WELSH STATUTORY INSTRUMENTS

2002 No. 3189 (W.305)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services) and (General Medical Services) (Amendment) (Wales) Regulations 2002

Made - - - - 18th December 2002

Coming into force - - 1st January 2003

The National Assembly for Wales, in exercise of the powers conferred upon it by sections 29, 41, 42, 43 and 126(4) of the National Health Service Act 1977(1) hereby makes the following Regulations:

Citation, commencement, interpretation and application

- 1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) and (General Medical Services) (Amendment) (Wales) Regulations 2002 and shall come into force on 1st January 2003.
 - (2) In these Regulations—

"the Pharmaceutical Services Regulations" ("Rheoliadau'r Gwasanaethau Fferyllol") means the National Health Service (Pharmaceutical Services) Regulations 1992(2);

Section 29 was extended by the Health and Medicines Act 1988 (c. 49) ("the 1988 Act"), section 17; and amended by the Health Services Act 1980 (c. 53) ("the 1980 Act"), sections 1 and 7 and Schedule 2, paragraph 16(a); by S.I.1985/39, article 7(3); by the Health Authorities Act 1995 (c. 17) ("the 1995 Act"), Schedule 1, paragraph 18 and by the National Health Service (Primary Care) Act 1997 (c. 46) ("the 1997 Act"), Schedule 2, paragraph 8.

Section 41 was amended by the Act 1980, sections 1 and 20(1) and Schedule 1, paragraph 53 and Schedule 7; by S.I. 1985/39, article 7(13); by the 1990 Act, Schedule 9, paragraph 18(1) and Schedule 10; by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 2; by the 1995 Act, Schedule 1, paragraph 29 and by the 1997 Act, Schedule 2, paragraph 13. Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c. 66), section 3(1); extended by the 1988 Act, section 17 and amended by S.I. 1987/2202, article 4; by the 1990 Act, section 12(3) and by the 1995 Act, Schedule 1, paragraph 30.

Section 43 was amended by the 1980 Act, Schedule 9, paragraph 18(2); by the 1995 Act, Schedule 1, paragraph 31; and by the 1997 Act, section 29(1) and Schedule 2, paragraph 14.

Section 126(4) was amended by the 1990 Act, section 65(2) and the 1999 Act, Schedule 4, paragraph 37(6).

The functions of the Secretary of State under sections 29, 41, 42, 43 and 126(4) of the National Health Service Act 1977 were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, S.I.1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5).

(2) S.I. 1992/662; the relevant amending instruments are S.I. 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681 and 2224, 1999/696 and 2001/1396.

^{(1) 1977} c. 49; see section 128(1) as amended by the National Health Service and Community Care Act 1990 (c. 19) ("the 1990 Act"), section 26(2)(g) and (i), and by the Health Act 1999 (c. 8) ("the 1999 Act"), Schedule 4, paragraph 38(2)(b), for the definitions of "prescribed" and "regulations".

"the General Medical Services Regulations 1992" ("Rheoliadau'r Gwasanaethau Meddygol") means the National Health Service (General Medical Services) Regulations 1992(3).

(3) These Regulations apply to Wales only.

Amendment of the Pharmaceutical Services Regulations 1992

- **2.**—(1) The Pharmaceutical Services Regulations 1992 shall be amended as follows.
- (2) In paragraph (1) of regulation 2 (interpretation)—
 - (a) in the definition of "dispensing doctor list", for "regulation 11" substitute "regulation 21B"(4);
 - (b) omit the definition of "listed drugs"(5);
 - (c) for the definition of "nurse prescriber" (6) substitute—

"" nurse prescriber" means a person who is registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(7) and against whose name is recorded in that register an annotation signifying that he or she is qualified to order drugs, medicines and appliances for patients;"; and

- (d) after the definition of "Remission of Charges Regulations" insert—
 - "" restricted availability appliance" means an appliance which is approved for particular categories of persons or particular purposes only;".
- (3) Omit paragraphs (1A)(8) and (1C)(9) of regulation 2.
- (4) In regulation 18(1) (standards of, and payments for, drugs and appliances), in subparagraph (a), at the end, insert "and, in the case of a restricted availability appliance, the categories of persons for whom or purposes for which the appliance is approved".
- (5) In regulation 19 (provision of pharmaceutical services for immediate treatment or personal administration)(10), at the end add "but shall, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff."
 - (6) In Part II of Schedule 2 (terms of service for chemists)—
 - (a) in paragraph 3(1)(11)—
 - (i) in sub-paragraph (a), after "or appliances," insert "not being restricted availability appliances,";
 - (ii) after sub-paragraph (b), insert.—
 - "(bb) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a doctor; or";
 - (iii) for sub-paragraph (d), substitute.—
 - "(d) an order for drugs or medicines, or listed appliances, not being restricted availability appliances, signed by a nurse prescriber"; and
 - (iv) after sub-paragraph (d), insert.—

⁽³⁾ S.I.1992/635; relevant amending instruments are S.I.1992/2412, 1993/2421, 1994/2620, 1997/981, 1999/1627 and 2000/1887

⁽⁴⁾ Regulation 21B was inserted by S.I. 1998/681.

⁽⁵⁾ The definition of "listed drugs" was inserted by S.I. 1994/2402.

⁽⁶⁾ The definition of "nurse prescriber" was inserted by S.I. 1994/2402.

⁽⁷⁾ S.I. 2002/253.

⁽⁸⁾ Paragraph (1A) was inserted by S.I. 1994/2402.

⁽⁹⁾ Paragraph (1C) was inserted by S.I. 1998/2224.

⁽¹⁰⁾ Regulation 19 was amended by S.I. 1998/681.

⁽¹¹⁾ Paragraph 3(1) was amended by S.I. 1994/2402.

"or

- (e) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a nurse prescriber,";
- (b) in paragraph 11(12).—
 - (i) in sub-paragraph (b), delete "and";
 - (ii) in sub-paragraph (c), at the end, insert "; and"; and
 - (iii) after sub-paragraph (c), add—
 - "(d) he shall provide the for patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.";
- (c) in paragraph 11A(13)—
 - (i) for sub-paragraph (2), substitute—
 - "(2) Where a patient presents an order on a prescription form for drugs or medicines or listed appliances signed by a nurse prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference "SLS" by a nurse prescriber, to a doctor who is authorised or required by regulation 20 to provide drugs or appliances to that patient, the doctor may provide to the patient such of the drugs, medicines or appliances so ordered as he supplies in the normal course of his practice."; and
 - (ii) in sub-paragraph (3), omit the word "listed" the first time it occurs;
- (d) in paragraph 11B(14), omit the word "listed" the second time it occurs;
- (e) in paragraph 12(2), after "in this paragraph", insert "or paragraph 11" and after "a scheduled drug", insert "or a restricted availability appliance".

Amendment of the General Medical Services Regulations 1992

- **3.**—(1) The General Medical Services Regulations 1992 shall be amended as follows.
- (2) In Schedule 2 to the General Medical Services Regulations (terms of service for doctors)—
 - (a) in paragraph 1 (interpretation), after the definition of "prescription form" insert—
 - ""restricted availability appliance" means an appliance which is approved for particular categories of persons or particular purposes only;";
 - (b) in sub-paragraph (5) of paragraph 43 (prescribing)—
 - (i) omit the words "or an appliance";
 - (ii) after sub-paragraph (5) of paragraph 43 add
 - "(6) In a case of urgency a doctor may request a chemist to dispense an appliance before a prescription form is issued only if—
 - (a) that appliance does not contain a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971(15), other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001(16);

⁽¹²⁾ Paragraph 11 was amended by S.I. 1994/2402.

⁽¹³⁾ Paragraph 11A was inserted by S.I. 1994/2402 and amended by S.I. 1995/644.

⁽¹⁴⁾ Paragraph 11B was inserted by S.I. 1999/696 and amended by S.I. 2001/1396...

^{(15) 1971 (}c. 38)

⁽¹⁶⁾ S.I. 2001/3998

- (b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (c) he undertakes to furnish the chemist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2).".
- (c) In paragraph 44, after sub-paragraph (2), add—
 - "(3) In the course of treating such a patient a doctor shall not order on a prescription form a restricted availability appliance unless—
 - (a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
 - (b) the doctor endorses the face of the form with the reference "SLS",

but may otherwise prescribe such an appliance for that patient in the course of that treatment.".

(3) In Schedule 11 (drugs to be prescribed under pharmaceutical services only in certain circumstances), after "Sildenafil (Viagra)" in columns 1 and 2 respectively, insert ", Apomorphine Hydrochloride (Uprima)".

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(17)

18th December 2002

D.Elis-Thomas
The Presiding Officer of the National Assembly

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the National Health Service (Pharmaceutical Services) Regulations 1992 ("the Pharmaceutical Services Regulations") which govern the arrangements for the provision of pharmaceutical services under the National Health Service Act 1977 and the National Health Service (General Medical Services) Regulations 1992 ("the General Medical Services Regulations") which regulate the terms on which doctors provide general medical services under the National Health Service Act 1977.

Regulation 3(3) of these Regulations adds Apomorphine Hydrochloride (Uprima) to Schedule 11 to the General Medical Services Regulations, which lists the drugs and other substances that may only be prescribed in certain circumstances in the course of pharmaceutical services provided under the National Health Service Act 1977.

The amendments within regulation 2 and 3(1) and (2) amend both sets of Regulations to take account of the fact that certain appliances may be available for prescription within the National Health Service only in circumstances that are specified by the National Assembly for Wales in the Drug Tariff.

Regulation 2(c) of these Regulations extends the definition of "nurse prescriber" in the Pharmaceutical Services Regulations to reflect the extended responsibilities granted to certain nurses. The determination of the National Assembly for Wales as to those drugs, medicines and listed appliances which may be ordered by nurse prescribers is currently set out in Part XVIIB of the Drug Tariff, copies of which may be obtained from the Stationery Office, PO Box 29, Norwich NR3 1GN.

Regulation 2(2)(b), (3) and (6) also make changes to the Pharmaceutical Services Regulations consequential upon the commencement of section 42 of the Health and Social Care Act 2001, which substituted section 41 to the National Health Service Act 1977.

Regulation 2(2)(a) corrects a numbering error in the Pharmaceutical Services Regulations.