would like to express particular gratitude to Professor Harry Sumnall for all of his efforts in the development of the logic model and the outline assessment framework set out in this document.

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