

2009 No. 3062

MEDICINES

**The Medicines (Exemptions and Miscellaneous Amendments)
Order 2009**

<i>Made</i> - - - -	<i>19th November 2009</i>
<i>Laid before Parliament</i>	<i>25th November 2009</i>
<i>Coming into force</i> - -	<i>21st December 2009</i>

The Secretary of State and the Minister for Health and Social Services and Public Safety, acting jointly, make the following Order in exercise of powers conferred upon them by sections 15(1) and (2), 57(1) and (2), 58(4) and (5) and 129(4) and (5) of the Medicines Act 1968(a), or, in the case of the Minister, the powers conferred by those provisions now vested in the Minister(b).

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by this Order. In accordance with sections 58(6) and 129(7) of that Act, they have consulted and taken into account the advice of the Commission on Human Medicines(c).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Exemptions and Miscellaneous Amendments) Order 2009 and shall come into force on 21st December 2009.

(2) In this Order—

“the Act” means the Medicines Act 1968;

“clinical management plan” means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

- (a) the patient to whom the plan relates;
- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

(a) 1968 c.67. The expression “the Ministers”, which is relevant to the powers being exercised in the making of this Order, is defined in section 1 of the Act as amended by S.I. 1999/3142 and S.I. 2006/2407. Section 15(1) was amended by S.I. 2006/2407. Section 57(1) was amended by S.I. 2006/2407. Section 58(4) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 1; the Health and Social Care Act 2001 (c.15), section 63(1) and (4) and by S.I. 2002/253 and 2006/2407. Section 58(5) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992, section 1 and by the Health and Social Care Act 2001, section 63(1) and (6).

(b) By virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister was responsible was renamed by virtue of article 3(6) of S.I. 1999/283 (N.I.1).

(c) In section 58(6) of the Act, the expression “the appropriate committee” is defined in section 4(6) of the Act, as amended by S.I. 2005/1094; the word “Ministers” was substituted by S.I. 2006/2407.

“medicinal product” includes any article or substance in respect of which section 130(1)(a) of the Act (meaning of “medicinal product” and related expressions) has effect;

“mixing of medicines” means the combining of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient;

“nurse independent prescriber” means a person (“N”)—

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that N is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;

“pharmacist independent prescriber” means a person (“P”)—

- (a) who is a pharmacist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that P is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

“the Pharmacy and General Sale Order” means the Medicines (Pharmacy and General Sale – Exemption) Order 1980(b);

“the POM Order” means the Prescription Only Medicines (Human Use) Order 1997(c);

“supplementary prescriber” means a person (“S”) who is a—

- (a) a registered nurse;
- (b) a pharmacist;
- (c) a registered midwife;
- (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(d) relating to—
 - (i) chiroprodists and podiatrists;
 - (ii) physiotherapists;
 - (iii) radiographers: diagnostic or therapeutic,
- (e) a registered optometrist,

against whose name is recorded in the relevant register an annotation or entry signifying that S is qualified to order drugs, medicines and appliances as a supplementary prescriber or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber.

Exemption to the restrictions imposed by sections 7 and 8 of the Medicines Act 1968

2. The restrictions imposed by sections 7 and 8 of the Medicines Act (general provisions as to dealing with medicinal products and provisions as to manufacture and wholesale dealing) do not apply to the mixing of medicines by—

- (a) a nurse independent prescriber or a pharmacist independent prescriber;
- (b) a supplementary prescriber but only where the mixing of medicines forms part of the clinical management plan for an individual patient;
- (c) a person in accordance with the written directions of a—
 - (i) doctor;
 - (ii) dentist;
 - (iii) nurse independent prescriber; or

(a) Relevant amending instrument is S.I. 2006/2407.

(b) S.I. 1980/1924.

(c) S.I. 1997/1830.

(d) S.I. 2002/254 as amended by S.I. 2009/1182.

- (iv) pharmacist independent prescriber;
- (d) a person in accordance with the written directions of a supplementary prescriber but only where the mixing of medicines forms part of the clinical management plan for an individual patient.

Amendment to Schedule 5 to the POM Order

3.—(1) Schedule 5 to the POM Order (exemption for certain persons from section 58(2) of the Act) is amended as follows.

(2) In Part 2 (exemptions from the restriction on supply)(a), at the end add—

“**9** Persons (“P”) who are members of Her Majesty’s armed forces.

9 All prescription only medicines.

9 The supply shall be—

(a) in the course of P undertaking any function as a member of Her Majesty’s armed forces; and

(b) where P is satisfied that it is not practicable for another person who is legally entitled to supply a prescription only medicine to do so; and

(c) only in so far as is necessary—

(i) for the treatment of a sick or injured person in a medical emergency, or

(ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not supplied.”.

(3) In Part 3 (exemptions from restriction on administration), at the end add—

“**10** Persons (“P”) who are members of Her Majesty’s armed forces.

10 All prescription only medicines.

10 The administration shall be—

(a) in the course of P undertaking any function as a member of Her Majesty’s armed forces; and

(b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine

(a) Part 2 was amended by S.I. 2005/1507 and 2006/2807.

to do so; and

(c) only in so far as is necessary—

(i) for the treatment of a sick or injured person in a medical emergency, or

(ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not administered.”.

Amendment of the Pharmacy and General Sale Order

4.—(1) The Pharmacy and General Sale Order is amended as follows.

(2) In article 1(2) (citation, commencement and interpretation) after the definition of “registered dietician” insert—

““registered dispensing optician” means a person who is registered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989(a);”.

(3) In Schedule 1 (exemptions for certain persons from sections 52 and 53)—

(a) in Part 1(b) at the end add—

“13. Registered dispensing opticians.	13. Pharmacy medicines for external use containing chloramphenicol at a strength not exceeding— (i) 0.5 per cent in eye drops; (ii) 1 per cent in ointment.	13. The sale or supply shall be only in the course of their professional practice.”
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(b) in Part 2(c) at the end add—

“16. Her Majesty’s armed forces.	16. All medicinal products.	16. The supply shall be only so far as is necessary for the treatment of a sick or injured person or the prevention of ill-health.”
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(a) Section 7 was amended by S.I. 2005/848, articles 2 and 7(1)(a) and (b).

(b) Paragraph 12 was inserted into Part 1 of Schedule 1 by S.I. 1997/1350.

(c) Paragraph 15 was inserted into Part 2 of Schedule 1 by S.I. 2006/2807.

Signed by authority of the Secretary of State for Health

16th November 2009

Mike O'Brien
Minister of State,
Department of Health

19th November 2009

Michael McGimpsey
Minister of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Order)

Article 2 of this Order creates new exemptions from the restrictions imposed by sections 7 and 8 of the Medicines Act 1968 (general provisions as to dealing with medicinal products and provisions as to manufacture and wholesale dealing). It provides that the restrictions imposed by those sections shall not apply to the mixing of medicinal products by a nurse independent prescriber, a pharmacist independent prescriber, a supplementary prescriber who mixes the medicinal products as a part of an individual's clinical management plan or any other person acting on the written directions of those persons.

The remainder of this Order makes amendments to—

- the Prescription Only Medicines (Human Use) Order 1997 (“the POM Order”) which specifies the description and classes of medicines (“prescription only medicines”) which may be sold or supplied only in accordance with the prescription of an “appropriate practitioner” and may be administered in accordance with the directions of such a practitioner; and
- the Medicines (Pharmacy and General Sale-Exemption) Order 1980 (“the Pharmacy and General Sale Order”) which provides for exemptions from sections 52 and 53 of the Medicines Act 1968 (restrictions on the sale and supply of medicinal products).

Article 3 amends Parts 2 and 3 of Schedule 5 to the POM Order to provide for members of Her Majesty's armed forces to be able to supply or administer prescription only medicines in some circumstances but only in so far as this is necessary.

Article 4 amends the Pharmacy and General Sale Order in order to provide—

- that registered dispensing opticians are able to sell or supply eye drops or ointment containing chloramphenicol of the specified strength in the course of their professional practice;
- that members of Her Majesty's armed forces are able to supply pharmacy only or general sale medicines in so far as is necessary for the treatment of sick or injured persons or the prevention of ill-health.

An Impact Assessment has not been prepared for this instrument as there is no impact on the private and voluntary sectors.

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STATUTORY INSTRUMENTS

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£5.50