

2019 No. 284

NATIONAL HEALTH SERVICE

**The National Health Service (Serious Shortage Protocols)
(Miscellaneous Amendments) (Scotland) Regulations 2019**

<i>Made</i>	- - - -	<i>10th September 2019</i>
<i>Laid before the Scottish Parliament</i>		<i>12th September 2019</i>
<i>Coming into force</i>	- -	<i>31st October 2019</i>

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 17E, 17N, 27, 28(1) and 105(7) of the National Health Service (Scotland) Act 1978(a) and all other powers enabling them to do so.

Citation and commencement

1. These Regulations may be cited as the National Health Service (Serious Shortage Protocols) (Miscellaneous Amendments) (Scotland) Regulations 2019 and come into force on 31 October 2019.

Amendment of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

2. The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(b) are amended in accordance with regulations 3 and 4.

3. In regulation 2(1) (interpretation and application)—

(a) after the definition of “prescription form” insert—

““prescription only medicine” has the meaning given in regulation 5 of the Human Medicines Regulations 2012(c),” and

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- (a) 1978 c.29; section 17E was inserted by the National Health Service (Primary Care) Act 1997 (c.46) (“the 1997 Act”), section 22(2) and amended by the Health Act 1999 (c.8) (“the 1999 Act”), paragraph 47 of schedule 4, and paragraph 1 of schedule 5, the Primary Medical Services (Scotland) Act 2004 (asp 1) (“the 2004 Act”), section 2(4) and S.I. 2003/1250; section 17N was inserted by the 2004 Act, section 4; section 27 was amended by the Health Services Act 1980 (c.53) (“the 1980 Act”), section 20(2), the National Health Service (Amendment) Act 1986 (c.66) (“the 1986 Act”), section 3(3), the 1990 Act, section 66(1) and schedule 9, paragraph 19(7), the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 3, the 1997 Act, schedule 2, paragraph 44, the Health and Social Care Act 2001 (c.15), section 44(2) and (3), the Health and Social Care Act 2012 (c.7), section 213(7)(c) and section 220(2), and S.I. 1987/2202, S.I. 2003/1590, S.I. 2004/1771, S.I. 2005/2011, S.I. 2007/289 and S.I. 2010/231; section 28(1) was amended by the 1986 Act, section 3(4) and the 2004 Act, paragraph 1(8) of schedule 1; section 105(7) was amended by the 1980 Act, schedule 6, paragraph 5 and schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), section 29(1) and schedule 9, paragraph 24, and the 1999 Act, schedule 4, paragraph 60. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).
- (b) S.S.I. 2009/183; relevant amending instruments are S.I. 2010/231, S.I. 2012/1479, S.I. 2012/1916 and S.I. 2013/235 and S.S.I. 2009/209, S.S.I. 2010/128, S.S.I. 2011/32, S.S.I. 2011/55, S.S.I. 2014/73, S.S.I. 2014/148, S.S.I. 2015/968, S.S.I. 2016/393, S.S.I. 2018/66, S.S.I. 2018/67 and S.S.I. 2018/68.
- (c) S.I. 2012/1916.

- (b) after the definition of “scheduled drug” insert—
- ““Scottish SSP” means a Scottish serious shortage protocol which is a written protocol in respect of any drug or appliance which is not a prescription only medicine that—
- (a) is issued by the Scottish Ministers in circumstances where Scotland or any part of Scotland is, in the opinion of the Scottish Ministers, experiencing or may experience a serious shortage of—
 - (i) a specified drug or appliance, or
 - (ii) drugs or appliances of a specified description,
 - (b) provides for the supply by a pharmacist or dispensing doctor, where there is an order on a prescription form or serial prescription for—
 - (i) the specified drug or appliance, or
 - (ii) a drug or appliance of the specified description, of a different drug or appliance or quantity or strength of a drug or appliance to that ordered by the prescriber or dentist, subject to such conditions as may be specified in the Scottish SSP, and
 - (c) specifies the period for which, and the parts of Scotland (which may be all of Scotland) for which the Scottish SSP is to have effect,
- “serious shortage protocol” means, in respect of a prescription only medicine, a serious shortage protocol for the purposes of regulation 226A of the Human Medicines Regulations 2012(a),
- “SSP” means a serious shortage protocol.”.

4. In paragraph 4 (provision of pharmaceutical services) of schedule 1 (terms of service for pharmacists and pharmacy contractors)—

- (a) in sub-paragraph (23) after “and (29)” insert “to (33)”, and
- (b) after sub-paragraph (29) insert—

“(30) This sub-paragraph applies where—

 - (a) a person requests a prescription only medicine—
 - (i) from a person lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act(b), and
 - (ii) in accordance with a prescription form or serial prescription, and
 - (b) a SSP has effect in respect of—
 - (i) the requested prescription only medicine, or
 - (ii) prescription only medicines of a specified description, and the requested prescription only medicine is of that description.

(31) Where sub-paragraph (30) applies, a pharmacist may supply a prescription only medicine in accordance with a SSP where—

 - (a) the conditions specified in regulation 226A of the Human Medicines Regulations 2012(c) are satisfied, and
 - (b) the pharmacist is able to do so with reasonable promptness.

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

(b) 1968 c.67; section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50), schedule 1, part XII, paragraph 1, S.I. 2007/289, S.I. 2007/3101 and S.I. 2010/231.

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

- (32) This sub-paragraph applies where—
- (a) a person requests a drug or appliance—
 - (i) from a person lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act^(a), and
 - (ii) in accordance with a prescription form or serial prescription, and
 - (b) a Scottish 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.

(33) Where sub-paragraph (32) applies, a pharmacist may supply a different drug or appliance or quantity or strength of a drug or appliance to that ordered on the prescription form or serial prescription where—

- (a) the pharmacist is able to do so with reasonable promptness,
- (b) to do so is in accordance with the Scottish SSP, and
- (c) the pharmacist is of the opinion, in the exercise of their professional skill and judgement, that the supply of a different drug or appliance or quantity or strength of a drug or appliance to that ordered by the prescriber or dentist is reasonable and appropriate.

(34) Where sub-paragraph (30) or (32) applies—

- (a) a pharmacist is of the opinion, in the exercise of their professional skill and judgement, that it is unreasonable or inappropriate to supply in accordance with the SSP or the Scottish SSP, and
- (b) the pharmacist is able to supply the prescription only medicine or other drug or appliance ordered by the prescriber or dentist within a reasonable timescale, but not with reasonable promptness,

the requirements to act with reasonable promptness in sub-paragraphs (1), (1A)(a) and (3) are to be read as requirements to act within a reasonable timescale.

(35) A pharmacist must refuse to supply a prescription only medicine or other drug or appliance ordered on a prescription form or serial prescription where—

- (a) sub-paragraph (30) or (32) applies, and
- (b) alternative supply has already taken place in accordance with the SSP or the Scottish SSP.

(36) A pharmacist may refuse to supply a prescription only medicine or other drug or appliance ordered on a prescription form or serial prescription where—

- (a) sub-paragraph (30) or (32) applies,
- (b) the pharmacist is of the opinion, in the exercise of their professional skill and judgement, that it is unreasonable or inappropriate to supply in accordance with the SSP or the Scottish SSP, and
- (c) the pharmacist is unable to provide the prescription only medicine or other drug or appliance ordered by the prescriber or dentist within a reasonable timescale.

(37) Where a pharmacist refuses to supply a prescription only medicine or other drug or appliance under sub-paragraph (36), the pharmacist must contact the prescriber or dentist to discuss alternative arrangements.

(a) 1968 c.67; section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50), schedule 1, part XII, paragraph 1, S.I. 2007/289, S.I. 2007/3101 and S.I. 2010/231.

(38) Where a pharmacist supplies a prescription only medicine in accordance with a SSP or other drug or appliance in accordance with a Scottish SSP the pharmacist must—

- (a) include in the dispensing label on the packaging of the prescription only medicine or other drug or appliance, for the patient’s benefit, information to the effect that the prescription only medicine or other drug or appliance is being supplied in accordance with a SSP or a Scottish SSP, identifying the particular SSP or Scottish SSP, and
- (b) supply the prescription only medicine or other drug or appliance in a suitable container.”.

Amendment of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018

5. The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018(a) are amended in accordance with regulations 6 and 7.

6. In regulation 3(1) (interpretation) after the definition of “Scheduled drug” insert—

““Scottish SSP” has the meaning given in regulation 2(1) of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(b),”.

7. In paragraph 44 (provision of dispensing services) of schedule 6 (other contractual terms) after sub-paragraph (10) insert—

“(11) A contractor who is required or authorised by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) may do so in accordance with a Scottish SSP.”.

Amendment of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018

8. The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018(c) are amended in accordance with regulations 9 and 10.

9. In regulation 3(1) (interpretation) after the definition of “Scheduled drug” insert—

““Scottish SSP” has the meaning given in regulation 2(1) of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009,”.

10. In paragraph 16 (provision of dispensing services) of schedule 1 (content of agreements) after sub-paragraph (10) insert—

“(11) A provider who is required or authorised by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) may do so in accordance with a Scottish SSP.”.

JEANE FREEMAN

A member of the Scottish Government

St Andrew’s House,
Edinburgh
10th September 2019

(a) S.S.I. 2018/66; relevantly amended by the Data Protection Act 2018 (c.12), paragraph 424 of schedule 19 and S.S.I. 2018/94.

(b) S.S.I. 2009/183; relevantly amended by S.S.I. 2019/284.

(c) S.S.I. 2018/67; relevantly amended by the Data Protection Act 2018 (c.12), paragraph 428 of schedule 19 and S.S.I. 2018/94.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (“the 2009 Regulations”), the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018 (“the GMS Contracts Regulations”) and the National Health Services (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018 (“the Section 17C Agreements Regulations”).

These Regulations amend the 2009 Regulations to allow pharmacists to supply prescription only medicines in accordance with a serious shortage protocol (“SSP”) issued in accordance with regulation 226A of the Human Medicines Regulations 2012. These Regulations also amend the 2009 Regulations, the GMS Contracts Regulations and the Section 17C Agreements Regulations to allow pharmacists and dispensing doctors to supply drugs and appliances, which are not prescription only medicines, in accordance with a Scottish serious shortage protocol (“Scottish SSP”). Similar provisions have been included for England in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended by the National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019.

Regulations 3 and 4 amend the 2009 Regulations.

Regulation 3 inserts new definitions into regulation 2(1) of the 2009 Regulations for “prescription only medicine”, “Scottish SSP”, “serious shortage protocol”, and “SSP”.

Regulation 4(b) inserts new sub-paragraphs (30) to (38) into paragraph 4 of schedule 1 of the 2009 Regulations which provide as follows—

- Sub-paragraphs (30) to (33) allow pharmacists to supply prescription only medicines in accordance with a SSP and other drugs and appliances in accordance with a Scottish SSP provided certain conditions are satisfied.
- Sub-paragraph (34) provides that where a pharmacist is of the opinion, in the exercise of their reasonable skill and judgement, that it is unreasonable or inappropriate to supply in accordance with a SSP or Scottish SSP, and they are able to supply the prescription only medicine or other drug or appliance ordered by the prescriber or dentist within a reasonable timescale, the requirements to act with reasonable promptness in paragraph 4(1), (1A)(a) and (3) of schedule 1 of the 2009 Regulations are to be read as requirements to act within a reasonable timescale.
- Sub-paragraph (35) makes provision for when a pharmacist is required to refuse to supply a prescription only medicine or other drug or appliance ordered on a prescription form or serial prescription.
- Sub-paragraph (36) makes provision for when a pharmacist may refuse to supply a prescription only medicine or other drug or appliance ordered on a prescription form or serial prescription.
- Sub-paragraph (37) provides that where a pharmacist refuses to supply a prescription only medicine or other drug or appliance under sub-paragraph (36), the pharmacist must contact the prescriber or dentist to discuss alternative arrangements.
- Sub-paragraph (38) requires a pharmacist who supplies a prescription only medicine in accordance with a SSP, or other drug or appliance in accordance with a Scottish SSP, to include in the dispensing label on the packaging of the prescription only medicine or other drug or appliance, information to the effect that it is being supplied in accordance with a SSP or a Scottish SSP. The pharmacist is also required to supply the prescription only medicine or other drug or appliance in a suitable container.

Regulation 4(a) makes a minor and consequential amendment to paragraph 4(23) of schedule 1 of the 2009 Regulations.

Regulations 6 and 7 amend the GMS Contracts Regulations.

Regulation 6 inserts a new definition into regulation 3(1) of the GMS Contracts Regulations for “Scottish SSP”.

Regulation 7 inserts new sub-paragraph (11) into paragraph 44 of schedule 6 of the GMS Contracts Regulations. Sub-paragraph (11) allows a contractor who is required or authorised by the Health Board to supply drugs, medicines and appliances to do so in accordance with a Scottish SSP.

Regulations 9 and 10 amend the Section 17C Agreements Regulations.

Regulation 9 inserts a new definition into regulation 3(1) of the Section 17C Agreements Regulations for “Scottish SSP”.

Regulation 10 inserts new sub-paragraph (11) into paragraph 16 of schedule 1 of the Section 17C Agreements Regulations. Sub-paragraph (11) allows a provider who is required or authorised by the Health Board to supply drugs, medicines and appliances to do so in accordance with a Scottish SSP.

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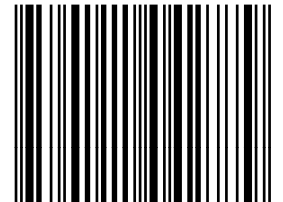
Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, the Queen’s Printer for Scotland.

£6.90

S201909111009 09/2019 19585

<http://www.legislation.gov.uk/id/ssi/2019/284>

ISBN 978-0-11-104277-9



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