STATUTORY INSTRUMENTS

2001 No. 3998

The Misuse of Drugs Regulations 2001

Production and supply of drugs in Schedules 3 and 4

- 9.—(1) Notwithstanding the provisions of section 4(1)(a) of the Act—
 - (a) a practitioner or pharmacist, acting in his capacity as such, may manufacture or compound any drug specified in Schedule 3 or 4;
 - (b) a person lawfully conducting a retail pharmacy business and acting in his capacity as such may, at the registered pharmacy at which he carries on that business, manufacture or compound any drug specified in Schedule 3 or 4;
 - (c) a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, produce any drug specified in Schedule 3 or 4;
- [F1(d)] a nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 3 or 4 for the purposes of administration in accordance with regulation 7;
 - (e) any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, [F2paramedic independent prescriber, therapeutic radiographer independent prescriber] or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 3 or 4 for the purposes of administration in accordance with regulation 7.]
- (2) Notwithstanding the provisions of section 4(1)(b) of the Act, any of the following persons, that is to say—
 - (a) a practitioner;
 - (b) a pharmacist;
 - (c) a person lawfully conducting a retail pharmacy business;
 - (d) a person in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research;
 - (e) a public analyst appointed under section 27 of the Food Safety Act 1990;
 - (f) a sampling officer within the meaning of Schedule 3 to the Medicines Act 1968;
 - (g) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 and the regulations made thereunder;
 - (h) [F3a person authorised by the General Pharmaceutical Council] for the purposes of section 108 or 109 of the Medicines Act 1968,

[F4(i) a supplementary prescriber acting under and in accordance with the terms of a clinical management plan,]

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession.

- (3) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) a person who is authorised as a member of a group, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto;
 - (b) the person in charge or acting person in charge of [F5a hospital, organisation providing ambulance services] or [F6care home];
- [F7(c)] in the case of such a drug supplied to her by a person responsible for the dispensing and supply of medicines at that hospital, care home or prison, the senior registered nurse, acting senior registered nurse or registered midwife, for the time being in charge of a ward, theatre or other department in the hospital, care home or prison.]
- [F8(d) in the case of such a drug supplied to him by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital;]

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 F9..., to any person who may lawfully have that drug in his possession, except that nothing in this paragraph authorises—

- (i) the person in charge or acting person in charge of [F10a hospital, organisation providing ambulance services] or [F11care home], having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug;
- (ii) a [F12] senior registered nurse, acting senior registered nurse or registered midwife] for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a [F13] doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber [F14] or a pharmacist independent prescriber]; or]
- [F15(iii)] an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to paragraph (3A), a nurse independent prescriber [F16 or a pharmacist independent prescriber].]
- [F17(iv)] the person in charge or acting person in charge of an organisation providing ambulance services to supply any drugs other than directly to employees of the organisation for the immediate treatment of sick or injured persons.]
- [F18(3A)] The directions given by a nurse independent prescriber or a pharmacist independent prescriber referred to in paragraph (3)(d)(ii) and (iii) shall relate only to a controlled drug which such nurse independent prescriber or such pharmacist independent prescriber respectively may prescribe under regulation 6B and a purpose for which it may be prescribed under that regulation.]
 - (4) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, supply or offer to supply any drug specified in Schedule 3 or 4 to any person who may lawfully have that drug in his possession;

- (b) a person who is authorised under paragraph (1)(c) may supply or offer to supply any drug which he may, by virtue of being so authorised, lawfully produce to any person who may lawfully have that drug in his possession.
- (5) Notwithstanding the provisions of section 4(1)(b) of the Act—
 - (a) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it;
 - (b) the installation manager of an offshore installation,

may supply or offer to supply any drug specified in Schedule 3, or any drug specified in Schedule 4 F19 ____

- (i) for the purpose of compliance with any of the provisions specified in regulation 8(6), to any person on that ship or installation; or
- (ii) to any person who may lawfully supply that drug to him.
- (6) Notwithstanding the provisions of section 4(1)(b) of the Act, a person in charge of a laboratory may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 3 which is required for use as a buffering agent in chemical analysis to any person who may lawfully have that drug in his possession.
- [F20] F21(7) Notwithstanding the provisions of section 4(1)(b) of the Act, a nurse independent prescriber may, when acting in her capacity as such, supply or offer to supply any controlled drug specified in Schedule 3 or 4 to any person who may lawfully have any of those drugs in his possession provided it is supplied or offered in circumstances where she may prescribe it under regulation 6B.]
- F22(7A) Notwithstanding the provisions of section 4(1)(b) of the Act, a paramedic independent prescriber or a therapeutic radiographer independent prescriber may, when acting in their capacity as such, supply or offer to supply any controlled drug specified in Schedule 3 or 4 to any person who may lawfully have any of those drugs in their possession provided it is supplied or offered in circumstance where they may prescribe it under regulation 6D.]
- (8) Notwithstanding the provisions of section 4(1)(b) of the Act, a registered nurse or a person specified in Schedule 8, when acting in their capacity as such, may supply or offer to supply, under and in accordance with the terms of a patient group direction, any drug specified in Schedule 4 [F23 or Midazolam] to any person who may lawfully have that drug in his possession, except that this paragraph shall not have effect in the case of—
 - (a) the supply or offer to supply of any of the anabolic steroid drugs specified in Part II of Schedule 4: and
 - (b) any drug or preparation which is designed for administration by injection and which is to be used for the purpose of treating a person who is addicted to a drug;
 - (c) for the purposes of paragraph (b) above, a person shall be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued.]

Textual Amendments

- Reg. 9(1)(d)(e) inserted (23.4.2012) by The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(a)
- Words in reg. 9(1)(e) inserted (31.12.2023) by The Misuse of Drugs (England and Wales and Scotland) (Amendment) (No. 2) Regulations 2023 (S.I. 2023/1345), regs. 1(2), 8(a)
- F3 Words in reg. 9(2)(h) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), Sch. 4 para. 34(3) (with Sch. 5); S.I. 2010/1621, art. 2(1), Sch.

- **F4** Reg. 9(2)(i) inserted (14.3.2005) by The Misuse of Drugs (Amendment) Regulations 2005 (S.I. 2005/271), regs. 1, **2**(7)
- F5 Words in reg. 9(3)(b) substituted (1.6.2015) by The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891), regs. 1(1), 8(a)
- **F6** Words in reg. 9(3) substituted (16.8.2007) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(1), **4(3)(b)**
- F7 Reg. 9(3)(c) substituted (1.6.2015) by The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891), regs. 1(1), 8(b)
- F8 Reg. 9(3)(d) inserted (16.8.2007) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(1), 4(6)(a)
- **F9** Words in reg. 9(3) omitted (23.4.2012) by virtue of The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), **10(b)**
- **F10** Words in reg. 9(3)(i) substituted (1.6.2015) by The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891), regs. 1(1), 8(c)
- F11 Words in reg. 9(3) substituted (16.8.2007) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(1), 4(4)(b)
- F12 Words in reg. 9(3)(ii) substituted (1.6.2015) by The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891), regs. 1(1), 8(d)
- F13 Words in reg. 9(3)(ii) substituted (16.8.2007) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(1), 4(6)(b)
- F14 Words in reg. 9(3)(ii) inserted (23.4.2012) by The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(c)
- F15 Reg. 9(3)(iii) inserted (16.8.2007) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(1), 4(6)(c)
- F16 Words in reg. 9(3)(iii) inserted (23.4.2012) by The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(d)
- F17 Reg. 9(3)(iv) inserted (1.6.2015) by The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891), regs. 1(1), 8(e)
- F18 Reg. 9(3A) substituted (23.4.2012) by The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(e)
- F19 Words in reg. 9(5) omitted (23.4.2012) by virtue of The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(f)
- **F20** Reg. 9(7)(8) inserted (15.10.2003) by The Misuse of Drugs (Amendment) (No. 3) Regulations 2003 (S.I. 2003/2429), regs. 1, **2(6)**
- F21 Reg. 9(7) substituted (23.4.2012) by The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (S.I. 2012/973), regs. 1(1), 10(g)
- **F22** Reg. 9(7A) inserted (31.12.2023) by The Misuse of Drugs (England and Wales and Scotland) (Amendment) (No. 2) Regulations 2023 (S.I. 2023/1345), regs. 1(2), **8(b)**
- **F23** Words in reg. 9(8) inserted (1.1.2008) by The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 (S.I. 2007/2154), regs. 2(3)(b), 4(6)(e)

Changes to legislation:
There are currently no known outstanding effects for the The Misuse of Drugs Regulations 2001, Section 9.