

2009 No. 1165

MEDICINES

**The Medicines for Human Use (Prescribing)(Miscellaneous
Amendments) Order 2009**

<i>Made</i> - - - -	<i>6th May 2009</i>
<i>Laid before Parliament</i>	<i>7th May 2009</i>
<i>Coming into force</i> - -	<i>8th May 2009</i>

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Order in exercise of powers conferred upon them by sections 57(1) and (2), 58(4) and (5) and 129(4) 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 and commencement

1. This Order may be cited as the Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 and shall come into force on 8th May 2009.

Amendment of article 1 of the Prescription Only Medicines (Human Use) Order 1997

2. In article 1 of the Prescription Only Medicines (Human Use) Order 1997 (citation, commencement and interpretation)(d), in paragraph (2), in the definition of “Health Authority”, delete sub-paragraph (a).

Amendment of article 8 of the Prescription Only Medicines (Human Use) Order 1997

3. Article 8 of the Prescription Only Medicines (Human Use) Order 1997 (exemptions for emergency sale or supply)(e) is amended as follows—

-
- (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 57(1) of that Act was amended by S.I. 2006/2407; section 58(4) and (5) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 1, and the Health and Social Care Act 2001 (c.15), section 63, and by S.I.2002/253 and 2006/2407.
- (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) The expression “the appropriate committee”, referred to in section 58(6) of the Act, is defined in section 4(6) of the Act, as amended by S.I. 2005/1094.
- (d) S.I.1997/1830; the definition of “health authority” was inserted into article 1(2) by S.I.2000/1917.
- (e) Relevant amending instruments are S.I.1998/2081, 2002/549, 2003/696, 2006/915 and 2008/1161.

- (a) in paragraph (2), after “optometrist independent prescriber” in each place in which those words appear, insert “, dentist”;
- (b) in paragraph (4)(a)—
 - (i) before “that the pharmacist”, insert “subject to paragraph (6)”; and
 - (ii) in sub-paragraph (ii), after “optometrist independent prescriber” insert the word “, dentist”;
- (c) in paragraph (4)(b), after “5 days’ treatment” insert “in the case of a controlled drug or 30 days in any other case”; and
- (d) after paragraph (5) insert the following paragraph—

“(6) Paragraph (4)(a) does not apply in relation to the sale or supply of a prescription only medicine where—

 - (a) the sale or supply is made—
 - (i) whilst a disease is, or
 - (ii) in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health; and
 - (b) the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has satisfied himself—
 - (i) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber or pharmacist independent prescriber for the person to be treated with it; and
 - (ii) as to the dose which in the circumstances it would be appropriate for that person to take.”.

Insertion of article 12F into the Prescription Only Medicines (Human Use) Order 1997

4. After article 12E of the Prescription Only Medicines (Human Use) Order 1997 (exemption for health professionals who supply or administer prescription only medicines 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)(a) insert the following article—

“Exemption for the supply of prescription only medicines in the event or anticipation of pandemic disease

12F. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by an individual where that supply is—

- (a) made—
 - (i) whilst a disease is, or
 - (ii) in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health; and
- (b) in accordance with a protocol which—
 - (i) is approved by—
 - (aa) the Ministers;
 - (bb) an NHS body (within the meaning of article 7A(4)(b)); or

(a) Article 12E was inserted by S.I.2003/696.
 (b) Article 7A was inserted by S.I.2004/2693.

- (cc) the Health Protection Agency established under section 1 of the Health Protection Agency Act 2004^(a); and
- (ii) contains criteria as to—
 - (aa) symptoms of, and treatment for, that disease;
 - (bb) the recording of the name of the person who supplies the prescription only medicine to the person to be treated (or to a person acting on that person’s behalf) and of the evidence that the medicine was supplied to the person to be treated (or to a person acting on that person’s behalf).”.

Insertion of article 8 in the Medicines (Pharmacy and General Sale—Exemption) Order 1980

5. After article 7 of the Medicines (Pharmacy and General Sale-Exemption) Order 1980 (exemption for foods and cosmetics)^(b) insert the following article—

“Exemption for the supply of medicines in the event, or anticipation, of pandemic disease

8. The restrictions imposed by sections 52 and 53 (sale or supply of medicinal products) shall not apply to the supply of a medicinal product by a person where that supply is—

- (a) made—
 - (i) whilst a disease is, or
 - (ii) in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health; and
- (b) in accordance with a protocol which—
 - (i) is approved by—
 - (aa) the Ministers;
 - (bb) an NHS body (within the meaning of article 7A(4) of the Prescription Only Medicines (Human Use) Order 1997); or
 - (cc) the Health Protection Agency established under section 1 of the Health Protection Agency Act 2004; and
 - (ii) contains criteria as to—
 - (aa) symptoms of, and treatment for, that disease;
 - (bb) the recording of the name of the person who supplies the prescription only medicine to the person to be treated (or to a person acting on that person’s behalf) and of the evidence that the medicine was supplied to the person to be treated (or to a person acting on that person’s behalf).”.

Signed by authority of the Secretary of State for Health.

6th May 2009

Dawn Primarolo
Minister of State,
Department of Health

6th May 2009

Michael McGimpsey
Minister for Health, Social Services and Public Safety

(a) 2004 c.17.
(b) S.I.1980/1924.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes amendments to—

- (a) 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 only by or in accordance with the directions of such a practitioner; and
- (b) 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 or supply of medicinal products).

Article 2 amends the POM order to remove an obsolete definition.

Article 3 amends the POM Order to enable a pharmacist to make an emergency sale or supply of a prescription only medicine at the request of a dentist who is unable to furnish a prescription immediately and to make an emergency sale or supply of a quantity of a prescription only medicine, except in the case of certain controlled drugs, sufficient to provide up to 30 days’ treatment to a person requesting the pharmacist to supply in the absence of a prescription from certain appropriate practitioners. It also amends the POM Order so that in the event of, or anticipation of, a pandemic disease which poses a serious threat to human health, a pharmacist need only satisfy himself that the person who is to be treated with a prescription only medicine has been prescribed that medicine before and that the dosage of that medicine is appropriate for that person.

Articles 4 and 5 amend the POM Order and Pharmacy and General Sale Order respectively to provide for the supply of a medicinal product during a pandemic in accordance with a protocol approved by the Secretary of State and Minister for Health, Social Services and Public Safety, or by an NHS body for the purpose of treating a pandemic disease which is a serious risk to human health or potentially a serious risk to human health.

An Impact Assessment has been prepared in respect of this Order which is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

© Crown copyright 2009

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty’s Stationery Office and Queen’s Printer of Acts of Parliament.

£4.00