ACMD

Advisory Council on the Misuse of Drugs

ACMD Chair: Prof. Owen Bowden-Jones
CBPM Working Group Secretary: Kieran O'Malley
4th Floor (NE), Peel Building
2 Marsham Street
London
SW1P 4DF
ACMD@homeoffice.gov.uk

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

27 November 2020

Dear Home Secretary,

Re: Commission to the ACMD – an assessment of the impact of the rescheduling of cannabis-based products for medicinal use (CBPMs) to Schedule 2 under the Misuse of Drugs Regulations 2001

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]

One of the three components of the commission asked the ACMD to carry out an assessment of the impact of the rescheduling of CBPMs to Schedule 2 of the Misuse of Drugs Regulations 2001 in November 2018 and to report its findings, and any recommendations to mitigate the issues identified, by November 2020. To guide this assessment, the ACMD had provided an outline assessment framework in December 2019 setting out how the ACMD would assess the various impacts of the rescheduling, and the data sources that would be used.[2]

[1] https://www.gov.uk/government/publications/cannabis-based-products-for-medicinal-use-in-humans-commission-to-the-acmd
[2] https://www.gov.uk/government/publications/cannabis-based-products-for-medicinal-use-assessing-the-impact

The ACMD has now carefully conducted this assessment and I am pleased to enclose our full report. To assess change over time, the ACMD has collated and examined datasets representing three time periods:

- one dataset relating to the year immediately preceding the rescheduling of CBPMs (i.e. 01/11/2017 – 31/10/2018);
- another dataset relating to the year immediately following the rescheduling (i.e. 01/11/2018 – 31/10/2019); and
- a final dataset corresponding to the period between November 2019 and summer 2020.

To summarise, from the evidence presented, the ACMD has drawn the following conclusions and recommendations.

Conclusions

1. Many of the various impacts of the rescheduling of CBPMs in November 2018 have been gradual, and the timeframe over which this review has been conducted is too short to reach a conclusive understanding of changes over time – particularly given the emergence of the COVID-19 pandemic, which has impacted on crucial data collection since March 2020. Data collection and comparison were further complicated by differing methods of data collection across each administration of the UK, which resulted in differently caveated data.

2. Three licensed cannabis-based medicines are now available in the UK and approved by the National Institute for Health and Care Excellence (NICE) for conditions where the evidence is strongest – around 800 patients a year received a licensed cannabis-based medicine from 2017 to 2019. There is evidence of an increase in the number of patients being prescribed licensed cannabis-based medicines across the UK in the four to six months following November 2019, possibly as a result of:
    - the publication of NICE guidance on 'cannabis-based medicinal products';
    - the publication of NICE's technology appraisal guidance for the treatment of Lennox-Gastaut and Dravet syndromes with Epidyolex; and/or
    - the granting of marketing authorisation for Epidyolex in the UK.

3. Currently, only a limited number of patients (strongly presumed to be fewer than five) have been prescribed unlicensed CBPMs by the NHS, despite a range of unlicensed CBPMs being available. This may be expected for a number of reasons, including:
    - licensed cannabis-based medicines are now available to clinicians and are recommended by NICE guidance for certain conditions – unlike unlicensed CBPMs;
    - there is a lack of safety and efficacy data for many unlicensed CBPMs;
    - prescription of unlicensed CBPMs is limited only to practitioners on the specialist register of the General Medical Council (GMC); and

- lack of evidence on cost effectiveness and the relatively high costs of these unlicensed medicines.

4. Compared with the number of patients prescribed unlicensed CBPMs by the NHS, there had been a considerable increase in the number of patients privately prescribed unlicensed CBPMs in England in the year immediately following the rescheduling of CBPMs (63 patients, up from 0 in the preceding year). A continuation of this trend is expected based on Department of Health and Social Care (DHSC) projections, with between 149 and 224 unique patients estimated to have been privately prescribed unlicensed CBPMs in England over the course of 2020. It is unclear how many of the patients receiving privately prescribed unlicensed CBPMs – products that often lack robust evidence of safety, quality and efficacy data – were first prescribed licensed cannabis-based medicines before commencing treatment with unlicensed CBPMs.

5. The development of a CBPM patient registry is a very significant step in allowing for a careful analysis of the extent and pattern of prescription of CBPMs and their benefits and risks.

6. The price of licensed cannabis-based medicines has remained largely unchanged. The price of unlicensed CBPMs is currently high in comparison to licensed cannabis-based medicines. The market for unlicensed CBPMs, licensed CBPMs and licensed cannabis-based medicines is still in its infancy.

7. There has been a considerable increase in CBPM import notifications made to the Medicines and Healthcare products Regulatory Agency (MHRA) – as well as the number of packs of CBPMs notified for import – which does not necessarily reflect an actual increase in the quantity of CBPM imports. It is currently unclear what this increase in CBPM import notifications represents, and whether it is indicative of increased CBPM usage within the UK.

8. MHRA Yellow Card data on adverse drug reactions indicated a low level of reported harm for unlicensed CBPMs, cannabidiol (CBD) food products and licensed cannabis-based medicines, although some of the harms that were reported (including one fatality associated with a licensed cannabis-based medicine) were severe. The level of adverse drug reaction (ADR) reporting associated with these products has increased since the rescheduling of CBPMs, however, this increase was from extremely limited levels of ADR reporting in 2017. It is too soon to draw conclusions about the safety of these products from the current Yellow Card data available.

9. There is a process in place by which the National Institute for Health Research (NIHR) can fund research into the medicinal use of cannabinoids, licensed cannabis-based medicines and unlicensed CBPMs. The availability of peer-reviewed research

will be essential in determining the benefits and harms of these products. Therefore, the extent of their therapeutic role is likely to emerge gradually and over the course of the next few years.

10. There appears to have been relatively little interest from the manufacturers of unlicensed CBPMs to apply for regulatory approval. There are only three licensed cannabis-based medicines for which the respective manufacturers have successfully applied for marketing authorisation in the UK.

11. A sufficient period of time has not yet passed for evidence to have emerged to indicate whether the rescheduling of CBPMs has had an impact on the prevalence of illicit cannabis use.

12. There is little current evidence of the diversion of unlicensed CBPMs or licensed cannabis-based medicines into illicit markets, following the rescheduling of CBPMs. However, several police forces across the country have reported observing illicit cannabis being mislabelled as a medicinal product. The impact of this mislabelling on policing is currently unclear.

Recommendations

1. The ACMD should be commissioned to conduct a further assessment of the impact of the rescheduling of CBPMs in the two years following the publication of this report, as there is not yet sufficient evidence available to fully assess any and all consequences of the legislative change. Much of this evidence would not be expected to fully emerge for several years.

   Lead: Home Office.

   Measure of outcome: Continued assessment of the impact of the rescheduling of CBPMs in November 2018 using the assessment framework developed by the ACMD; a further ACMD report to be published in November 2022.

2. The availability of a CBPM patient registry should be recognised as crucial for future assessments of the impact of the rescheduling of CBPMs in November 2018. The Government should continue to support the development of an official CBPM patient registry. Depending on whether the official CBPM patient registry is developed to be able to collect all necessary CBPM private prescription data, the Government may wish to consider how the official registry can interact with those in development outside of Government.

   Lead: Department of Health and Social Care (DHSC); NHS England and NHS Improvement.

Measure of outcome: Availability of an official CBPM patient registry.

3. Research should be commissioned:
   a) to assess the impacts of the rescheduling of CBPMs in November 2018 on public knowledge and attitudes towards cannabis, unlicensed CBPMs, licensed CBPMs and licensed cannabis-based medicines; and
   b) to explore the safety, quality and efficacy of unlicensed CBPMs, licensed CBPMs and licensed cannabis-based medicines.

   Lead: National Institute for Health Research.

   Measure of outcome: Reports available containing information about the impact of the rescheduling of CBPMs on public perception of cannabis, unlicensed CBPMs and licensed cannabis-based medicines.

4. Government departments should conduct a full review of international approaches to legislation facilitating the medicinal usage of cannabis-based medicines.

   Leads: Home Office; DHSC.

   Measure of outcome: A joint report compiled by both leads to explore recommended initiatives, technologies or investments which could be beneficial in the UK.

We look forward to discussing this report with you in due course.

Yours sincerely,

Professor Owen Bowden-Jones
Chair of ACMD

CC: Kit Malthouse MP (Minister of State for Crime and Policing)
Rt Hon. Matt Hancock MP (Secretary of State for Health and Social Care)