



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

Dear Professor Bowden-Jones,

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

The Covid-19 pandemic is expected to place very high demands on our health service, and we must be as prepared as possible. We intend to put in place emergency measures to:

- i) legislate to allow registered pharmacies to supply substances in Schedule 2, 3 and Part 1 Schedule 4 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') without a prescription, where the patient has been receiving them as part of on-going treatment.
- ii) allow supply of Schedule 2, 3 and Part 1 Schedule 4 substances under a Serious Shortage Protocol. These allow on-going treatment with alternative products where prescribed items are unavailable or are in short supply; and
- iii) allow pharmacists without prescribing rights to change the frequency of instalments on instalment prescriptions without the immediate need for a new prescription from a prescriber.

These measures help secure access to controlled drugs within the healthcare system in a pandemic and where there is a serious risk to human health. They will ensure patients continue to have access to medicines critical for on-going treatment, build resilience and help relieve pressure elsewhere in the health system. There are risks of making these changes related to greater access to controlled drugs and risk of diversion or misuse which have been taken into account in developing the measures. There are also limitations to the evidence base on which to make decisions about when to apply these greater flexibilities. My officials will provide you further detail on the proposals, which are set out in outline below.

The request of the ACMD is to advise on the potential harms or risks relating to these three measures, and the balance of the harms and risks of not proceeding in the current exceptional circumstances. Any advice that the ACMD is able to provide on mitigations to minimise risks would be appreciated.

Emergency supply without prescription

The emergency supply of prescription-only medicines during a pandemic is enabled by the Human Medicines Regulations 2012. However, this does not extend to Schedule 2, 3 and Part 1 Schedule 4 substances. We propose to legislate to allow registered pharmacies to supply these drugs without a prescription, where the patient has been receiving them as part of on-going treatment. To do this, patients must lawfully be able to possess those drugs and we propose to amend the 2001 Regulations to enable them to do so.

Safeguards – emergency supply without prescription

The capacity for supply by pharmacists without prescription would:

- apply only to patients who have been receiving the drug as part of on-going treatment;
- be subject to the pharmacist's professional judgment - relying on their knowledge and experience of working with a range of patients, albeit this will be an additional responsibility that they will not have had to date - pharmacists would not be obliged to supply the drugs;
- remain subject to existing safeguards, including record-keeping and checking the identity of the patient or the person obtaining the medicines on their behalf.

Mechanism for bringing the arrangements into place

The arrangements would be made operational through specific routes in England, Wales and Scotland. In England, this would be through NHSE-I commissioning routes and sign-off by a Senior Civil Servant on behalf of DHSC Ministers. The measures would require consultation with Welsh and Scottish Ministers when they are affected. Any arrangements would be:

- limited to a defined time period (a maximum of three months, which can be extended for further periods of not more than three months); and
- limited to a defined geographical area (potentially, limited only to defined GP practices and pharmacy services or, if required, nationwide);

The measures would apply in England, Wales and Scotland. The Department of Health in Northern Ireland has said that it supports the proposals and indicated that it will introduce similar measures to align with Great Britain.

SERIOUS SHORTAGE PROTOCOLS (SSPS)

SSPs manage the shortage for individual drugs. They enable community pharmacists, in the event of a serious shortage of a prescribed item, to supply in accordance with the Protocol rather than against a prescription, without going back to the prescriber. SSPs are currently not available for use for Schedule 2, 3 and Part 1 Schedule 4 substances. There is a significant risk of supply shortages, given the impact of Covid-19 on the supply chain. We therefore propose to allow SSPs to apply to these substances in anticipation of possible shortages.

Safeguards – SSPs for controlled drugs

SSPs are only introduced with the involvement of clinicians (doctors and pharmacists). Additionally, as appropriate, there will be consultation with relevant patient groups, the devolved administrations, NHS England and Improvement, relevant manufacturers and relevant pharmacy organisations including Pharmaceutical Services Negotiating Committee (PSNC).

The following controls and safeguards would apply as part of introducing this measure:

- The measures would only apply to medicines in Schedule 2, 3 and Part 1 of Schedule 4. It would not affect Schedule 1 drugs.
- Drugs would only be supplied in accordance with an SSP – one criteria of which is that there is a prescription from a prescriber.
- Drugs would only be supplied through registered pharmacies – regulated by the General Pharmaceutical Council.
- Pharmacists would only supply under an SSP at their professional discretion and in cases where they deem it reasonable and appropriate for the patient and would refer any complex cases back to a prescriber.
- Where a controlled drug is supplied in accordance with an SSP, NHS terms of service provide that the pharmacist must notify the patient's GP of the alternative SSP supply, but this will not automatically apply to substances in Schedule 2, 3 and Part 1 of Schedule 4 because they have previously been out of scope of SSPs. In England, we will seek in discussions with the Pharmaceutical Services Negotiating Committee to trigger automatic notifications in such cases.

Mechanism for bringing the arrangements into place

Any arrangements would be implemented through specific routes in England, Wales and Scotland. In England, this would be through NHSE-I commissioning routes and would require approval by DHSC senior civil servants on behalf of DHSC Ministers. The measures would require consultation with Welsh and Scottish Ministers when they are affected. Any arrangements would be:

- limited to a defined time period (a maximum of three months, which can be extended for further periods of not more than three months); and
- limited to England, Scotland, Wales, any combination of which, or the whole of the UK (Northern Ireland can issue their own or joint protocol).

FREQUENCY OF INSTALMENTS ON INSTALMENT PRESCRIPTIONS

The Government is putting in place various measures to free-up capacity and maintain safe supply of medicines. As part of this, we propose to amend the 2001 Regulations to allow pharmacists to vary the frequency of supply from an instalment prescription, following the instructions of the prescriber or their appointed representative of the NHS service responsible for the original prescription (if available). For example, moving from “three times a week” to “once a week”. These instructions could be by phone or email but, if by phone, must be followed up by written confirmation. The total quantity supplied would remain as specified on the prescription.

The proposals will also minimise social contact within pharmacies, helping to protect front-line staff and patients by enabling reductions in the frequency of collections of medication.

Safeguards – variation of instalment prescriptions

Pharmacists would be expected to use their professional judgement, relying on their knowledge and experience of working with a range of patients, albeit this will be an additional responsibility that they will not have had to date. Existing clinical guidance and best practice should be maintained as far as possible, for example UK clinical guidance on Drug misuse and dependence (Section 4.6.3.3), state that no instalment should usually be

given if the patient has missed 3 days' supply. National guidance will be issued by NHS services to ensure common application across services.

The following controls and safeguards would apply as part of introducing this measure:

- The measures would only apply to medicines in Schedule 2, 3 and Part 1 of Schedule 4. It would not affect Schedule 1 drugs.
- Changes to intervals on an instalment prescription would be on the basis of agreement with the prescriber. If the prescriber is unavailable, the pharmacist will have to use their professional judgement, but in England we would expect the relevant NHS arrangements to provide that contact should be made with the prescriber's agreed representative of the service responsible for the original prescription (if available);
- Any change to the interval on an instalment prescription would be recorded by the pharmacy and prescriber.
- Drugs would only be supplied through registered pharmacies – regulated by the General Pharmaceutical Council.

Mechanism for bringing the arrangements into place


Any arrangements would be implemented through specific routes in England, Wales and Scotland. In England, this would be through NHSE-I commissioning routes and would require approval by DHSC senior civil servants on behalf of DHSC Ministers. The measures would require consultation with Welsh and Scottish Ministers when they are affected. Any arrangements would be:

- time limited (a maximum of three months, which can be extended for further periods of not more than three months); and
- limited to England, Scotland, Wales, any combination of which, or the whole of the UK.

Timescale

Subject to the advice of the ACMD, the Government intends to lay regulations enabling emergency supply as soon as possible and I therefore ask that the ACMD expedites consideration of this request and responds by 3 April.

I recognise that the council has a full work programme and that this is request is a challenging one at extremely short notice. However, I am sure you recognise the urgency of this request and I would like to thank the council for its flexibility.

With our great wishes


Rt Hon Priti Patel MP