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The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020

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STATUTORY INSTRUMENTS

2020 No. 468

DANGEROUS DRUGS

The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020

Made

28th April 2020

Laid before Parliament

29th April 2020

Coming into force in accordance with regulation 1(2)

The Secretary of State, in exercise of the powers conferred by sections 7(1)(b) and (2)(b), 10(1) and (2)(g), 22(1)(a)(i) and 31(1)(a) of the Misuse of Drugs Act 1971(1), makes the following Regulations.

In accordance with section 31(3) of that Act, the Secretary of State has consulted with the Advisory Council on the Misuse of Drugs.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020.

(2) These Regulations come into force on the day after the day on which they are laid before Parliament.

(3) These Regulations extend to England and Wales and Scotland.

Amendment of the Misuse of Drugs Regulations 2001

2. The Misuse of Drugs Regulations 2001(2) are amended as follows.

Amendment of regulation 2

3. In regulation 2(3) (interpretation), in paragraph (1), after the definition of "health prescription" insert—

"health service" means—

- (a) in England, the health service as defined by section 275(1) of the National Health Service Act 2006(4);
- (b) in Scotland, the health service as defined by section 108(1) of the National Health Service (Scotland) Act 1978(5); and
- (c) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006(6);".

New regulation 10A

4. After regulation 10 (possession of drugs in Schedules 2, 3 and 4), insert—

"Directions of a practitioner while a disease is, or in anticipation of a disease being imminently, pandemic etc.

10A.—(1) For the purposes of regulation 10(2)(7), the directions of a practitioner may be the directions of a pharmacist, which do not require a prescription, in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—

- (i) pandemic, and
- (ii) a serious risk or potentially a serious risk to human health,

in order to assist in the management of the serious risk or potentially serious risk to human health, the Secretary of State has made an announcement in respect of the supply of drugs specified in Schedule 2, 3 or Part 1 of Schedule 4 as part of the health service;

- (b) as part of the announcement, the Secretary of State has issued advice to the effect that—
 - (i) in the area to which the announcement relates,
 - (ii) in the particular circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement,

arrangements for the provision of services as part of the health service ("NHS arrangements") with a person lawfully conducting a retail pharmacy business may include provisions permitting the supply of drugs specified in Schedule 2, 3 or Part 1 of Schedule 4 in accordance with the directions of a pharmacist, provided that the supply is in accordance with regulation 226 or 226A of the Human Medicines Regulations 2012(8);

- (c) the person lawfully conducting a retail pharmacy business with whom the NHS arrangements are made complies with the requirements in respect of the supply of drugs specified in Schedule 2, 3 or Part 1 of Schedule 4; and
- (d) the period specified in the announcement (taking into account any extension) has not ended and the announcement has not been amended in a way that means that the relevant provisions in the NHS arrangements are no longer permitted by the announcement

(2) The period specified in the announcement, as mentioned in paragraph (1)(b)(iii), must initially not be for more than three months, but it may be extended for further periods of not more than three months at a time.

(3) Before making, amending (including by way of extension) or withdrawing an announcement under paragraph (1) which relates to—

- (a) all or any area of Scotland, the Secretary of State must consult the Scottish Ministers;
- (b) all or any area of Wales, the Secretary of State must consult the Welsh Ministers."

Amendment of regulation 15

5. In regulation 15(9) (form of prescriptions), after paragraph (4), insert—

"(5) For the purposes of paragraph (1)(g), if the intervals to be observed when supplying are changed by a pharmacist in the following circumstances, the changed intervals are treated as the intervals specified by the prescriber—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (i) pandemic, and
 - (ii) a serious risk or potentially a serious risk to human health,

in order to assist in the management of the serious risk or potentially serious risk to human health, the Secretary of State has made an announcement in respect of the supply of drugs specified in Schedule 2 or 3 as part of the health service;

- (b) as part of the announcement, the Secretary of State has issued advice to the effect that—
 - (i) in the area to which the announcement relates,
 - (ii) in the particular circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement,

arrangements for the provision of services as part of the health service ("NHS arrangements") with a person lawfully conducting a retail pharmacy business may include provisions permitting pharmacists to change the intervals in prescriptions for drugs specified in Schedule 2 or 3 supplied under NHS arrangements;

- (c) the pharmacist who changes the intervals—
 - (i) is the person who is, for the purposes of regulation 16(1)(10), the person who supplies the drug on the prescription;
 - (ii) does so as part of and in accordance with NHS arrangements to which the announcement relates; and
 - (iii) does so with the agreement of the prescriber or, if the prescriber is unavailable, a person who is part of the same team treating the patient for whom the drug is prescribed as the prescriber, and who has been designated by the prescriber as able to agree this type of change if the prescriber is unavailable; and
- (d) the period specified in the announcement (taking into account any extension) has not ended and the announcement has not been amended in a way that means that the relevant provisions in the NHS arrangements are no longer permitted by the announcement

(6) The period specified in the announcement, as mentioned in paragraph (5)(b)(iii), must initially not be for more than three months, but it may be extended for further periods of not more than three months at a time.

(7) Before making, amending (including by way of extension) or withdrawing an announcement under paragraph (5) which relates to—

- (a) all or any area of Scotland, the Secretary of State must consult the Scottish Ministers;
- (b) all or any area of Wales, the Secretary of State must consult the Welsh Ministers."

Priti Patel
Secretary of State
Home Office

28th April 2020

EXPLANATORY NOTE (This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) ("the 2001 Regulations").

Section 5 of the Misuse of Drugs Act 1971 (c. 38) places a general restriction on possessing controlled drugs, subject to exceptions in regulations. In the case of drugs supplied by pharmacists, drugs specified in Schedules 2 to Part 1 of Schedule 4 to the 2001 Regulations presuppose the existence of directions of a person lawfully entitled to prescribe the drug.

In a pandemic situation, the Secretary of State may make an announcement permitting pharmacists without prescribing rights to issue the necessary directions themselves in relation to NHS supplies, in two circumstances. Both of these relate to easements from the normal restrictions on supplies of prescription only medicines in the Human Medicines Regulations 2012 (S.I. 2012/1916) – and both relate to continuity of treatment.

The first easement relates to a pharmacist's ability, in a pandemic situation, to supply at registered pharmacy premises prescription only drugs previously supplied to a patient on prescription. The second easement relates to supplies under a serious shortage protocol, where to help manage a serious shortage (not necessarily in a pandemic situation), a pharmacist at a registered pharmacy may, under a Secretary of State protocol, reduce the amount to be supplied to a patient or substitute a different product (for example, a different pharmaceutical form of the drug that was prescribed). Regulation 4 inserts a new regulation 10A into the 2001 Regulations to enable these easements to apply, in a pandemic situation, to drugs specified in Schedule 2 to Part 1 of Schedule 4, in the case of NHS supplies. The announcement may only permit this utilisation for up to three months, but that period may be extended for further periods of up to three months.

The 2001 Regulations contain restrictions on the form of prescriptions of Schedule 2 and 3 drugs, which include, in the case of drugs intended to be supplied by instalments, requiring the prescriber to specify the intervals between the supply of the instalments. Regulation 5 amends regulation 15 of the 2001 Regulations 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 drugs with the agreement of the prescriber or their appointed representative, where these are supplied under NHS arrangements.

There is also a consequential amendment to the interpretation provision of the 2001 Regulations (regulation 3).

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.


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- (1) 1971 c. 38. Section 7 was amended by the Police Reform and Social Responsibility Act 2011 (c. 13) ("the 2011 Act"), Schedule 17, paragraph 7. Section 10 was amended by the 2011 Act, Schedule 17, paragraph 10. Section 22 was amended by the 2011 Act, Schedule 17, paragraph 14. See the definition of "prescribed" in section 37(1).
 - (2) S.I. 2001/3998. The relevant amending instrument is S.I. 2015/891.
 - (3) There are amendments to regulation 2(1), but none is relevant.
 - (4) 2006 c. 41. There are amendments to section 275(1), but none is relevant.
 - (5) 1978 c. 29. There are amendments to section 108(1), but none is relevant.
 - (6) 2006 c. 42. There are amendments to section 206(1), but none is relevant.
 - (7) Notwithstanding the provisions of section 5(1) (which criminalises the possession of controlled drugs) of the Misuse of Drugs Act 1971, a person may possess any drug specified in Schedule 2, 3 or Part 1 of Schedule 4 to that Act for administration for medical, dental or veterinary purposes in accordance with the provisions of regulation 10(2).
 - (8) S.I. 2012/1916. Regulation 226A was inserted by S.I. 2019/62.
 - (9) There are amendments to regulation 15, but none is relevant.
 - (10) There are amendments to regulation 16(1), but none is relevant.

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