DRAFT STATUTORY INSTRUMENTS

2010 No.

The Pharmacy Order 2010

PART 1

Preliminary

Citation and commencement

1.—(1) This Order may be cited as the Pharmacy Order 2010.

(2) The following provisions come into force on the day after the day on which this Order is made— $\!\!\!$

- (a) this article;
- (b) articles 2, 3, 4(1), (2), (3)(b), (5) and (8) and 7 and Schedule 1; and
- (c) articles 65, 66, 69(1) to (4) and 70 and Schedules 5 and 6.

(3) Except as provided for by paragraph (2), the provisions of this Order which confer powers enabling rules or orders to be made, or which enable standards or requirements to be set by the Council, come into force on the making of this Order, but for the purpose only of the exercise of those powers.

(4) Rules under article 7(1) and (4) are not to come into force before the end of the period of two years beginning with the day on which this Order is made.

(5) Except as provided for by paragraphs (2) and (3), this Order comes into force on such day as the Privy Council may by order appoint.

(6) Different days may be appointed by an order under paragraph (5) for different provisions or different purposes.

Extent

2.—(1) Subject to paragraph (2), this Order extends to England and Wales and Scotland.

(2) The extent of any amendment, revocation, repeal or saving of any enactment set out in Schedules 4 and 6 is the same as that of the enactment amended, revoked, repealed or saved.

Interpretation

3.—(1) In this Order—

"the 2007 Order" means the Pharmacists and Pharmacy Technicians Order 2007(1);

"annotation" means an annotation in the Register;

"assessment team" means an assessment team appointed under rules made under article 55;

(1) S.I.2007/289; amended by S.I.2007/3101.

"competent authority" means any authority or body of a relevant European State designated by that State for the purposes of the Directive as competent, in connection with practice as a pharmacist or pharmacy technician—

- (a) to receive or issue evidence of qualifications or other information or documents; and
- (b) to receive applications and take the decisions referred to in the Directive;

"controlled drugs" has the meaning given in section 2(1)(a) of the Misuse of Drugs Act 1971(2) (controlled drugs and their classification);

"the Council" means the General Pharmaceutical Council established by article 4;

"the Directive" means Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications(3), and references in this Order to the Directive, or to any provision of the Directive, are references to the Directive, or to that provision, as amended from time to time;

"electronic communication" has the meaning given in section 15(1) of the Electronic Communications Act 2000(4) (general interpretation);

"enactment" means an enactment contained in, or in an instrument made under-

- (a) an Act of Parliament;
- (b) an Act of the Scottish Parliament; or
- (c) a measure or Act of the National Assembly for Wales;

"European mutual recognition area" means the territory of the EEA States(5) and Switzerland;

"exempt person" means-

- (a) a national of a relevant European State other than the United Kingdom;
- (b) a national of the United Kingdom who is seeking access to, or is pursuing, the profession of pharmacist or pharmacy technician by virtue of an enforceable Community right; or
- (c) a person who is not a national of a relevant European State but who is, by virtue of an enforceable Community right, entitled to be treated, for the purposes of access to and pursuit of the profession of pharmacist or pharmacy technician, no less favourably than a national of a relevant European State;

"General Systems Regulations" means the European Communities (Recognition of Professional Qualifications) Regulations 2007(6);

"improvement notice" means a notice served on any person under article 13;

"individual assessor" means an individual assessor appointed under rules made under article 55;

"inspector" means an inspector appointed by the Council under article 8(1);

"medical device" has the meaning given in regulation 2(2) of the Medical Devices Regulations 2002(7);

"medicinal product" has the same meaning as it has in the Medicines Act 1968 by virtue of section 130 of that Act(8) (meaning of "medicinal product" and related expressions);

^{(2) 1971} c.38.

⁽³⁾ OJNo. L255, 30.09.2005, p22, as amended by Council Directive 2006/100/EEC of 20 November 2006, OJ No. L363 of 20.12.2006, p141.

⁽**4**) 2000 c.7.

⁽⁵⁾ See Schedule 1 to the Interpretation Act 1978 (c.30) for the definition of the "EEA State" which was inserted by section 26(1) of the Legislative and Regulatory Reform Act 2006 (c.51).

⁽⁶⁾ S.I.2007/2781 as amended by S.I.2009/1182.

⁽⁷⁾ S.I.2002/618. There are no relevant amendments.

^{(8) 1968} c.67. Section 130 was amended by section 12(2) of, and paragraph 3 of Schedule 1 to, the Animal Health and Welfare Act 1984 (c.40) and by S.I.1994/3119, 2005/50 and 2006/2407.

"medicinal product on a general sale list" means a medicinal product of a description, or falling within a class, specified in an order which is for the time being in force under section 51 of the Medicines Act 1968 (9)(general sale lists);

"the Pharmacy Acts" means the Pharmacy Act 1852(10), the Pharmacy Act 1868(11), the Pharmacy Act 1908(12), the Pharmacy and Poisons Act 1933(13) and the Pharmacy Act 1954(14);

"the Poisons Rules" means rules made by the Secretary of State under section 7 of the Poisons Act 1972(**15**) (poisons rules);

"prescribed" means prescribed by rules made by the Council;

"the Register" means the register established and maintained under article 19;

"registered pharmacist" means a person who is entered in Part 1 or 4 of the Register;

"registered pharmacy technician" means a person who is entered in Part 2 or 5 of the Register;

"registered pharmacy" means premises that are entered in Part 3 of the Register;

"registrant" means a registered pharmacist or a registered pharmacy technician;

"Registrar", except where used in the expression "Registrar General", is to be construed in accordance with article 18(1) and (6);

"Registrar General" means-

- (a) the Registrar General for England and Wales appointed under section 1 of the Registration Service Act 1953(16) (Registrar General); or
- (b) the Registrar General for Scotland appointed under section 1(1) of the Registration of Births, Deaths and Marriages (Scotland) Act 1965(17) (the Registrar General);

"regulatory body" means a regulatory body which has the function of authorising persons to practise as a member of a health or social care profession;

"relevant European State" means an EEA State or Switzerland;

"retail pharmacy business" has the meaning given in section 132 of the Medicines Act 1968(**18**) (general interpretation provisions);

"retail sale" is to be construed in accordance with section 131(3) of the Medicines Act 1968(19) (meaning of "wholesale dealing", "retail sale" and related expressions);

"the Society" means the Royal Pharmaceutical Society of Great Britain;

"statutory committees" means the Committees of the Council listed in article 4(6);

"superintendent pharmacist" means a pharmacist who is a superintendent for the purposes of section 71(1) of the Medicines Act 1968(**20**) (business carried on by body corporate); and

⁽⁹⁾ See the Medicines (Products other than Veterinary Drugs) (General Sale List) Order 1984 (S.I.1984/769).

^{(10) 1852} c.56; repealed by the Pharmacy Act 1954 (c.61).

^{(11) 1868} c.121; repealed by the Pharmacy Act 1954.

^{(12) 1908} c.55; repealed by the Pharmacy Act 1954.

^{(13) 1933} c.25; repealed by the Statute Law Revision Act 1950 (c.6), by Schedule 4 to the Pharmacy Act 1954, by Schedule 6 to the Medicines Act 1968 (c.67) and by Schedule 2 to the Poisons Act 1972 (c.66).

^{(14) 1954} c.61; repealed by S.I.2007/289.

^{(15) 1972} c.66. The rules currently in force are S.I.1982/218. These Rules have been amended by S.I.1985/1077, 1968/10, 1986/1704, 1989/112 and 1992/2293.

^{(16) 1953} c.37. Section 1 was amended by section 68 of the Statistics and Registration Service Act 2007 (c.18).

^{(17) 1965} c.49. Section 1(1) was amended by the Scotland Act 1998 (c.46), section 125.

^{(18) 1968} c.67. There are no relevant amendments.

^{(19) 1968} c.67. The definition of retail sale was amended by paragraph 138(2) of Schedule 4 to the National Health Service Reorganisation Act 1973 (c.32), by paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978 (c.29) and by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006 (c.43).

⁽²⁰⁾ Section 71 is substituted by section 28 of the Health Act 2006 (as amended by S.I.2007/3101) from 1 October 2007 (see S.I.2008/2714b (C.114)).

"supply in circumstances corresponding to retail sale" is to be construed in accordance with section 131(4) of the Medicines Act 1968.

(2) For the purposes of this Order, a person practises as a pharmacist or a pharmacy technician if, whilst acting in the capacity of or purporting to be a pharmacist or a pharmacy technician, that person undertakes any work or gives any advice in relation to the preparation, assembly, dispensing, sale, supply or use of medicines, the science of medicines, the practice of pharmacy or the provision of healthcare.

(3) For the purposes of articles 34 and 35, "emergency" means an emergency of the type described in subsection (1)(a) of section 19 of the Civil Contingencies Act 2004(21) (meaning of "emergency"), read with subsection (2)(a) and (b) of that section.