
STATUTORY INSTRUMENTS

1996 No. 3193

MEDICINES

**The Medicines (Products Other Than Veterinary Drugs)
(Prescription Only) Amendment (No. 2) Order 1996**

Made - - - - *18th December 1996*
Laid before Parliament *18th December 1996*
Coming into force - - *13th January 1997*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred on them by sections 58(1) 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 consulting and taking into account the advice of the Medicines Commission pursuant to sections 58(6) and 129(7) of that Act, hereby makes the following Order:

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1996 and shall come into force on 13th January 1997.

(2) In this Order “the principal Order” means the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(3).

Amendment of article 4 of the principal Order

2. In article 4 of the principal Order (medicinal products that are not prescription only)—
- (a) in paragraph (1C) (mebendazole) for “400 milligrams” substitute “800 milligrams”;

(1) 1968 c. 67. The expressions “the appropriate Ministers” and “the Health Ministers” are defined in section 1 of that Act as amended by S.I. 1969/388, Schedule 1.

(2) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Department of Health and Social Services for Northern Ireland by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(3) S.I. 1983/1212, amended by S.I. 1984/756, 1986/586, 1987/674 and 1250, 1988/2017, 1989/1852, 1991/962, 1992/1534 and 2937, 1993/1890 and 3256, 1994/558, 3016 and 3050, 1995/1384 and 3174 and 1996/1514.

- (b) in paragraph (1N) (famotidine) for sub-paragraph (a) there is substituted the following sub-paragraph—
- “(a) the medicinal product is indicated for—
- (i) the short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion or hyperacidity, or
 - (ii) the prevention of the symptoms of heartburn, dyspepsia, indigestion, acid indigestion or hyperacidity where they are associated with the consumption of food or drink, including the prevention of sleep disturbance due to those symptoms, and”.

Amendment of Part I of Schedule 1 to the principal Order

3. In Part I of Schedule 1 to the principal Order (which lists substances which render a medicinal product a prescription only medicine except in the circumstances also listed)—

- (a) in Column 1—
- (i) after the entry “Amygdalin” there is inserted the entry “Amyl Nitrite”,
 - (ii) after the entry “Argipressin” there are inserted the following entries—
 - “Aristolochia
 - Aristolochia Clematitis
 - Aristolochia Contorta
 - Aristolochia Debelis
 - Aristolochia Fang-chi
 - Aristolochia Manshuriensis
 - Aristolochia Serpentaria”,
 - (iii) for the entry “Lodoxamide Trometamol” there is substituted the entry “Lodoxamide Trometamol”,
 - (iv) after the entry “Tolmetin Sodium” there is inserted the entry “Trandolapril”,
 - (v) in the entry for Vaccines, after “Meningococcal Polysaccharide Vaccine” there is inserted “Mumps Vaccine”;
- (b) in Column 3 in relation to Mebeverine Hydrochloride there is inserted the following entry—
- “For the symptomatic relief of irritable bowel syndrome”,
- (c) in Column 4—
- (i) for the entry relating to Mebeverine Hydrochloride there is substituted the following entry—
 - “135mg (MD)
 - 405mg (MDD)”,
 - (ii) in the entry relating to Pseudoephedrine Hydrochloride for “90mg (MD)” there is substituted “120mg (MD)”.

Amendment of Table A of Part IV of Schedule 1 to the principal Order

4. In Table A of Part IV of Schedule 1 to the principal Order (name and product licence number of medicinal products that are not prescription only medicines), the following entries are inserted at the appropriate points in the alphabetical order of the entries in that Table—

“Canesten Hydrocortisone Cream	0010/0216
Herpetad Cold Sore Cream	4986/0007
Jungle Formula Bite & Sting Relief Cream	2855/0010
Soothelip Cold Sore Cream	0142/0426
Timocort Hydrocortisone Cream 1 per cent	0063/0076
Zaclovir Cold Sore Cream	4986/0007”.

Amendment of Schedule 3 to the principal Order

5. In Part I of Schedule 3 to the principal Order (exemptions for certain persons from the provisions of section 58(2)(a) of the Medicines Act 1968) at the end there are inserted the entries set out in the Schedule to this Order.

Signed by authority of the Secretary of State for Health

Department of Health
17th December 1996

Gerald Malone
Minister of State,

Welsh Office
18th December 1996

Gwilym Jones
Parliamentary Under Secretary of State,

The Scottish Office
18th December 1996

James Douglas-Hamilton
Minister of State,

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 17th December 1996.

L.S.

F. A. Elliott
Permanent Secretary

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

THE SCHEDULE

Article 5

ENTRIES INSERTED IN PART I OF SCHEDULE 3 TO THE PRINCIPAL ORDER

<i>Column 1</i> <i>Persons exempted</i>	<i>Column 2</i> <i>Prescription only medicines to which the exemption applies</i>	<i>Column 3</i> <i>Conditions</i>
<p>9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972 or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons) or article 6 (exemptions with respect to certain sales) of the Poisons (Northern Ireland) Order 1976.</p>	<p>9. Amyl nitrite.</p>	<p>9. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.</p>
<p>a 1972 c. 66.</p>		
<p>b S.I.1976/1214 (N.I. 23).</p>		

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 (“the principal Order”) which specifies descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail only in accordance with a prescription given by an appropriate practitioner and which may be administered only by or in accordance with the directions of such a practitioner). Under the principal Order products are included in a class of such medicines by reason of the substances contained in them, subject to their being excluded in specified circumstances.

The amendments made by this Order are as follows—

- amendments to the exclusions for certain products containing mebendazole or famotidine (article 2);
- the inclusion of products containing mumps vaccine, trandolapril or various forms of the substance aristolochia (article 3);
- the inclusion of products containing amyl nitrite subject to an exemption where it is sold or supplied as an antidote for cyanide poisoning (articles 3 and 5 and the Schedule);

the substitution of the British Approved Name lodoxamide trometamol for that in an existing entry (article 3);

amendments to the conditions under which medicines containing Mebeverine Hydrochloride or Pseudoephedrine Hydrochloride may be sold or supplied otherwise than as prescription only medicines (article 3);

the exclusion of the products listed in article 4.