

2008 No. 464

MEDICINES

**The Prescription Only Medicines (Human Use) Amendment
Order 2008**

<i>Made</i> - - - -	<i>20th February 2008</i>
<i>Laid before Parliament</i>	<i>29th February 2008</i>
<i>Coming into force</i> - -	<i>1st April 2008</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 58(1), (1A), (4), (4A), (4B) 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 Committee on Safety of Medicines(c) and the Commission on Human Medicines(d).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Amendment Order 2008 and shall come into force on 1st April 2008.

(2) In this Order, “the principal Order” means the Prescription Only Medicines (Human Use) Order 1997(e).

Amendment of article 2 of the principal Order

2. In article 2 of the principal Order (appropriate practitioners)—

- (a) in paragraph (a), after “supplementary prescribers,” add “nurse independent prescribers, pharmacist independent prescribers,”; and

(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 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. 2003/1590, 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.I.).

(c) See paragraph 1 of Part 2 of Schedule 5 to S.I. 2005/2754.

(d) 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.

(e) S.I. 1997/1830; relevant amending instruments are S.I.1998/108, 2000/1917, 2002/549, 2003/696 and 2915, 2004/2, 1189, 1771 and 2693, 2005/765, 1507 and 3324 and 2006/915.

- (b) omit paragraphs (c) and (d).

Amendment of article 3 of the principal Order

3. In article 3 of the principal Order (medicinal products on prescription only), after paragraph (g) insert the following paragraph—

“(h) medicinal products in respect of which a marketing authorization has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all pharmaceutical forms which in the marketing authorization are classified as being pharmacy only medicines”.

Omission of article 3A of the principal Order

4. Article 3A of the principal Order (prescribing and administration by nurse independent prescribers) is omitted.

Amendment of article 3B of the principal Order

5. In article 3B of the principal Order (prescribing and administration by supplementary prescribers)(a), for paragraph (2) substitute the following paragraph—

“(2) Paragraph (1) does not apply if the supplementary prescriber is a community practitioner nurse prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3.”.

Amendment of article 3C of the principal Order

6. In article 3C of the principal Order (exemptions from conditions in respect of the cases or circumstances in which a nurse independent prescriber or supplementary prescriber may administer a medicinal product)(b)—

- (a) in the heading, omit “ nurse independent prescriber or ” ; and
- (b) (i) omit “article 3A(3) and in”, and
- (ii) omit “nurse independent prescriber or”.

Insertion of article 5B in the principal Order

7. After article 5A of the principal Order, insert the following article—

“Exemption for products consisting of or containing pseudoephedrine salts or ephedrine base or salts

5B.—(1) A medicinal product falling within article 3(h) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the conditions in paragraph (2) are satisfied—

(2) The conditions referred to in this paragraph are that—

- (a) the medicinal product sold or supplied to a person must not be sold or supplied at the same time as another medicinal product that consists of or contains—
 - (i) in the case of pseudoephedrine salts, ephedrine base or salts;
 - (ii) in the case of ephedrine base or salts, pseudoephedrine salts; and
- (b) the medicinal product or products sold or supplied to a person at any one time must not in total contain more than—

(a) Article 3B was inserted by S.I. 2003/696 and amended by S.I. 2005/765 and 2006/915.

(b) Article 3C was inserted by S.I. 2003/696 and amended by S.I. 2006/915.

- (i) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts;
- (ii) in the case of ephedrine base or salts, 180mg ephedrine base or salts. ”.

Amendment of article 12 of the principal Order

8. In article 12 of the principal Order (exemption for sale and supply in hospitals)(a), in paragraph (3)—

- (a) omit “a nurse independent prescriber or”; and
- (b) omit “3A or”.

Amendment of article 13A of the principal Order

9. In article 13A of the principal Order (exemptions relating to prescriptions given by certain health professionals)(b), in paragraph (2)—

- (a) omit in both places where it occurs “nurse independent prescriber or”; and
- (b) for “articles 3A(2) and (3) or” substitute “article”.

Omission of Schedule 3A to the principal Order

10. Schedule 3A to the principal Order (controlled drugs which may be prescribed, administered or directed for administration by nurse independent prescribers and conditions for such prescription or administration) is omitted.

Signed by authority of the Secretary of State for Health.

20th February 2008

Dawn Primarolo
Minister of State,
Department of Health

20th February 2008

Michael McGimpsey
Minister of Health, Social Services and Public Safety

(a) Article 12 was substituted by S.I. 2000/1917 and 2004/2 and amended by S.I. 2006/915.

(b) Article 13A was inserted by S.I. 2002/549 and amended by S.I. 2003/696 and 2005/765 and 1507 and 2006/915.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 (“the principal Order”) which specifies the description and classes of medicines (“prescription only medicines”) which, subject to exemptions specified in the Order, 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 2 amends article 2 and articles 4 and 10 omit article 3A of, and Schedule 3A to, the principal Order which provide that nurses and pharmacists who meet certain conditions (“nurse independent prescribers” and “pharmacist independent prescribers”) are able to prescribe and administer prescription only medicines. The amendments allow pharmacist independent prescribers to prescribe and administer medicinal products that are controlled drugs and remove existing limitations on the prescription and administration of controlled drugs by nurse independent prescribers. Articles 5, 6, 8 and 9 make other amendments to the principal Order, as a consequence of these changes.

Article 3 amends article 3 of the principal Order (which specifies classes of medicinal products which are prescription only medicines) to provide that products consisting of or containing pseudoephedrine salts or ephedrine base or salts are prescription only medicines. Article 7 inserts a new article 5B into the principal Order which makes provision for a medicinal product consisting of or containing pseudoephedrine salts or ephedrine base or salts to be exempt from the restrictions on prescription only medicines when sold or supplied to a person at any one time subject to conditions. The conditions are firstly that a product consisting of or containing pseudoephedrine salts is not sold or supplied at the same time as a product consisting of or containing ephedrine base or salts and similarly a product consisting of or containing ephedrine base or salts is not sold or supplied at the same time as a product consisting of or containing pseudoephedrine salts. Secondly, the product or products sold or supplied must not contain in total more than 720mg pseudoephedrine salts in the case of pseudoephedrine salts and 180mg ephedrine base or salts in the case of ephedrine base or salts.

An impact assessment has not been produced for this instrument as there is no significant impact on the private or voluntary sectors.

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