
STATUTORY INSTRUMENTS

2003 No. 697

MEDICINES

**The Medicines (Pharmacy and General Sale
—Exemption) Amendment Order 2003**

<i>Made</i>	- - - -	<i>13th March 2003</i>
<i>Laid before Parliament</i>		<i>14th March 2003</i>
<i>Coming into force</i>	- -	<i>4th April 2003</i>

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 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 2003 and shall come into force on 4th April 2003.

(2) In this Order, “the principal Order” means the Medicines (Pharmacy and General Sale—Exemption) Order 1980(3).

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- (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 amendments in S.I. 2000/1919.

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 “health authority”, insert the following definition—

““health care” means services for or in connection with the prevention, diagnosis or treatment of disease;”;

(b) after the definition of “homoeopathic certificate of registration”(4), insert the following definitions—

““independent clinic”—

(a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000(5), and

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001(6);

“independent hospital”—

(a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and

(b) in relation to Scotland, means—

(i) an independent hospital, or

(ii) a private psychiatric hospital,

as defined by section 77(1) of the Regulation of Care (Scotland) Act 2001;

“independent medical agency”—

(a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;”;

(c) after the definition of “NHS trust”(7), insert the following definition—

““nursing home” has the meaning given by article 16 of the Registered Homes (Northern Ireland) Order 1992(8);”;

(d) after the definition of “Primary Care Trust”(9), insert the following definition—

““prison service” means—

(a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952(10)),

(b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989(11)), and

(c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953(12));”;

(4) The definition of “homoeopathic certificate of registration ” was inserted by S.I. [2000/1919](#).

(5) [2000 c. 14](#).

(6) [2001 asp 8](#).

(7) The definition of “NHS trust” was inserted by S.I. [2000/1919](#).

(8) S.I. [1992/3204 \(N.I.20\)](#)

(9) The definition of “Primary Care Trust” was inserted by S.I. [2000/1919](#).

(10) [1952 c. 52](#).

(11) [1989 c. 45](#).

(12) [1953 \(c. 18 \(N.I.\)\)](#).

- (e) after the definition of “registered ophthalmic optician”, insert the following definition—
- ““registered provider” means—
- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
 - (i) in relation to England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency,
 - (ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and
 - (b) in relation to a nursing home, the person registered under Part III of the Registered Homes (Northern Ireland) Order 1992 as the person carrying on the nursing home, other than a manager who is to be treated as carrying on the home by virtue of article 17(2) of that order;
- “relevant manager” means—
- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
 - (i) in relation to England and Wales—
 - (aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
 - (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,
 - (ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of the Regulation of Care (Scotland) Act 2001, and
 - (b) in relation to a nursing home, the manager of the nursing home, unless they are the registered provider for that home;”.

Insertion of articles 4C and 4D in the principal Order

3. After article 4B of the principal Order⁽¹³⁾ (exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist doctors or dentists in providing national health services) insert the following articles—

“Exemption for the supply of medicinal products by independent hospitals, clinics and agencies

4C.—(1) The restrictions imposed by sections 52 and 53 shall not apply to the supply of a medicinal product in the course of the business of—

- (a) in England, Wales or Scotland—
 - (i) an independent hospital,
 - (ii) an independent clinic, or
 - (iii) an independent medical agency; or

(13) Article 4B was inserted by S.I. 2000/1919.

(b) in Northern Ireland, a nursing home,
where the product is supplied for the purpose of being administered in accordance with a Patient Group Direction where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to are that—

- (a) the Patient Group Direction relates to the supply of a description or class of medicinal product by the person by whom the medicinal product is supplied, and the Direction has effect at the time at which the product is supplied;
- (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 3 to this Order;
- (c) the Patient Group Direction is signed—
 - (i) by or on behalf of the registered provider, and
 - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager;
- (d) the individual who supplies the product belongs to one of the classes of individual specified in Part III of Schedule 3 to this Order, and is designated in writing—
 - (i) by or on behalf of the registered provider, or
 - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager,
 for the purpose of the supply of products under the Patient Group Direction; and
- (e) at the time at which the product is supplied, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

(3) In this article, “medicinal product” does not include a medicinal product which is a veterinary drug.

Exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces

4D.—(1) The restrictions imposed by sections 52 and 53 shall not apply to the supply of a medicinal product by an individual belonging to one of the classes specified in Part III of Schedule 3 to this Order where—

- (a) that individual supplies the product in order to assist the provision of health care by, on behalf of, or under arrangements made by—
 - (i) a police force in England, Wales or Scotland,
 - (ii) the Police Service of Northern Ireland,
 - (iii) a prison service, or
 - (iv) Her Majesty’s Forces;
 - (b) the product is supplied for the purpose of being administered to a particular person in accordance with a Patient Group Direction; and
 - (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
- (a) the Patient Group Direction relates to the supply of a description or class of medicinal product in order to assist the provision of health care by, or on behalf of, or under arrangements made by the police force or service, the prison service or, as the case may be, Her Majesty’s Forces;

- (b) the Patient Group Direction has effect at the time at which the product is supplied;
 - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 3 to this Order;
 - (d) the Patient Group Direction is signed—
 - (i) by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 3 to this Order (“the authorising person”) against the entry in column 1 of that Table for the police force or service, the prison service or Her Majesty’s Forces by whom or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care; and
 - (ii) in the case of a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;
 - (e) the individual referred to in paragraph (1) is designated in writing, by or on behalf of the authorising person, for the purpose of the supply of medicinal products under the Patient Group Direction; and
 - (f) at the time at which the product is supplied, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (3) In this article, “medicinal product” does not include a medicinal product which is a veterinary drug.”.

Amendment of Schedule 3 to the principal Order

4. In Schedule 3 to the principal Order(14), after Part II, insert the following Part—

“PART IIA

PERSONS BY WHOM OR ON WHOSE BEHALF A PATIENT GROUP DIRECTION USED IN THE PROVISION OF HEALTH CARE BY OR ON BEHALF OF THE POLICE, THE PRISON SERVICES OR THE ARMED FORCES MUST BE SIGNED

<i>Column 1</i>	<i>Column 2</i>
Force or service by whom or on whose behalf the health care is provided	Person by whom or on whose behalf the Direction must be signed
A police force in England and Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996(15))
A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1997(16))

(14) Schedule 3 was inserted by S.I. 2000/1919.

(15) 1996 c. 16.

(16) 1997 c. 77.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Column 1</i> Force or service by whom or on whose behalf the health care is provided	<i>Column 2</i> Person by whom or on whose behalf the Direction must be signed
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(i) the Surgeon General, (ii) a Medical Director General, or (iii) a chief executive of an executive agency of the Ministry of Defence".

Signed by authority of the Secretary of State for Health

13th March 2003

Hunt
Parliamentary Under Secretary of State,
Department of Health

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

11th March 2003

D. C. Goudy
Permanent Secretary
Department of Health, Social Services and
Public Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 (“the principal Order”) and provides for exemptions from sections 52 and 53 of the Medicines Act 1968 for the supply of a medicinal product for human use under a Patient Group Direction (i.e. a written direction providing for the supply of a description or class of medicines to persons generally) to assist the provision of health care by certain non-NHS health care providers (i.e. a provider of health care other than a National Health Service body or a person providing services under an arrangement with such a body). In particular, article 3 inserts new articles 4C and 4D of the principal Order—

- (a) article 4C provides for the supply of medicinal products for human use by designated health professionals in the course of the business of an independent hospital, clinic or agency, or nursing home, in accordance with a Patient Group Direction; and
- (b) article 4D provides for the supply of medicinal products for human use by designated health professionals in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces, in accordance with a Patient Group Direction.

Article 4 inserts new Part IIA of Schedule 3 to the principal Order, which specifies the persons by whom or on whose behalf a Patient Group Direction for the police, prison services or armed forces must be signed.

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 Control Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.