

# ACMD

## Advisory Council on the Misuse of Drugs

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Rt. Hon. Priti Patel MP  
Home Secretary  
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7<sup>th</sup> April 2020

Dear Home Secretary,

**RE: COVID-19: ACMD advice on proposed legislative changes to enable supply of controlled drugs during a pandemic**

Thank you for your letter of 1 April 2020 in which you commissioned the Advisory Council on the Misuse of Drugs (ACMD) to consider the Government's proposed measures to help secure access to controlled drugs within the healthcare system during a pandemic, and where there is a serious risk to human health.

The ACMD has been requested to advise on the potential harms or risks relating to three proposed measures, the balance of the harms and risks of *not proceeding* with these measures in the current exceptional circumstances, and on mitigations to minimise the risks associated with these measures.

As required under section 31(3) of the Misuse of Drugs Act 1971, the ACMD is providing advice in its role as statutory consultee to changes to the Misuse of Drugs Regulations 2001 (MDR).

The proposed measures developed by the Department of Health and Social Care (DHSC) and the Home Office and presented to the ACMD, were:

- *Measure 1*: Enabling registered pharmacies to supply controlled drugs without a prescription (where the patient has been receiving those controlled drugs as part of on-going treatment);

- *Measure 2:* Extension of Serious Shortage Protocols (SSPs) to include controlled drugs in Schedules 2, 3 and 4 (Part I) of the Misuse of Drugs Regulations 2001 (MDR), and;
- *Measure 3:* Enabling pharmacists to vary the frequency of dispensing of an instalment prescription.

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**Measure 1: Enabling registered pharmacies to supply controlled drugs without a prescription (where the patient has been receiving those controlled drugs as part of on-going treatment) during a pandemic**

*a) Outline of measure*

The Government has proposed an amendment to the MDR to enable registered pharmacies, *during a pandemic*, to supply controlled drugs in Schedules 2, 3, and 4 (Part I) of the MDR without a prescription where the patient has been receiving those drugs as part of on-going treatment. In accordance with the Human Medicines Regulations 2012, pharmacists are already enabled to supply controlled drugs in Schedules 4 (Part II) and 5 without a prescription (where the patient has been receiving those drugs as part of on-going treatment) during a pandemic.

This policy measure was proposed to offer flexibility in exceptional circumstances (such as the current coronavirus disease [“COVID-19”] pandemic).

The ACMD has been given the following assurances:

- That controlled drugs would only be supplied through registered pharmacies regulated by the General Pharmaceutical Council (GPhC), and would only be supplied by pharmacists at their professional discretion. Any cases where there is insufficient information available to dispense safely would be referred back to the original prescribing service;
- That the measure would only relate to NHS services – where the Government is assured that the correct governance processes will be in place. The measure would not apply to private prescriptions of controlled drugs;
- That the relevant leads in the National Police Chiefs Council (NPCC), the National Crime Agency (NCA), the Ministry of Justice and HM Prisons and Probation Service have been consulted and view the risks of diversion (resulting from this measure) as low, or at least outweighed by the need to continue to supply medicines to those in need, and;

- That this measure would be limited to a defined geographical area in defined circumstances, where the relevant Minister is able to withdraw or amend this measure at any time.

*b) Risks of proceeding with the measure*

Although the measure could only apply in a pandemic for a limited, defined time-period (up to a maximum of three months) subject to extension (for further periods of up to three months at a time), amendment, or withdrawal by Ministers, there remains a risk that this measure could apply longer than is necessary i.e. where there is no longer the risk of discontinuity of supply of repeat prescriptions.

The measure would rely on the professional judgement of pharmacists, who will be working outside of the scope of their usual practice. Without adequate support and guidance for the healthcare professionals affected by the proposed legislative change, there is a risk that pharmacists struggling to follow best practices could inadvertently lead to an increase in drug misuse and diversion. This is a particular risk for patient groups requiring opioid pain medicines e.g. for palliative care or for opioid substitution therapy (OST).

Additionally, whilst it will be necessary for the Government to publicly announce in an emergency that these measures are to apply, common knowledge of the applicability of this measure may increase the risk of the misuse and diversion of controlled drugs. For example, patients with substance misuse issues might attempt to place pressure on a pharmacist to dispense in accordance with this measure, or might visit a range of pharmacists in an attempt to locate and exploit weaknesses in any of their practices in order to be supplied with medicines against best practice.

*c) Risks of not proceeding with the measure*

There is a risk that some General Practitioner (GP) surgeries and pharmacies could close in the current pandemic as a result of staff shortages resulting from illness and/or self-isolation requirements, or the need to undertake a lengthy deep-cleaning of the premises. The ACMD have been alerted to an example where one GP surgery had closed, leading a nearby surgery to struggle to cope with the resultant increased demand on their services.

Without proceeding with this measure, the ACMD considers there to be a significant and potentially urgent risk of discontinuity of supply of repeat prescriptions, with associated risk of harms for those patients affected by that discontinuity.

A discontinuity of supply would pose a particular risk for patients receiving OST. In the event that GP surgeries were closed during the pandemic, those patients might find they have less support and oversight from the relevant healthcare professionals, leading to an increased risk of relapse to illicit drug use.

*d) Conclusions and recommendations on mitigations to minimise risks*

**Conclusion 1:** On balance, considering the harms and risks of *not* proceeding with 'Measure 1' (as presented by DHSC) in the exceptional circumstances presented by the COVID-19 pandemic, the ACMD is generally supportive of the legislative measure to enable registered pharmacies to supply controlled drugs without a prescription during a pandemic, where there is a risk of discontinuity of supply of repeat prescriptions. However, pharmacists will require additional support and guidance, as they will be working outside of the scope of their usual practice in exceptional circumstances.

**Recommendation 1:** The ACMD recommends that *national-level* guidance is produced in consultation with the relevant medical Royal Colleges and professional bodies (such as the Royal College of Psychiatrists, the General Pharmaceutical Council, the Pharmaceutical Services Negotiating Committee, and the Royal Pharmaceutical Society) to support the Government's proposal, and should note:

- That whilst patient groups requiring opioid pain medicines for palliative care and for OST would be at greater risk from a discontinuity of supply, for the latter patient group, this measure would be associated with a greater risk of misuse and diversion;
- That pharmacists considering whether to supply controlled drugs via this route should consult with, and refer any concerns back to the original prescribing service as far as possible – to minimise the risk of misuse and/or diversion;
- How the supply of a controlled drug by a pharmacy via this route, and the risk assessment carried out by the pharmacist (balancing the clinical need to supply against potential harms) is to be documented and recorded - and how the original prescribing service is to be notified;
- The necessity of more rigorous checks (e.g. additional ID checks) for patients attempting to obtain a controlled drug via this route - particularly where the supply may be given to a representative of that patient, or another individual;
- How pharmacists will determine whether a treatment should be considered 'on-going' – this may vary according to the indication for which the controlled drug is prescribed, and;
- How pharmacists should feed-back to the original prescribing service any changes in the patient's condition or situation (for example, if a patient clinically deteriorates, or is being found to be bullied for their medicine).

Lead: DHSC

**Conclusion 2:** During a pandemic, pharmacists will need to be informed by Government:

- That the measures will apply;
- The defined time period for which the measures will apply, and;
- The defined geographical area in which these measures will apply.

**Conclusion 3:** The proposed measure weighs the increased risk of diversion against the need to ensure a continuity of supply of controlled drug medicines in a pandemic situation. Risks will be minimised where this measure is withdrawn as soon as possible after a pandemic situation ceases to threaten the continuity of medicine supplies.

**Recommendation 2:** The ACMD recommends that, in a pandemic situation, the Government aims to end the period in which this measure will apply as soon as possible after the measure ceases to be necessary. The relevant Ministers should therefore:

- Define the period in which the measure will apply to less than the maximum period of three months where appropriate, and;
- Withdraw these measures as a matter of urgency where they cease to be necessary before the end of the defined period set out in the announcement.

Lead: Home Office

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**Measure 2: Extension of Serious Shortage Protocols (SSPs) to include controlled drugs in Schedules 2, 3 and 4 (Part I) of the Misuse of Drugs Regulations 2001**

*a) Outline of measure*

The Government has proposed a measure to allow the supply of controlled drugs in Schedules 2, 3 and 4 (Part I) of the MDR under a Serious Shortage Protocol (SSP) in a pandemic situation. Pharmacists are already enabled to supply controlled drugs in Schedules 4 (Part II) and 5 of the MDR in accordance with an SSP.

SSPs enable community pharmacists to supply alternative products, formulations, quantities, or strengths of medicines (to be established within the protocol) to those specified on the prescription without referring back to the prescriber. SSPs will be issued where the prescribed items are unavailable or there is a serious supply shortage.

The ACMD has been given the following assurances:

- That controlled drugs supplied in accordance with an SSP require a prescription from a prescriber to be in place. Furthermore, only pharmacists from registered pharmacies regulated by GPhC could supply under an SSP – and would only do so at their professional discretion. Cases where there is insufficient information available to dispense safely would be referred back to the original prescribing service;
- That the measure would only relate to NHS services – where the Government is assured that the correct governance processes will be in place. The measure would not apply to private prescriptions of controlled drugs;
- That the NCA and NPCC have been consulted and view the risks of misuse and diversion resulting from this measure as low, or at least outweighed by the need to continue to supply medicines to those in need;
- That SSPs will, for a defined length of time, only extend to Schedules 2, 3 and 4 (Part I) of the MDR during a pandemic situation. The relevant Minister will be able to withdraw or amend these measures at any time;
- That SSPs can be issued within very short timescales ensuring they will be of use in a pandemic situation, and;
- That although the alternative medicines provided for by SSP would not *legally* have to have the same quantity of active ingredient as that which was written on the prescription, *in practice* this will be the case in the majority of situations. Clinicians, patient groups and other relevant organisations will be consulted when SSPs are to be introduced, allowing them to reflect any concerns at that stage.

*b) Risks of proceeding with the measure*

The risk of diversion and misuse is expected to be unchanged by including controlled drugs in Schedules 2, 3 and 4 (Part I) of the MDR under SSPs - as the supply of active ingredient is in accordance with a prescription under the MDR.

Under this measure, the legislation would allow for the alternative medicine provided for by an SSP to have a different strength or quantity of active ingredient to that which was written on the prescription, or for a therapeutic equivalent to be provided. Without sufficient consultation with relevant clinicians, patient groups and other relevant organisations, an SSP could be issued which would enable pharmacists to practice well outside of the scope of their usual practice. This could present a particular risk of harm where medicines are dispensed under an SSP to patients with changing mental or physical health problems.

SSPs issued to date have been very specific and limited in scope, for example, supplying haloperidol 500 microgram tablets in the place of haloperidol 500

microgram capsules [NHSBSA, 2019]. In the event that the COVID-19 pandemic escalates, there is a risk that many more SSPs would have to be issued, thus placing a burden on DHSC, who would therefore lose capacity to work elsewhere in the pandemic.

There are also substantial patient safety risks for therapeutic equivalents of some controlled drugs. For example, the 'conversion factors' used when switching opioids (e.g. morphine to oxycodone, or a fentanyl patch) are only rough estimates. If these conversion factors are used incorrectly, or if the switch is not monitored closely, opioid toxicity or an increase in pain may result.

Similarly, there are some controlled drugs where it would be more complex to attempt to exchange for an 'alternative'. For example, there is the risk of precipitated withdrawal if a patient on OST previously receiving methadone was instead dispensed buprenorphine.

There is also a risk that SSPs, without the appropriate consultation before introduction, might trigger the allergies/intolerances of certain patient groups. For example, on rare occasions a prescriber might prescribe a specific brand where a specific patient has experienced side-effects from some of the excipients of other products. As with other SSPs, the pharmacist will be responsible for discussing this with the patient in order to avoid these side effects, which could include an allergic reaction.

#### *c) Risks of not proceeding with the measure*

As discussed earlier in this advice, there is a significant risk that some GP surgeries and pharmacies could be placed under great pressure during the current COVID-19 pandemic. There is also a significant risk of supply shortages, given the impacts of COVID-19 on global supply chains. This disruption may extend to impact medicines which are controlled drugs in Schedules 2, 3 and 4 (Part I) of the MDR.

Without proceeding with this measure, the ACMD considers there to be a significant and potentially urgent risk of discontinuity of supply of repeat prescriptions with associated risk of harms for those patients affected by that discontinuity.

#### *d) Conclusions and recommendations on mitigations to minimise risks*

**Conclusion 4:** On balance, considering the harms and risks of *not* proceeding with 'Measure 2' in the exceptional circumstances presented by the COVID-19 pandemic, the ACMD is generally supportive of the legislative measure to allow SSPs to include controlled drugs in Schedules 2, 3 and 4 (Part I) of the MDR in a pandemic situation. There are, however, substantial patient safety risks for therapeutic equivalents of some controlled drugs.

**Recommendation 3:** The ACMD recommends that SSPs are only issued for controlled drugs in Schedules 2, 3 and 4 (Part I) of the MDR as a last-resort and after an in-depth consultation of patient groups, clinicians and other relevant organisations has been undertaken.

Lead: DHSC

**Conclusion 5:** As the situation of the COVID-19 pandemic develops, it may become necessary for an increasing number of SSPs to be issued.

**Recommendation 4:** The ACMD recommends that SSPs should continue to be highly specific and limited in scope, despite the burden that might result from doing so as the COVID-19 pandemic develops, so that pharmacists – who will be operating outside their normal scope of practice – can be reassured that they are ensuring patient safety under clear instruction.

Lead: DHSC

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### **Measure 3: Enabling pharmacists to vary the frequency of dispensing of an instalment prescription in a pandemic situation**

#### *a) Outline of measure*

The Government has proposed an amendment to the MDR which would allow pharmacists, in a pandemic and where there is a serious risk to human health, the flexibility to vary – where possible, in consultation with the prescriber or the prescriber’s appointed representative – the frequency with which an instalment prescription is dispensed. The measure also aims to minimise social contact within pharmacies, in line with the Government’s current advice on social-distancing.

The ACMD has been given the following assurances:

- As with Measures 1 and 2, only pharmacists from registered pharmacies regulated by the GPhC can vary the frequency of the dispensing of controlled drugs in this way;
- That the NCA and NPCC have been consulted, and that their concerns have been considered by Government when developing this measure. These include that the measure:
  - would cover high-risk individuals,
  - could result in greater quantities of controlled drug medicines such as methadone being stored in the homes of patients on drug treatment programmes;



- Wherever possible, changes to the intervals of dispensing for an instalment prescription would be made with the agreement of the prescriber or (or an agreed representative of the service responsible for) the original prescription.

*b) Risks of proceeding with the measure*

The measure could enable a patient to have increased quantities of take-home OST in their possession. This is a particular risk as toxicology studies have shown that take-home doses of OST (particularly methadone) can lead to overdose [Seymour *et al.*, 2003; Scott *et al.*, 1999]. This risk of overdose may be enhanced without the suitable provision of naloxone to any individual who needs access to it [PHE, 2015].

It is possible that this measure may reduce the contact between patients and drug treatment services, which could result in increased risks of overdose and drug-related death.

There is a risk involving patients not safely storing OST medicines in their homes if they have greater quantities of medicine dispensed to them at any one time. This would present a risk not just to the patient receiving take-home OST, but also to children and other vulnerable dependants residing in the homes of patients receiving take-home OST [Adfam, 2014]. This risk is further enhanced during the COVID-19 pandemic, with many children staying at home whilst schools are closed. The National Institute for Health and Care Excellence (NICE) have noted that there is a high mortality risk associated with methadone in those who are 'opioid-naïve' [NICE, 2007].

The risk of patients receiving OST having their prescriptions or medicines stolen from them may be increased if this measure results in patients having greater quantities of medicine dispensed to them by pharmacies (at any one time). This risk may also apply to theft from patients' homes, particularly where the relevant safe-storage options have not been discussed with patients before dispensing [NICE, 2016]. The risk of theft of OST medicines may also be enhanced during the COVID-19 "lockdown" period if, for example, street heroin prices increase and/or purity decreases as a result of restricted supply.

Similarly, the adoption of this measure may lead to an increasing quantity of controlled drugs being stored in a community pharmacy at any one time, which may increase the likelihood of theft.

Under this measure, where the original prescriber and the prescriber's agreed representative from the service responsible for the original prescription are unavailable, a pharmacist would be enabled to act unilaterally. In this event, pharmacists would be expected to use their professional judgement to establish whether to change the dispensing intervals of an instalment prescription. As pharmacists would be expected to operate beyond their usual scope of practice, it

will be very difficult for them to judge the impact of changing the frequency of instalments, given:

- A pharmacist might not possess a complete set of clinical details for every patient (including: how that patient responded to previous treatment; a risk assessment of that patient's likelihood of relapse; whether that patient has a history of poly-drug use, and; whether that patient's household has safeguarding concerns or multiple people taking-home OST);
- It would be high-risk for some particularly vulnerable patient groups including those recently released from prison [Clinical Guidelines on Drug Misuse and Dependence Update 2017 Independent Expert Working Group, 2017], and;
- Most drug and alcohol treatment services and GP prescribers are currently reviewing their caseloads, with the intention of reducing the frequency of 'pick-ups' to account for the impact of the pandemic. It is therefore increasingly likely that patients continuing to receive prescriptions by regular instalments do so for a clear clinical reason.

Pharmacists might also find themselves under pressure from patients to extend the intervals between their instalment prescription, as a result of this measure.

#### *c) Risks of not proceeding with the measure*

As noted elsewhere in this advice, there is a possible risk that some GP surgeries and pharmacies could be placed under great pressure in the current COVID-19 pandemic. Without proceeding with this measure, the burden on these services may pose a significant and potentially urgent risk of discontinuity of supply of repeat prescriptions (with associated risk of harms for those patients affected by that discontinuity).

There is also an increased risk of patients receiving OST turning to acquisitive crime in the event of the discontinuity in supply of their prescribed medicines.

In addition, there is a risk that patients who are required to go regularly to pharmacies to collect an instalment prescription may struggle to comply with the Government's current advice on social-distancing during the COVID-19 pandemic. This is particularly problematic to those who misuse opioids, where evidence has shown this group to be at an already significantly elevated risk of mortality from the underlying health conditions that commonly cause complications in those who contract COVID-19. For example, a study in England has shown those who misuse opioids to be approximately nine times more likely to die due to respiratory disease, and three times as likely to die due to circulatory disease [Pierce *et al.*, 2015].

#### *d) Conclusions and recommendations on mitigations to minimise risks*

**Conclusion 6:** The risks associated with this measure will be substantially greater if pharmacists are enabled to vary the frequency of dispensing an instalment prescription in a pandemic without having consulted the original prescriber, or their appointed representative.

**Recommendation 5:** The ACMD recommends that the legislative measure to enable pharmacists to vary the frequency of dispensing an instalment prescription in a pandemic should be amended before implementation, such that pharmacists may *only* vary the frequency of dispensing where they have consulted with the prescriber (or an appointed representative of the prescriber).

Leads: Home Office, DHSC

**Conclusion 7:** To minimise the risks associated with this measure, patients receiving take-home OST medicines will need to be able to safely store those medicines, have access to opioid-receptor antagonist medicines (such as naloxone), and have a means of maintaining regular contact with the relevant healthcare professionals responsible for these prescriptions. Pharmacists will also need to be supported by the original prescribing service to minimise the risks associated with this measure, which include the possible increase in risk of drug-related death.

**Recommendation 6:** With pharmacists enabled to vary the frequency of dispensing of an instalment prescription in a pandemic, prescribing services should attempt to ensure that patients on courses of take-home OST who will be affected by this measure:

- a) Have lock-boxes to store those medicines in;
- b) Are provided with take-home naloxone, and;
- c) Maintain regular contact with the prescriber or prescribing service and can contact relevant healthcare professionals.

Lead: DHSC

**Recommendation 7:** Pharmacists and prescribing services should be supported by the development of:

- A mechanism whereby prescribers can easily indicate to pharmacists where any relaxation in supervision requirements or frequency of instalment prescription would be unsuitable, and;
- A professional-professional phone link for pharmacists to easily access prescribing services.

Lead: DHSC

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## Quality of Evidence

The quality of evidence supporting/opposing the implementation of these measures is limited and largely anecdotal given the unprecedented situation the UK is in during the current COVID-19 pandemic.

There is limited evidence which suggests that there may be widespread closures of GP practices (DHSC).

UK data and statistics which might normally have been used by the ACMD as evidence will have been collected in circumstances quite different to those during the COVID-19 pandemic – their availability and usefulness is therefore limited.

There is also no evidence to indicate whether SSPs covering controlled drugs have, to date, been linked to an increased risk of misuse and diversion. DHSC have confirmed to the ACMD that no SSPs have yet been issued for any controlled drugs in Schedules 4 (Part II) and 5 of the MDR.

There is, however, high-quality evidence to suggest that the inability to meet the Government's current advice on social-distancing could present a particular risk to those who misuse opioids, since this group is already at an increased risk of mortality from the underlying health conditions that commonly cause complications in those who contract COVID-19.

There is anecdotal evidence to support the risk of patients experiencing their OST medicines being stolen from them during the COVID-19 pandemic. For example, there have been crime reports already during the pandemic, reporting multiple bottles of methadone at the crime scene.

**Conclusion 8:** Although the proposals have been drawn up in response to the current COVID-19 pandemic, each measure is associated with risks. The quality of available evidence to support the proposals is limited and as a result it is difficult to determine their impact.

**Recommendation 8:** The ACMD recommends that the implementation of each legislative measure includes a review process to allow the Home Office and DHSC to assess whether the amendments to the MDR have worked as intended and if there have been any unintended consequences. These reviews should consider at least the following data:

- Reports of GP practice closures/lack of availability of a prescriber, and the impact of this on service provision;
- Level of uptake of the three measures and their effectiveness;

- Unintended consequences associated with the implementation of the three measures;
- Crime reported at pharmacies;
- Changes in patterns of illicit drug use and availability during the pandemic;
- Patient safety incidents with controlled drugs; and
- Drug-related morbidity and deaths (broken down by underlying and contributory causes of death, where possible - to correctly identify those drug users who have died of COVID-19 associated issues).

Leads: Home Office, DHSC

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The ACMD reiterates the importance of ensuring that, during a pandemic, these measures do not extend any longer than is necessary to minimise any disruption to normal routes of supply of controlled drug medicines. The ACMD welcomes the opportunity to discuss this advice in due course – and remains ready to provide further advice as the COVID-19 pandemic progresses.

Yours sincerely,



**Prof Owen Bowden-Jones**  
**Chair of ACMD**



**Prof Roger Knaggs**  
**Chair of ACMD's Technical Committee**

CC:

Rt Hon. Matt Hancock MP (Secretary of State for Health and Social Care)  
Kit Malthouse MP (Minister of State for Crime, Policing and the Fire Service)  
Jo Churchill MP (Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care)

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