STATUTORY RULES OF NORTHERN IRELAND

2019 No. 186

HEALTH AND PERSONAL SOCIAL SERVICES

The Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (Northern Ireland) 2019

Made - - - -	*26th September 2019*
Coming into operation -	*31st October 2019*

The Department of Health(**a**), in conjunction with the Department of Finance(**b**), makes the following Regulations in exercise of the powers conferred by Articles 63(1) and (2), 64, 106(b) and 107(6) of the Health and Personal Social Services (Northern Ireland) Order 1972(**c**).

In accordance with Article 63(3) of that Order, the Department of Health has consulted with such organisations as appear to it to be representative of the pharmaceutical profession.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (Northern Ireland) 2019 and shall come into operation on 31st October 2019.

(2) In these Regulations "the Pharmaceutical Regulations" means the Pharmaceutical Services Regulations (Northern Ireland) 1997(**d**).

Amendment of regulation 2 of the Pharmaceutical Regulations

2.—(1) Regulation 2(1) of the Pharmaceutical Regulations (interpretation) is amended as follows.

(2) At the appropriate places insert—

> ""dispensing doctor" means a doctor authorised or required by the Board under regulation 12 to provide pharmaceutical services to a patient;";
>
> ""serious shortage protocol" means—

(**a**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), section 1(5).
(**b**) Formerly the Department of Finance and Personnel; see 2016 c.5 (N.I.), section 1(4).
(**c**) S.I. 1972/1265 (N.I. 14); the relevant amending instruments are S.I. 1978/1907 (N.I. 26) Article 14; S.I. 1986/2023 (N.I. 20) Articles 5(1) and (2); S.I. 1986/2229 (N.I. 24); S.I. 1988/2249 (N.I. 24) Article 7; S.I. 1991/194 (N.I. 1) Articles 3(1) and (2), 34 and Part II of Schedule 5; S.I. 1992/2671 (N.I. 18) Article 3; S.I. 1997/1177 (N.I. 7) Article 29; 2001 c.3 (N.I.) section 48 and 2008 c.2 (N.I.) section 10.
(**d**) S.R. 1997 No. 381; relevant amending instruments are S.R. 1998 No.95, S.R. 1999 Nos. 100, 254 and 405, S.R. 2001 No. 222, S.R. 2002 Nos. 92 and 397, S.R. 2003 No. 447, S.R. 2005 No. 231, S.R. 2009 Nos. 191 and 320, S.R. 2010 No. 72, S.R. 2014 No. 170 and S.R. 2016 No. 104.

(a) in the case of a prescription only medicine, a serious shortage protocol for the purposes of regulation 226A of the Human Medicines Regulations 2012(**a**) (sale etc by a pharmacist in accordance with a serious shortage protocol); or

(b) in the case of any other drug or appliance, a written protocol that—

(i) is issued by the Department in circumstances where Northern Ireland or any part of Northern Ireland is, in the opinion of the Department, experiencing or may experience a serious shortage of—

(aa) a specified drug or appliance, or

(bb) drugs or appliances of a specified description,

(ii) provides for the supply by a provider of pharmaceutical services, where there is an order on a prescription form or a repeatable prescription for—

(aa) the specified drug or appliance, or

(bb) a drug or appliance of the specified description,

of a different product or quantity of product to the product or quantity of product ordered, subject to such conditions as may be specified in the protocol, and

(iii) specifies the period for which, and the parts of Northern Ireland (which may be all of Northern Ireland) in which, the protocol is to have effect;"; and

""SSP" means a serious shortage protocol;".

New regulation 18 of the Pharmaceutical Regulations

3. After regulation 17 of the Pharmaceutical Regulations (transitional provisions), insert—

"**Transitional provisions in respect of drugs or appliances supplied in accordance with SSPs**

18.—(1) This paragraph applies where—

(a) pursuant to paragraph 5A(4)(a) or 15A(2)(a) of Schedule 2, a pharmacist, or a dispensing doctor is required to endorse a prescription or an associated batch issue; and

(b) the Board (or RBSO acting on the Board's behalf) is only able, or is also able, to process a claim for pharmaceutical reimbursement in respect of the product being provided if the claim is made using a separate token ("a dispensing token"), which is in a form approved by the Department for the purposes of making such claims.

(2) Where paragraph (1) applies—

(a) to the extent required or permitted by the Drug Tariff, a dispensing token recording the provision of the product is treated as being, as regards that product, the prescription for product reimbursement purposes;

(b) if the manner for recording the provision of the product in the dispensing token is provided for in the Drug Tariff, the recording of the provision of the product in the dispensing token must be in the manner provided for in the Drug Tariff; and

(c) the manner of the endorsement of the original prescription or associated batch issue (where provided for in the Drug Tariff) may vary, depending on whether or not it is to be used for product reimbursement purposes.

(3) Where, by virtue of paragraph (2)(a), a dispensing token is the prescription for product reimbursement purposes, paragraph 5A(6) of Schedule 2 applies as if the reference to paragraph 5A(4)(a) of that Schedule included a reference, in the alternative, to paragraph (2)(a).

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

(4) For the purposes of this regulation, "pharmaceutical reimbursement" means pharmaceutical remuneration of the type payable to those providing pharmaceutical services in accordance with Part 2 or Part 3 of Schedule 2 to these Regulations.".

Amendment of Schedule 2 to the Pharmaceutical Regulations

4.—(1) Schedule 2 to the Pharmaceutical Regulations is amended in accordance with paragraph (2) and (3) as follows.

(2) After paragraph 5 (supply of drugs and fitting of appliances) insert—

"**Supply in accordance with a SSP**

5A.—(1) This sub-paragraph applies where—

(a) any person requests a drug or appliance from a chemist in accordance with a prescription form or repeatable prescription; and

(b) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, the chemist must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, the chemist may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

(a) the chemist is able to do so with reasonable promptness;

(b) to do so is in accordance with the SSP; and

(c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where the chemist, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

(a) the pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription); and

(b) if the patient to or for whom the product is provided is on a patient list, and the supply—

(i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012 (sale etc by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or

(ii) is of any other type, and the Department has issued and publicised in such manner as it sees fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on its patient list that is in accordance with a SSP instead of in accordance with the prescription form or repeatable prescription,

the chemist must notify the provider of primary medical services on whose patient list the patient is of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(5) Where—

(a) sub-paragraph (1) applies;

(b) a pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) the chemist is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 5(2) and (3) are to be read as requirements to act within a reasonable timescale.

(6) Sub-paragraphs (3) to (5) apply to the provision of a drug or appliance in accordance with a SSP as they apply to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes, the prescription for product reimbursement purposes, as mentioned in paragraph 5A(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).

5B.—(1) Where the chemist provides a drug or appliance under paragraph 5A, the chemist must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with an SSP, identifying the particular SSP.

(2) A chemist must refuse to provide a drug or appliance ordered on a prescription or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description; and

(b) alternative provision has already taken place in accordance with the SSP.

(3) A chemist may refuse to provide a drug or appliance ordered on a prescription or a repeatable prescription where—

(a) an SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description;

(b) a pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) the chemist is unable to provide the drug or appliance within a reasonable timescale,

but if the chemist does refuse to do so, the chemist must provide the patient or the person requesting the drug or appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber to review the patient's treatment.".

(3) In Part 3 (terms of service for doctors who provide pharmaceutical services), after paragraph 15 insert—

"**Supply in accordance with a SSP**

15A.—(1) This sub-paragraph applies where, in relation to an order for a drug or an appliance on a prescription or a repeatable prescription—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies and the dispensing doctor provides a different product or quantity of product to the product or quantity of product ordered on prescription or on repeatable prescription, in accordance with the SSP—

(a) the dispensing doctor must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff); and

(b) the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription).

(3) Where the dispensing doctor provides a drug or appliance under this paragraph, the dispensing doctor must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with an SSP, identifying the particular SSP.

(4) A dispensing doctor must refuse to provide a drug or appliance ordered on a prescription or on a repeatable prescription where—

(a) an SSP has effect in respect of—

(i) the requested drug or appliance; or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description; and

(b) alternative provision has already taken place in accordance with the SSP.".

Sealed with the Official Seal of the Department of Health on 26th September 2019.

L.S.

Cathy Harrison
A senior officer of the Department of Health

Sealed with the Official Seal of the Department of Finance on 26th September 2019.

L.S.

Emer Morelli
A senior officer of the Department of Finance

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Pharmaceutical Services Regulations Northern Ireland 1997 ("the Pharmaceutical Services Regulations") which govern the arrangements for the provision of pharmaceutical services under the Health and Personal Social Services (Northern Ireland) Order 1972 ("the 1972 Order").

They make provision in relation to serious shortage protocols (SSPs). SSPs allow the Department to put in place alternative arrangements for supply, where a drug or appliance is ordered on prescription but there is, or may in the future be, a serious shortage of the drug or appliance.

SSPs under the Human Medicines Regulations 2012 ("the 2012 Regulations") allow pharmacists to supply a different prescription only medicine, or a different quantity of a prescription only medicine, to that ordered by a prescriber, without breaching the restrictions on the sale or supply of prescription only medicine in Part 12 of the 2012 Regulations. These Regulations extend the potential scope of SSPs to all drugs and appliances that may be dispensed as part of the provision of pharmaceutical services in Northern Ireland – not just prescription only medicines.

Where an SSP is in place for a particular product, a chemist must consider supplying in accordance with the SSP rather than fulfilling a Health Service prescription for that product. It may, instead of fulfilling the Health Service prescription, supply a different product, or a different quantity of the ordered product, in the circumstances and subject to the conditions set out in the SSP. If the chemist or dispensing doctor does change a Health Service prescription (rather than, in the case of a dispensing doctor, issuing a new prescription), the original Health Service prescription must be endorsed with the change.

If a product supplied by a chemist in accordance with an SSP is a prescription only medicine that is different to but has the same therapeutic effect as the product originally ordered, it must notify the patient's Health Service GP practice of the substitution (if the patient has one). A chemist must also notify a patient's Health Service GP practice in other cases of supply in accordance with an SSP, if a requirement to notify that substitution has been recommended, for clinical reasons, by the Department.

A number of consequential changes are also made to the Health Service terms of service for chemists and dispensing doctors in Schedule 2 to the Pharmaceutical Regulations. In particular, the original Health Service prescription remains the essential record of the transaction for payment, and if a chemist or dispensing doctor makes a supply in accordance with an SSP, the original prescription can no longer be fulfilled. Also, when a chemist or dispensing doctor changes an order for a product so that there is a supply in accordance with an SSP, a warning about the change must be included in the dispensing label on the packaging of the product supplied.

There is a transitional provision that allows for the issuing of tokens ("dispensing tokens") that can function, instead of a prescription, as the record of the supply for the purposes of reimbursing the dispenser (regulation 3).

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