



Professor Owen Bowden-Jones  
Chair of the Advisory Council on the Misuse of Drugs  
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22 April 2020

Dear Professor Bowden-Jones,

## **COVID-19: EMERGENCY LEGISLATION TO ENABLE SUPPLY OF CONTROLLED DRUGS**

Thank you for your advice of 7 April and your conversation with the Minister for Crime and Policing on Thursday April 9 on the proposed emergency measures to help secure access to controlled drugs within the healthcare system in a pandemic and where there is a serious risk to human health. I have considered the advice carefully and I agree with all the recommendations. This response has been agreed by Jo Churchill MP, the Minister for Prevention, Public Health and Primary Care and follows consultation with the NHS England-NHS Improvement (NHSE-I) and Public Health England.

### **Recommendation 1: Guidance**

The ACMD recommended 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. The ACMD noted six key points that should be included in the guidance.

Health is a devolved matter. The health services in each nation will develop and issue guidance on the implementation of the measures. However, the Government will continue to work collaboratively with the Devolved Administrations to ensure that health service guidance is aligned across Great Britain. It is important that guidance is developed in consultation with relevant professional bodies and royal colleges.

### **Recommendation 2: duration of measures**

The ACMD recommended 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.

The Government is clear that all three measures will only be engaged in very limited circumstances. These measures are enabling and would only be used if demand pressures and workforce illness during the pandemic meant that local health services were at imminent risk of failing to fulfil their duties and only last the duration of the emergency. These measures aim to ensure that pharmaceutical services will continue to be able to deliver the best possible care and service during the peak of the pandemic and to protect the lives of the most vulnerable members of society.

I must be clear that these measures will not come into use with immediate effect. The Government, in close liaison with the NHS service and Devolved Administrations, will carefully consider when to 'switch on' these measures. I agree with the Council's recommendation: before these measures are engaged, clear guidance will need to be in place for healthcare professionals and the precise scope and duration of the measures clearly defined, where appropriate. Equally, these measures will only be engaged for as long as necessary and will be time limited, which may be less than the maximum three months.

### **Recommendation 3 and 4: Serious Shortage Protocols (SSPs)**

The ACMD recommended 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. 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.

SSPs, including those for controlled drugs, would only be used in the case of a serious shortage if, in the opinion of Ministers, it would help manage the supply situation and if clinicians advising Ministers think it is appropriate. Protocols would be developed with input from expert clinicians but will only be considered in exceptional circumstances.

This work is overseen by the Medicines Shortages Response Group (MSRG), chaired by one of NHSE-I's Deputy Chief Pharmaceutical Officers. Established since January 2019, the MSRG provides clear governance, communication and decision making to the Department of Health and Social Care (DHSC) Medicines Supply Team, and NHSE-I's Commercial Medicines Unit on individual critical issues for serious medicines shortages, which would include controlled drugs. They will advise on whether the development of an SSP would be beneficial to help mitigate a shortage and provide a recommendation to the National Medical Director and Chief Pharmaceutical Officer on this basis. The National Medical Director and Chief Pharmaceutical Officer will then provide the final recommendation to Ministers.

### **Recommendation 5: instalment prescriptions**

The ACMD recommended 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).

In my letter of 1 April, we proposed to enable pharmacists without prescribing rights to change the frequency of instalments on instalment prescriptions without the immediate need for a new prescription from a prescriber. We proposed that the pharmacist should make the change with the agreement of the prescriber, or, if the prescriber is unavailable, only if they are satisfied, in the exercise of professional skill and judgement, that the change is appropriate and safe.

The ACMD has recommended that it should be a requirement in all circumstances that the prescriber, or an appointed representative, is consulted. I agree with the recommendation and will reflect it in the legislation.

### **Recommendation 6: instalment prescriptions and reducing harms**

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.

The Government will pass on the ACMD recommendation to the health services and encourage them to consider it when developing the guidance.

### **Recommendation 7: support to pharmacists and prescribing services**

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.

The Government will pass on the ACMD recommendation to the health services and encourage them to consider it when developing the guidance.

### **Recommendation 8: review**

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. The ACMD set out seven key data that should be considered.

The Government will set out in the Explanatory Memorandum a commitment to review the measures, using the data suggested if possible.

I intend to introduce legislation to bring these measures into effect as soon as possible. I would like to again emphasise that the amendments would only be used in limited

circumstances following an announcement by the Secretary of State and under conditions specified by the health service in the area to which the announcement applies.

I would like to extend my thanks to all members of the ACMD for their flexibility and professionalism in providing swift and expert advice.

W. K. are your wishes  
PK

**Rt Hon Priti Patel MP**