STATUTORY INSTRUMENTS

2000 No. 1919

MEDICINES

The Medicines (Pharmacy and General Sale —Exemption) Amendment Order 2000

Made - - - -	*17th July 2000*
Laid before Parliament	*19th July 2000*
Coming into force - -	*9th August 2000*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Minister 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 and commencement

1.—(1) This Order may be cited as the Medicines (Pharmacy and General Sale—Exemption) Amendment Order 2000 and shall come into force on 9th August 2000.

Amendment of the Medicines (Pharmacy and General Sale—Exemption) Order 1980

2. The Medicines (Pharmacy and General Sale—Exemption) Order 1980(**3**) shall be amended as follows—

(a) by inserting in sub-paragraph (a) of paragraph (2) of article 1, in the appropriate place in the alphabetical order of the entries in that sub-paragraph—

(**1**) 1968 c. 67; the expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388.

(**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 Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**3**) 1980/1924, to which there are amendments not relevant to this Order.

""Common Services Agency" means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978(**4**);

"Community marketing authorization" means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93(**5**);

"homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**6**);

"marketing authorization" includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;

"NHS trust"—

(a) in relation to England and Wales, has the same meaning as in the National Health Service and Community Care Act 1990(**7**);

(b) in relation to Scotland, has the same meaning as in the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Health and Social Services trust established under article 10 of the Health and Social Services (Northern Ireland) Order 1991(**8**);

"Patient Group Direction" means a written direction which relates to the supply and administration of a description or class of medicinal product and which—

(a) is signed by a doctor or dentist, and by a pharmacist; and

(b) relates to supply and administration to persons generally (subject to any exclusions which may be specified in the Direction);

"Primary Care Trust" has the same meaning as in the National Health Service Act 1977(**9**);

"Special Health Authority"—

(a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977(**10**);

(b) in relation to Scotland, means a Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and

(c) in relation to Northern Ireland, means a Special Health and Social Services Agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(**11**);

"United Kingdom marketing authorization" means a marketing authorization granted by the licensing authority under the Medicines For Human Use (Marketing Authorisations Etc.) Regulations 1994 (including a product licence having effect as such an authorization by virtue of Schedule 6 to those Regulations)(**12**).";

(**4**) 1978 c. 29.
(**5**) OJ No. L214, 24.8.93, p.1.
(**6**) S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566 and 2000/592.
(**7**) 1990 c. 19.
(**8**) S.I. 1991/194 (N.I. 1).
(**9**) 1997 c. 49; section 16A, which deals with the establishment of Primary Care Trusts, was inserted by section 2 of the Health Act 1999 (c. 8).
(**10**) *See* section 11, which was amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 2, and by the Health Act 1999 (c. 8), Schedule 4, paragraph 6.
(**11**) S.I. 1990/247 (N.I. 3).
(**12**) S.I. 1994/3144, amended by 1998/3105 and 2000/292.

(b) by inserting in paragraph (2) of article 1, after sub-paragraph (b)—

"(c) in articles 4A and 4B, a reference to a product being supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a particular person, or in accordance with a Patient Group Direction, includes a reference to it being supplied in accordance with such directions or such a Direction; and

(d) in Schedule 3, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.";

(c) by inserting after article 4—

"**Exemption for the supply of medicinal products by national health service bodies**

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

(a) the Common Services Agency;

(b) a health authority or Special Health Authority;

(c) an NHS trust;

(d) a Primary Care Trust; or

(e) where sub-paragraphs (a) to (d) of this paragraph do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply of medicinal products,

where the product is supplied for the purpose of being administered to a particular person in accordance with the written directions of a doctor or dentist relating to that person, or in accordance with a Patient Group Direction where the conditions specified in paragraph (2) are fulfilled.

(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 on behalf of the person specified in column 2 of the Table in Part II of Schedule 3 to this Order ("the authorising person") against the entry in column 1 of that Table for the class of person by whom the product is supplied;

(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, on behalf of the authorising person, 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—

(a) a reference to an arrangement for the supply of medicinal products includes a reference to an arrangement which covers such supply and other matters;

(b) "excepted person" means—

(i) a doctor or dentist; or

(ii) a person lawfully conducting a retail pharmacy business within the meaning of section 69;

(c) "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 doctors or dentists in providing national health services

4B.—(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 a doctor or dentist in the provision of, respectively, NHS primary medical services or NHS primary dental services;

(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 fulfilled.

(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 doctor or dentist in question in providing the services referred to in paragraph (1)(a) (whether or not it also relates to such supply in order to assist any other doctor or dentist);

(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 the doctor or dentist in question or, alternatively, where the Direction also relates to supply in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a) above, by one of those other doctors or dentists; and

(ii) on behalf of the health authority—

(a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or

(b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;

(e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply of medicinal products under the Patient Group Direction, by the doctor or dentist in question or, alternatively, where the Direction also relates to supply in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a) above, by one of those other doctors or dentists; 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—

(a) a reference to the provision of NHS primary dental services shall be construed as a reference to—

(i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997(**13**);

(ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and

(iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972(**14**), or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997(**15**);

(b) a reference to the provision of NHS primary medical services shall be construed as a reference to—

(i) in relation to England and Wales, the provision of general medical services under Part II of the National Health Service Act 1977, or the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997;

(ii) in relation to Scotland, the provision of general medical services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and

(iii) in relation to Northern Ireland, the provision of general medical services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal medical services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997;

(c) "medicinal product" does not include a medicinal product which is a veterinary drug."; and

(d) by inserting after Schedule 2—

"SCHEDULE 3 Articles 4A and 4B

PART I

PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

(a) the period during which the Direction shall have effect;

(**13**) 1997 c. 46.
(**14**) S.I. 1972/1265 (N.I. 14).
(**15**) 1997/1177 (N.I. 7).

(b) the description or class of medicinal product to which the Direction relates;

(c) the clinical situations which medicinal products of that description or class may be used to treat;

(d) whether there are any restrictions on the quantity of medicinal product that may be supplied on any one occasion, and, if so, what restrictions;

(e) the clinical criteria under which a person shall be eligible for treatment;

(f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;

(g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;

(h) the pharmaceutical form or forms in which medicinal products of that description or class are to be administered;

(i) the strength, or maximum strength, at which medicinal products of that description or class are to be administered;

(j) the applicable dosage or maximum dosage;

(k) the route of administration;

(l) the frequency of administration;

(m) any minimum or maximum period of administration applicable to medicinal products of that description or class;

(n) whether there are any relevant warnings to note, and, if so, what warnings;

(o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;

(p) arrangements for referral for medical advice;

(q) details of the records to be kept of supplies of products under the Direction.

PART II

PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED

Column 1 Class of person by whom a product is supplied	**Column 2** Person on whose behalf Direction must be signed
Common Services Agency	The Agency
Health authority	The health authority
NHS trust	The trust
Primary Care Trust	The Trust
A person who supplies medicinal products pursuant to an arrangement made with the Common Services Agency, a health authority, a Special Health Authority, an NHS trust or a Primary Care Trust	The Common Services Agency, where the arrangement has been made with the Agency; or the health authority, Special Health Authority, NHS trust or Primary Care Trust with which the arrangement has been made

PART III

CLASSES OF INDIVIDUAL BY WHOM SUPPLIES MAY BE MADE

Individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Paramedics Board(**16**).

Pharmacists.

Registered health visitors(**17**).

Registered midwives(**17**).

Registered nurses.

Registered ophthalmic opticians.

State registered chiropodists.

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Orthoptists Board (state registered orthoptists)(**18**).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Physiotherapists Board (state registered physiotherapists).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Radiographers Board (state registered radiographers).".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
15th July 2000 Department of Health

Bairbre de Brún
Minister of Health, Social Services and Public
17th July 2000 Safety

(**16**) 1960 c. 66; section 2(1) of the Act has effect as if it mentioned the profession of paramedic, by virtue of S.I. 1999/1853.
(**17**) By virtue of section 7(7) of the Nurses, Midwives and Health Visitors Act 1997 (c. 24), "registered", in relation to health visitors and midwives, means registered in the register maintained under that section by virtue of qualifications in health visiting and midwifery respectively.
(**17**) By virtue of section 7(7) of the Nurses, Midwives and Health Visitors Act 1997 (c. 24), "registered", in relation to health visitors and midwives, means registered in the register maintained under that section by virtue of qualifications in health visiting and midwifery respectively.
(**18**) Section 2(1) of the Act has effect as if it mentioned the profession of orthoptist, by virtue of S.I. 1966/990.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 and provides, in new articles 4A and 4B and Schedule 3, for exemptions from sections 52 and 53 of the Medicines Act 1968 for the supply of a medicinal product for human use by—

(a) a specified national health body, where the product is supplied for the purpose of being administered in accordance with the patient specific directions of a doctor or dentist, or is supplied by a designated health professional belonging to a class specified in Schedule 3 to the Order for the purpose of being administered in accordance with a Patient Group Direction (i.e. a written direction providing for the supply and administration of a description or class of product to persons generally), where the Direction is signed by a doctor or a dentist and by a pharmacist, and certain other conditions are fulfilled;

(b) a designated health professional, in order to assist a doctor or a dentist in the provision of national health services, where the product is supplied for the purpose of being administered in accordance with a Patient Group Direction and the conditions referred to in (a) are fulfilled.

An assessment of the cost to business of complying with this Order has been made, copies of which have been placed in the libraries of both Houses of Parliament. Further 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.