STATUTORY INSTRUMENTS

2005 No. 766

MEDICINES

The Medicines (Pharmacy and General Sale —Exemption) Amendment Order 2005

Made - - - - 16th March 2005

Laid before Parliament 17th March 2005

Coming into force - - 7th April 2005

As regards England, Scotland and Wales, the Secretary of State concerned with health in England, and, as regards Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 57(1) and (2) and 129(4) of the Medicines Act 1968(1) or, as the case may be, those powers conferred by the said provisions and now vested in them(2), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, pursuant to section 129(6) of that Act, and after taking into account the advice of the Committee on Safety of Medicines and of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Order:

Citation, commencement and interpretation

- **1.**—(1) This Order may be cited as the Medicines (Pharmacy and General Sale—Exemption) Amendment Order 2005 and shall come into force on 7th April 2005.
- (2) In this Order, "the principal Order" means the Medicines (Pharmacy and General Sale—Exemption) Order 1980(3).

^{(1) 1968} c. 67. The expressions "the appropriate Ministers" and "the Health Ministers", which are relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794.

⁽²⁾ In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142: and in the case of the Department for Health, Social Services and Public Safety, by virtue of the powers vested in the Minister in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47), which may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Department was renamed by virtue of article 3(6) of S.I. 1999/283 (N.I.1).

^{(3) 1980/1924;} relevant amending instruments are S.I. 2000/1919, 2003/697 and 2004/1 and 1771.

Amendment of article 1 of the principal Order

- 2. In article 1 of the principal Order (citation, commencement and interpretation), in paragraph (2), in sub-paragraph (a)—
 - (a) after the definition of "independent medical agency" (4), insert the following definition— ""juvenile justice centre" means a juvenile justice centre established under the Criminal Justice (Children) Northern Ireland) Order 1998(5);";
 - (b) after the definition of "Primary Care Trust" (6), insert the following definitions—

""prison" means a prison established under the Prison Act 1952(7), the Prisons (Scotland) Act 1989(8) or the Prison Act (Northern Ireland) 1953(9);

"prison officer" means an officer of a prison, young offender institution, remand centre, juvenile justice centre, young offenders centre or secure training centre and includes a prisoner custody officer;";

(c) after the definition of "prison service" (10), insert the following definitions—

""prisoner" means any person, aged sixteen years or more, for the time being detained in legal custody in a prison, young offenders institution, young offenders centre, remand centre, secure training centre or juvenile justice centre, as a result of a requirement imposed by a court or otherwise that he be so detained;"

"prisoner custody officer means—

- as respects a prison situated in England or Wales, a person certified as such pursuant to section 89(1) of the Criminal Justice Act 1991(11),
- as respects a prison situated in Scotland, a person certified as such pursuant to section 114 of the Criminal Justice and Public Order Act 1994(12),
- as respects a prison situated in Northern Ireland, a person certified as such pursuant to section 122 of the Criminal Justice and Public Order Act 1994, or
- as respects a secure training centre situated in England or Wales, a person certified as such pursuant to section 12 of the Criminal Justice and Public Order Act 1994;";
- (d) in the definition of "relevant register" (13)—
 - (i) in paragraph (a) omit "and";
 - (ii) in paragraph (b), after "the Pharmacy (Northern Ireland) Order 1976(14);" insert "and"; and
 - (iii) after paragraph (b), insert
 - in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(15) relating to-
 - (i) chiropodists and podiatrists;

⁽⁴⁾ The definition of "independent medical agency" was inserted by S.I. 2003/697.

S.I. 1998/1504 (N.I. 9).

⁽⁶⁾ The definition of "Primary Care Trust" was inserted by S.I. 2000/1919.

^{(7) 1952} c. 52. (8) 1989 c. 45.

^{(9) 1953} c. 18.

⁽¹⁰⁾ The definition of "prison service" was inserted by S.I. 2003/697.

^{(11) 1991} c. 53.

^{(12) 1994} c. 33.

⁽¹³⁾ The definition of "relevant register" was inserted by S.I. 2004/1 and amended by S.I. 2004/1771.

⁽¹⁴⁾ S.I. 1976/1213 (N.I. 22).

⁽¹⁵⁾ S.I. 2002/254.

- (ii) physiotherapists; or
- (iii) radiographers: diagnostic or therapeutic,

that register";

- (e) after the definition of "relevant register", insert the following definition—
 - ""remand centre" means a remand centre established under the Prison Act 1952(16) or the Prisons (Scotland) Act 1989;";
- (f) after the definition of "Special Health Authority" (17), insert the following definition—
 - ""secure training centre" means a secure training centre established under the Prison Act 1952;";
- (g) in the definition of "supplementary prescriber" (18)—
 - (i) in paragraph (b), omit "or",
 - (ii) in paragraph (c), after "a registered midwife;" insert "or",
 - (iii) after paragraph (c), insert—
 - "(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) radiographers: diagnostic or therapeutic,"; and
 - (iv) after "an annotation" insert "or entry"; and
- (h) after the definition of "United Kingdom marketing authorisation" (19), insert the following definitions-

""young offender institution" means a young offender institution established under the Prison Act 1952 or the Prisons (Scotland) Act 1989;

"young offenders centre" means a young offenders centre established under the Treatment of Offenders Act (Northern Ireland) 1968(20).".

Amendment of Schedule 1 to the principal Order

- 3. In Schedule 1 to the principal Order (exemptions for certain purposes from the provisions of sections 52 and 53 of the Medicines Act)—
 - (a) in Part I, in paragraph 2—
 - (i) in the entry in column 2, in paragraph (b)—
 - (aa) omit "Atrophine sulphate,", "Bethanecol chloride", and "Carbachol,";
 - (bb) after "Cyclopentolate hydrochloride," insert "Fusidic acid,"; and
 - (cc) omit "Homatrophine hydrobromide,", "Hyoscine hydrobromide,", "Naphazoline hydrochloride,", "Naphazoline nitrate,", "Neostigmine methylsulphate,", "Physostigmine methylsulphate,", "Physostigmine

⁽¹⁶⁾ See section 43(1)(a) of the Prison Act 1952 which will be repealed by the Criminal Justice and Court Services Act 2000 (c.. 43), on a date which is to be appointed pursuant to section 80 of that Act.

⁽¹⁷⁾ The definition of "Special Health Authority" was inserted by S.I. 2000/1919.
(18) The definition of "supplementary prescriber" was inserted by S.I. 2004/1.

⁽¹⁹⁾ The definition of "United Kingdom marketing authorisation" was inserted by S.I. 2000/1919.

^{(20) 1968} c. 29 (N.I.).

salicylate,", "Physostigmine sulphate,", "Pilocarpine hydrochloride," and "Pilocarpine nitrate.";

- (ii) for the entry in column 3, substitute the following entry—
 - "2. The sale or supply shall be only (a) in the case of medicinal products on a general sale list and pharmacy medicines, in the course of their professional practice; (b) in the case of prescription only medicines, in the course of their professional practice and in an emergency.";
- (b) insert, at the end of Part II, the following paragraph—

"14.	A prison officer.	All medicinal products on a general sale list.	The supply shall only be so far as is necessary for the treatment of prisoners.".
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Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

16th March 2005

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

L.S.

Deirdre Kenny
A Senior Officer of the
Department of Health, Social Services and
Public Safety

15th March 2005

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Pharmacy and General Sale – Exemption) Order 1980 ("the principal Order") which provides for exemptions to sections 52 and 53 of the Medicines Act 1968(restrictions on the sale or supply of medicinal products).

Article 2 inserts additional definitions into the principal Order. In particular, it amends the definition of "supplementary prescriber" to include chiropodists and podiatrists, physiotherapists and diagnostic or therapeutic radiographers. It also inserts various definitions relevant to the amendment made in article 3, which permits the supply of general sale medicines by a prison officer to a prisoner for the purpose of treatment of that prisoner.

Article 3 amends Schedule 1 to the principal Order. It makes changes to the exemptions from sections 52 and 53 of the Medicines Act 1968, (restrictions on the sale or supply of medicinal products), contained in that Schedule. First, the article makes changes to the list of medicines which may be sold or supplied by a registered ophthalmic optician. Secondly, the article provides for the supply of general sale medicines by a prison officer to a prisoner for the purpose of treatment of that prisoner.

A Regulatory Impact Assessment in relation to this Order has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.