

**2007 No. 2178**

**MEDICINES**

**The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007**

<i>Made</i> - - - -	<i>24th July 2007</i>
<i>Laid before Parliament</i>	<i>26th July 2007</i>
<i>Coming into force</i> - -	<i>1st September 2007</i>

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Order in the 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 and now vested in him(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 for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 and shall come into force on 1st September 2007.

(2) In this Order—

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

“the Pharmacy and General Sale Order” means the Medicines (Pharmacy and General Sale—Exemption) Order 1980(e).

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- (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 article 2(2) of, and Schedule 1 to, S.I. 1969/388, paragraph 1(1) of the Schedule to S.I. 1999/3142 and paragraph 2 of Part 1 of Schedule 8 to S.I. 2006/2407; section 57(1) of that Act was amended by paragraph 28(a) of Part 1 of Schedule 8 to S.I. 2006/2407; section 58 of that Act was amended by section 1 of the Prescription by Nurses etc. Act 1992 (c.28), by section 63 of the Health and Social Care Act 2001 (c.15), by paragraph 2 of Schedule 5 to S.I. 2002/253, by paragraph 6 of Part 1 of Schedule 1 to S.I. 20003/1590, by paragraph 10 of Schedule 1 to S.I. 2005/1094 and by paragraph 29 of Part 1 of Schedule 8 to S.I. 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 is 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; relevant amending instruments are S.I. 2000/1917 and 2899, 2003/696 and 2915.
- (e) S.I. 1980/1924; relevant amending instruments are S.I. 2000/1919 and 2003/697.

## **Amendment of article 1 of the POM Order**

2.—(1) Article 1 of the POM Order (citation, commencement and interpretation) is amended as follows.

(2) In paragraph (2)—

- (a) in the definition of “independent clinic”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b) insert—
    - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(a);”;
- (b) in the definition of “independent hospital”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b) insert—
    - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (c) in the definition of “independent medical agency”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b) insert—
    - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (d) in the definition of “nursing home”, for the words from “article 16” to the end of the paragraph substitute “article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003”;
- (e) in the definition of “Patient Group Direction”—
  - (i) in paragraph (a)—
    - (aa) after “with the” insert “sale or”, and
    - (bb) for “supply and administration” substitute “sale or supply, and administration,”, and
  - (ii) in sub-paragraph (ii), after “relates to” insert “sale or”;
- (f) in the definition of “registered provider”—
  - (i) in paragraph (a), after sub-paragraph (ii) insert—
    - “(iii) in relation to Northern Ireland, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment or agency, and”, and
  - (ii) for paragraph (b), substitute—
    - “(b) in relation to a nursing home, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment;”;
- (g) in the definition of “relevant manager”—
  - (i) in paragraph (a), after sub-paragraph (ii) insert—
    - “(iii) in relation to Northern Ireland—

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(a) S.I. 2003/431 (N.I.9).

- (aa) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 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, and”, and

(ii) for paragraph (b), substitute—

“(b) in relation to a nursing home—

- (i) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
- (ii) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person;”.

(3) In paragraph (8)—

- (a) after “arrangement for the” insert “sale,;” and
- (b) after “such” insert “sale,.”.

#### **Amendment of article 12C of the POM Order**

3. In article 12C of the POM Order (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a patient group direction)—

(a) in paragraph (1)—

- (i) after “apply to the” insert “sale or”,
- (ii) for sub-paragraph (a) substitute the following paragraph—

“(a) the medicine—

- (i) is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—
  - (aa) a body referred to in article 12A(a) to (d),
  - (bb) a force or service referred to in article 12E(1)(a)(i) to (iii), or
  - (cc) Her Majesty’s Forces,
 for the supply or, as the case may be, the administration of prescription only medicines; or
- (ii) is sold or supplied or, as the case may be, is administered by such a person pursuant to an arrangement made with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1) for the sale or supply or, as the case may be, the administration of prescription only medicines;”, and

(iii) in sub-paragraph (b), after “medicine is” insert “sold or”; and

(b) in paragraph (2)—

- (i) in sub-paragraph (a)—
  - (aa) after “relates to the” insert “sale or”,
  - (bb) after “who” insert “sells or”, and
  - (cc) after “medicine is” insert “sold or”, and
- (ii) in sub-paragraph (d), after “medicine is” insert “sold or”.

#### **Amendment of article 12D of the POM Order**

4. In article 12D of the POM Order (exemption for the supply and administration of prescription only medicines in independent hospitals, clinics and agencies)—

- (a) in paragraph (1)—
  - (i) after “apply to the” insert “sale or”,
  - (ii) for sub-paragraphs (a) and (b) substitute—
    - “(a) an independent hospital,
    - (b) an independent clinic,
    - (c) an independent medical agency, or
    - (d) in Northern Ireland, a nursing home,” and
  - (iii) after “medicine is” insert “sold or”; and
- (b) in paragraph (2)—
  - (i) in sub-paragraph (a)—
    - (aa) after “relates to the” insert “sale or”,
    - (bb) after “who” insert “sells or”, and
    - (cc) after “medicine is” insert “sold or”,
  - (ii) in sub-paragraph (d)—
    - (aa) after “the individual who” insert “sells or” and
    - (bb) after “purpose of the” insert “sale or”, and
  - (iii) in sub-paragraph (e), after “medicine is” insert “sold or”.

#### **Amendment of Schedule 7 to the POM Order**

5. In Schedule 7 to the POM Order, in Part 1 (particulars to be included in a patient group direction), in paragraph (c), after “may be” insert “sold or”.

#### **Amendment of article 1 of the Pharmacy and General Sale Order**

6. In article 1 of the Pharmacy and General Sale Order (citation, commencement and interpretation), in paragraph (2), in sub-paragraph (a)—

- (a) in the definition of “independent clinic”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b), insert—
    - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (b) in the definition of “independent hospital”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b) insert—
    - “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (c) in the definition of “independent medical agency”—
  - (i) in paragraph (b), for “2001;” substitute “2001, and”, and
  - (ii) after paragraph (b) insert—

- “(c) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;”;
- (d) in the definition of “nursing home”, for the words from “article 16” to the end of the paragraph substitute “article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003”;
- (e) in the definition of “Patient Group Direction”—
  - (i) for “supply and administration” substitute “sale or supply, and administration,”, and
  - (ii) in paragraph (b), after “relates to” insert “sale or”;
- (f) in the definition of “registered provider”—
  - (i) in paragraph (a), after sub-paragraph (ii) insert—
    - “(iii) in relation to Northern Ireland, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment or agency, and”, and
  - (ii) for paragraph (b), substitute—
    - “(b) in relation to a nursing home, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment;”;
- (g) in the definition of “relevant manager”—
  - (i) in paragraph (a), after sub-paragraph (ii) insert—
    - “(iii) in relation to Northern Ireland—
      - (aa) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 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, and”
  - (ii) for paragraph (b), substitute—
    - “(b) in relation to a nursing home—
      - (i) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
      - (ii) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person;”.

#### **Amendment of article 4C of the Pharmacy and General Sale Order**

7. In article 4C of the Pharmacy and General Sale Order (exemption for the supply of medicinal products by independent hospitals, clinics and agencies)—

- (a) in the heading, after “the” insert “sale or”;
- (b) in paragraph (1)—
  - (i) after “apply to the” insert “sale or”,
  - (ii) for sub-paragraphs (a) and (b) substitute—
    - “(a) an independent hospital,
    - (b) an independent clinic,
    - (c) an independent medical agency, or

- (d) in Northern Ireland, a nursing home,” and
- (iii) after “product is” insert “sold or”; and
- (c) in paragraph (2)—
  - (i) in sub-paragraph (a)—
    - (aa) after “relates to the” insert “sale or”,
    - (bb) after “medicinal product is” insert “sold or”, and
    - (cc) after “the product is” insert “sold or”,
  - (ii) in sub-paragraph (d)—
    - (aa) after “the individual who” insert “sells or”, and
    - (bb) after “purpose of the” insert “sale or”, and
  - (iii) in sub-paragraph (e), after “product is” insert “sold or”.

**Amendment of Schedule 3 to the Pharmacy and General Sale Order**

**8.** In Schedule 3 to the Pharmacy and General Sale Order, in Part 1 (particulars to be included in a patient group direction), in paragraph (d), after “may be” insert “sold or”.

Signed by authority of the Secretary of State for Health

24th July 2007

*Dawn Primarolo*  
Minister of State  
Department of Health

24th July 2007

*Andrew McCormick*  
Permanent Secretary  
Department of Health, Social Services and Public Safety

## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order makes further amendments to certain Orders relating to the administration and sale or supply of medicines for human use.

Articles 2 to 5 amend 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. Article 12D of the POM Order provides an exemption for the supply (otherwise than by retail sale) and administration of prescription only medicines by designated health professionals in the course of the business of an independent hospital, clinic or agency in accordance with a Patient Group Direction. Article 12C of the POM Order makes provision for a person conducting a retail pharmacy business to supply (otherwise than by retail sale) or administer prescription only medicines under an arrangement with specified bodies, including those specified under article 12D.

Articles 2 and 4 of this Order extend the exemption to include independent hospitals, clinics and agencies in Northern Ireland. Articles 2 to 5 of this Order also extend the exemptions to cover the retail sale of medicinal products in accordance with a Patient Group Direction, by, or under arrangements made by a retail pharmacy with, an independent hospital, clinic or agency.

Articles 6 to 8 amend the Medicines (Pharmacy and General Sale—Exemption) Order 1980 (“the Pharmacy and General Sale Order”) which provides exemptions from sections 52 and 53 of the Medicines Act 1968 (restrictions on sale or supply of medicinal products). Article 4C of the Pharmacy and General Sale Order makes provision for a person conducting a retail pharmacy business to supply, otherwise than by retail sale, prescription only medicines under an arrangement with specified bodies, including independent hospitals, clinics and nursing homes. Articles 6 and 7 of this Order amend articles 1 and 4C to extend the exemption to include independent hospitals, clinics and medical agencies in Northern Ireland. Articles 6 to 8 also make provision for the retail sale of medicinal products in accordance with a Patient Group Direction.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the libraries of both Houses of Parliament.

**2007 No. 2178**

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**The Medicines for Human Use (Administration and Sale or  
Supply) (Miscellaneous Amendments) Order 2007**

**£3.00**

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E1139 7/2007 171139T 19585