EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (CORONAVIRUS) (AMENDMENTS RELATING TO THE SUPPLY OF CONTROLLED DRUGS DURING A PANDEMIC ETC.) REGULATIONS 2020

2020 No. 468

1. Introduction

1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument amends the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') in order to allow pharmacists at a registered pharmacy business to supply, in a pandemic situation, medicines without a prescription, where the patient has been receiving a Schedule 2 to Part 1 Schedule 4 controlled drug as part of on-going treatment, and to supply Schedule 2 to Part 1 Schedule 4 controlled drugs under a Serious Shortage Protocol. The amendments also allow pharmacists, in a pandemic situation, to change the intervals on instalment prescriptions for Schedule 2 and 3 controlled drugs without the immediate need for a new prescription from an authorised prescriber under the 2001 Regulations provided this is agreed with the prescriber or their appointed representative.

2.2 The amendments are enabling and 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(s) to which the announcement applies.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 These are emergency regulations in relation to the Government's response to the coronavirus ('Covid-19'). The regulations have been prepared as soon as it became clear that there was a need for the measures they contain. The measures aim to improve resilience within the health system, where local prescribing workforces may be diminished and ensure patients continue to receive essential medication while also reducing the burden on the rest of the health system. It is for these reasons that these regulations will come into force the day after they are laid, meaning that the usual period of 21 days between laying and coming into force will be breached on this occasion.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England, Wales and Scotland**.**

4.2 The territorial application of this instrument is England, Wales and Scotland.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The Misuse of Drugs Act 1971 ('the 1971 Act') applies to "controlled drugs" and sets out the offences and penalties for breach of the restrictions relating to controlled drugs. Controlled drugs are substances or products specified in Schedule 2 to the 1971 Act. Controlled drugs are divided into one of three Classes – A, B and C – based on their relative harms, with Class A drugs considered the most harmful.

6.2 The 2001 Regulations make lawful what would otherwise be unlawful and impose administrative obligations or requirements to mitigate risks of harm, misuse and diversion of controlled drugs.

6.3 The 2001 Regulations regulate legitimate access to drugs considered 'dangerous or otherwise harmful' and therefore controlled under Schedule 2 to the 1971 Act. Drugs so controlled are scheduled in one of five schedules under the 2001 Regulations. The schedule in which a drug is placed is based on an assessment of its medicinal or therapeutic usefulness, the need for legitimate access and the potential harm when misused. Scheduling dictates the extent to which it is lawful to import, export, produce, possess and supply controlled drugs. It also imposes requirements around the prescribing, record-keeping, labelling, destruction or safe custody of controlled drugs.

6.4 The 2001 Regulations prohibit the supply of Schedule 2 to Part 1 Schedule 4 controlled drugs to patients without the directions of a practitioner or other authorised prescriber. The list of authorised prescribers does not include pharmacists. The 2001 Regulations also indirectly prevent the supply of Schedule 2 to Part 1 Schedule 4 controlled drugs under a Serious Shortage Protocol, where a pharmacist at a registered pharmacy may reduce the amount to be supplied to a patient or substitute a different product. This instrument therefore introduces Regulation 10A to the 2001 Regulations in order to enable, in a pandemic situation, the Secretary of State to make an announcement that would permit pharmacists at registered pharmacies to undertake these activities in specified circumstances.

6.5 The 2001 Regulations also contain restrictions on the form of prescriptions. In the case of Schedule 2 or 3 controlled drugs intended to be supplied by instalments, the prescriber must specify the intervals between the supply of instalments. Regulation 15 of the 2001 Regulations is amended to enable, in a pandemic situation, the Secretary of State to make an announcement that would permit pharmacists to change the intervals for Schedule 2 and 3 controlled drugs in specified circumstances.

7. Policy background

What is being done and why?

7.1 The Covid-19 pandemic is placing very high demands on our health service. This instrument puts in place 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. This 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.

7.2 The emergency supply of prescription-only medicines during a pandemic without a prescription is enabled by the Human Medicines Regulations 2012. However, this does not extend to all controlled drugs. This instrument implements parallel measures to enable registered pharmacies to supply Schedule 2 to Part 1 Schedule 4 controlled drugs without a prescription in a pandemic, if the patient has been receiving them as part of on-going treatment.

7.3 The supply of a different strength, quantity or pharmaceutical form of a prescription only medicine to that ordered by the prescriber, in accordance with a Serious Shortage Protocol, is enabled by the Human Medicines Regulations 2012. However, this does not extend to all controlled drugs. This instrument implements parallel measures to enable registered pharmacies to supply Schedule 2 to Part 1 Schedule 4 controlled drugs in a pandemic in accordance with a Serious Shortage Protocol.

7.4 The instrument also provides flexibility for pharmacists to vary the frequency of dispensing of Schedule 2 and 3 controlled drugs from an instalment prescription in a pandemic, with the agreement of the prescriber or their appointed representative.

7.5 The Secretary of State may, as a consequence of a disease being, or in anticipation of a disease being imminently pandemic, and a serious risk or potentially a serious risk to human health, make an announcement in respect of the measures outlined in paragraphs 7.2, 7.3 and 7.4, bringing them into operation. The announcement will relate to arrangements for the provision of services as part of the health service with registered pharmacies in England, Wales or Scotland. The announcement by the Secretary of State must specify the area and circumstances to which the announcement relates and the period of its effect. Before making an announcement that relates to Scotland and Wales, or to an area of Scotland or Wales, the Secretary of State must consult Scottish or Welsh Ministers as the case may be.

8. European Union (Withdrawal) Act/ Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 The Government intends to consolidate the 2001 Regulations in the future.

10. Consultation outcome

10.1 The Home Secretary consulted the Advisory Council on the Misuse of Drugs ('ACMD'), the independent advisory body set up under the 1971 Act, and they are generally supportive of the measures. The ACMD's advice is available at:

https://www.gov.uk/government/publications/acmd-advice-on-covid-19-emergency-legislation-to-enable-supply-of-controlled-drugs

10.2 The Department of Health and Social Care has consulted with the Scottish Government, the Welsh Government, and the Chief Pharmaceutical Officers in

England, Wales, and Scotland and they agree that the measures are necessary. Given the urgency of these regulations, no public consultation has been conducted.

11. Guidance

11.1 Guidance will be issued to the healthcare sector to ensure a consistent approach in application of these measures.

12. Impact

12.1 The impact on business, charities or voluntary bodies will fall to retail pharmacy businesses that are providing pharmacy services in the circumstances specified in an announcement. Any retail pharmacy business that supplies controlled drugs under these measures will be subject to remuneration and reimbursement.

12.2 The impact on the public sector is on NHS prescribers, including GPs' surgeries in England, Wales and Scotland in areas subject to the measures, whose patients will be able to continue with treatment during a pandemic.

12.3 An Impact Assessment has not been prepared for this instrument because the amendments made by these regulations are enabling and the new arrangements will only be used in limited circumstances. It is not possible to predict the frequency of their use and necessarily it will be fact dependent. Notwithstanding that, the expectation is that the measures introduced by this instrument will only ever be needed in exceptional circumstances.

12.4 The benefits of the measures will be to help ease pressure on the health system and to enable continuity of supply of medicines to patients who are unable to access repeat prescriptions if, for example, their surgery is closed or their practitioner is unable to issue repeat prescriptions or who have been prescribed medicines that are subject to a serious shortage. The measures will also help patients for whom pressures on the system mean that changes are required to the frequency of dispensing under instalment prescriptions.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 Many of the pharmacies affected by this instrument are likely to be small businesses and they will be subject to the same renumeration and reimbursement as other pharmacy businesses commissioned to provide pharmaceutical services under these measures.

14. Monitoring & review

14.1 The Government will review the measures through the healthcare regulatory bodies' oversight in England, Wales and Scotland. The review will include an assessment of the measures' impact in order to ensure that they are achieving their desired effect. Where possible, the review will consider the data identified by the ACMD in their advice, which is available at: https://www.gov.uk/government/publications/acmd-advice-on-covid-19-emergency-legislation-to-enable-supply-of-controlled-drugs. Further, the measures under these regulations will be monitored when they are engaged. They will only be introduced for a limited time, which initially must not be

for more than three months, but the specified period may be extended for further periods of not more than three months at a time.

14.2 A review provision in the instrument is not appropriate as the measures are deregulatory in nature and the impact of the measures is expected to be beneficial.

15. Contact

15.1 Paul Nicol at the Home Office, telephone: 0207 035 1535 or email: Paul.Nicol@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Gwen Nightingale and Katherine Merrifield, Joint Heads of the Drugs and Alcohol Unit at the Home Office, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Secretary of State for the Home Department, Priti Patel, can confirm that this Explanatory Memorandum meets the required standard.