STATUTORY RULES OF NORTHERN IRELAND

2020 No. 73

DANGEROUS DRUGS

The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2020

Made - - - -	*29th April 2020*
Coming into operation -	*30th April 2020*

The Department of Health(**a**) makes the following Regulations in exercise of the powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971(**b**) as adapted by sections 7(9), 31(4) and 38 of that Act and now vested in it(**c**) and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2020 and shall come into operation on 30th April 2020.

(2) The Interpretation Act (Northern Ireland) 1954(**d**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendment of the Misuse of Drugs Regulations (Northern Ireland) 2002

2. The Misuse of Drugs Regulations (Northern Ireland) 2002(**e**) are amended in accordance with regulations 3 to 5 below.

Amendment of regulation 2

3. In regulation 2(2) after the definition of "health prescription" insert—

> ""health service" means the general health services provided for in Part VI of the Health and Personal Social Services (Northern Ireland) Order 1972(**f**);"

(**a**) Formerly the Department of Health, Social Services and Public Safety, see 2016 c. 5 (N.I.), s. 1(5)

(**b**) 1971 c. 38. Section 7 was amended by the Police Reform and Social Responsibility Act 2011 (c. 13) ("the 2011 Act"), Sch 17, para 17. Section 10 was amended by the 2011 Act, Sch 17, para 10. Section 22 was amended by s. 177(1) of, and para 12 of Sch 4 to, the Customs and Excise Management Act 1979 (c. 2). Section 31 has been amended by the Drugs Act 2005 (c. 17), s. 2, and the Policing and Crime Act 2009 (c. 26), Sch 7, para 122, and Sch 8, Part 13. Section 38 was amended by the 2011 Act, Sch 17, para 20. See the definition of "prescribed" in s. 37(1) (as adapted by s. 38), which is relevant to the powers being exercised

(**c**) S.R. & O. (N.I.) 1973 No. 504, Article 5(a) and S.I. 1999/283 (N.I. 1), Article 3(6)

(**d**) 1954 c. 33 (N.I.)

(**e**) S.R. 2002 No. 1. Relevant amending Regulations are S.R. 2019 Nos. 208 and 21, S.R. 2018 Nos. 173 and 4, S.R. 2016 No. 29, S.R. 2015 No. 227, S.R. 2015 No 53, S.R. 2014 Nos 261, 158 and 21, S.R. 2013 No 78, S.R. 2012 No. 213, S.R. 2011 No. 153, S.R. 2010 Nos 247 and 148, S.R. 2009 No. 390, S.R. 2007 No. 348 and S.R. 2005 No. 360

(**f**) S.I. 1972/1265 (N.I. 14)

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), 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 Department 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 Department 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 ("health service 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(**a**);

(c) the person lawfully conducting a retail pharmacy business with whom the health service arrangements are made complies with the requirements of the arrangements 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 withdrawn or amended in a way that means that the relevant provisions in the health service 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.".

Amendment of regulation 15

5. In regulation 15 (form of prescriptions), after paragraph (3), insert—

"(4) 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

(**a**) S.I. 2012/1916. Regulation 226A was inserted by S.I. 2019/62

(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 Department 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 Department 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 ("health service 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 health service arrangements;

(c) the pharmacist who changes the intervals—

(i) is the person who is, for the purposes of regulation 16(1), the person who supplies the drug on the prescription;

(ii) does so as part of and in accordance with health service 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 responsible for treating the patient for whom the drug is prescribed as the prescriber, and who has been designated by the prescriber as a person who is 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 withdrawn or amended in a way that means that the relevant provisions in the health service arrangements are no longer permitted by the announcement.

(5) The period specified in the announcement, as mentioned in paragraph (4)(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.".

Sealed with the Official Seal of the Department of Health on 29th April 2020.

(L.S.)

Cathy Harrison
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations (Northern Ireland) 2002 (S.R. 2002 No.1) ("the 2002 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 2002 Regulations presuppose the existence of directions of a person lawfully entitled to prescribe the drug.

In a pandemic situation, the Department may make an announcement permitting pharmacists without prescribing rights to issue the necessary directions themselves in relation to health service 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) - 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 currently, to help manage a serious shortage (not necessarily in a pandemic situation), a pharmacist at a registered pharmacy may, under a serious shortage protocol issued by the Secretary of State for Health and Social Care and the Minister for Health (NI) acting jointly or alone, supply an alternative quantity, strength, pharmaceutical form or medicine that is both available and suitable as prescribed in the protocol. Regulation 4 inserts a new regulation 10A into the 2002 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 health service 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 2002 Regulations contain restrictions on the form of prescriptions of Schedules 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 2002 Regulations to enable, in a pandemic situation, the Department 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 health service arrangements. 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.

There is also a consequential amendment to the interpretation provision of the 2002 Regulations (regulation 3).

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