

1989 No. 1852

MEDICINES

**The Medicines (Prescription Only, Pharmacy and
General Sale) Amendment Order 1989**

Made - - - - - *9th October 1989*

Laid before Parliament *11th October 1989*

Coming into force *1st November 1989*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 1, 57(1) and (2), 58(1), (4)(a) and (5), 129(4) and 132(1) of the Medicines Act 1968(a) and now vested in them(b), and of all other powers enabling them in that behalf, after consulting in accordance with section 129(6) of that Act such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, after consulting the Medicines Commission in accordance with section 58(6) of that Act so far as this Order is made under section 58 of that Act and after taking into account the advice of the Medicines Commission in accordance with section 129(7) of that Act, hereby make the following Order:-

Citation, commencement and interpretation

1.—(1) This Order, which may be cited as the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989, shall come into force on 1st November 1989.

(2) In this Order-

“the Pharmacy and General Sale Exemption Order” means the Medicines (Pharmacy and General Sale-Exemption) Order 1980(c);

“the Prescription Only Medicines Order” means the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(d);

Amendment of article 1 of the Prescription Only Medicines Order

2. In article 1(2)(a) of the Prescription Only Medicines Order (interpretation), the following definition is inserted after the definition of “occupational health scheme”:-

(a) 1968 c.67; see the meaning assigned to “the appropriate Ministers” by sections 1 and 132(1).

(b) 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 Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments 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).

(c) S.I. 1980/1924, as amended by S.I. 1982/27.

(d) S.I. 1983/1212, as amended by S.I. 1984/756, 1986/586, 1987/674, 1250 and 1988/2017.

““offshore installation” means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(a) which is within–

- (a) tidal waters and parts of the sea in or adjacent to Great Britain up to the seaward limit of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(b);”.

Amendment of article 4 of the Prescription Only Medicines Order

3. In article 4 of the Prescription Only Medicines Order (medicinal products that are not prescription only), the following paragraph is inserted after paragraph (1B):–

“(1C) Notwithstanding Article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason of the fact that it consists of or contains the substance mebendazole where it is sold or supplied in a container or package containing only a single dose of not more than 100 mg of mebendazole for oral use and for the treatment of enterobiasis.”.

Amendment of Part 1 of Schedule 1 to the Prescription Only Medicines Order

4. In Part I of Schedule 1 to the Prescription Only Medicines Order (which lists substances which render a medicinal product a prescription only medicine except in circumstances also listed)–

- (a) the following substances are inserted at the appropriate points in the alphabetical order of the substances listed in Column 1–

Acipimox
Aztreonam
Bentiromide
Bisoprolol Fumarate
Buserelin Acetate
Carboplatin
Carteolol Hydrochloride
Ceftriaxone Sodium
Ceruletide Diethylamine
Doxazosin Mesylate
Enoximone
Famotidine
Felodipine
Fenofibrate
Flumazenil
Fluorescein Dilaurate
Fluoxetine Hydrochloride
Ganciclovir
Gestodene
Goserelin Acetate
Lisinopril
Lofexidine Hydrochloride
Lysuride Maleate
Meglumine Gadopentetate
Meglumine Iothalamate
Metipranolol
Misoprostol
Naltrexone Hydrochloride
Nimodipine
Nizatidine
Oxidronate Sodium
Somatropin
Sulbencillin
Sultamicillin Tosylate

(a) 1971 c.61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c.23).

(b) 1964 c.29.

Tenoxicam
Terazosin Hydrochloride
Xamoterol Fumarate;

- (b) for the entries relating to the substances Dextromethorphan Hydrobromide and Ibuprofen respectively there are substituted the entries relating respectively to those substances set out in Schedule 1 to this Order.

Amendment of Table A of Part IV of Schedule 1 to the Prescription Only Medicines Order

5. In Table A of Part IV of Schedule 1 to the Prescription Only Medicines Order (medicinal products specified by name and product licence number which are not prescription only medicines), the following entries are deleted:—

Femafen
0188/0071;
Oriol Capsules
0073/0023;
Proflex Sustained Relief Capsules
0001/0109; and
Suspren
0188/0072.

Amendment of Schedule 3 to the Prescription Only Medicines Order

6. In Schedule 3 to the Prescription Only Medicines Order (exemptions for certain persons from the provisions of section 58(2) of the Medicines Act 1968)—

- (a) in paragraph 5 in Column 2 of Part I, the following sub-paragraphs are substituted for sub-paragraph (a)—

“(a) are eye drops and are prescription only medicines by reason only that they contain not more than—

- (i) 30.0 per cent Sulphacetamide Sodium, or
(ii) 0.5 per cent Chloramphenicol, or

(aa) are eye ointments and are prescription only medicines by reason only that they contain not more than—

- (i) 30.0 per cent Sulphacetamide Sodium, or
(ii) 1.0 per cent Chloramphenicol, or”;

- (b) at the end of Part II there is inserted the paragraph set out in Part I of Schedule 2 to this Order; and
(c) at the end of Part III there is inserted the paragraph set out in Part II of Schedule 2 to this Order.

Amendment of article 1 of the Pharmacy and General Sale Exemption Order

7. In article 1(2)(a) of the Pharmacy and General Sale Exemption Order (interpretation), the following definition is inserted after the definition of “occupational health scheme”:-

““offshore installation” means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(a) which is within—

- (a) tidal waters and parts of the sea in or adjacent to Great Britain up to the seaward limit of territorial waters;
(b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(b);”.

Amendment of Schedule 1 to the Pharmacy and General Sale Exemption Order

8. In Schedule 1 to the Pharmacy and General Sale Exemption Order (exemptions for certain persons from the provisions of sections 52 and 53 of the Medicines Act 1968)—

(a) 1971 c.61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c.23).
(b) 1964 c.29.

- (a) in paragraph 2 in Column 2 of Part I, the following sub-paragraphs are substituted for sub-paragraph (a)-
- “ (a) are eye drops and are prescription only medicines by reason only that they contain not more than-
 - (i) 30.0 per cent Sulphacetamide Sodium, or
 - (ii) 0.5 per cent Chloramphenicol, or
 - (aa) are eye ointments and are prescription only medicines by reason only that they contain not more than-
 - (i) 30.0 per cent Sulphacetamide Sodium, or
 - (ii) 1.0 per cent Chloramphenicol, or”;
- (b) at the end of Part II there is inserted the paragraph set out in Schedule 3 to this Order.

Signed by authority of the Secretary of State for Health

9th October 1989 *D. Mellor*
Minister of State, Department of Health

4th October 1989 *Peter Walker*
Secretary of State for Wales

9th October 1989 *Malcolm Rifkind*
Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th October 1989.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this fifth day of October 1989.

F. A. Elliott
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 6th day of October 1989.

W. J. Hodges
Permanent Secretary

SCHEDULE 1

Article 4(b)

ENTRIES SUBSTITUTED IN PART I OF SCHEDULE 1 TO THE PRESCRIPTION ONLY MEDICINES ORDER

CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES

Column 1	Column 2	Column 3	Column 4
<i>Substances</i>	<i>Maximum strength</i>	<i>Use, pharmaceutical form or route of administration</i>	<i>Maximum dose and maximum daily dose</i>
Dextromethorphan Hydrobromide		Internal	<p>(a) In the case of a controlled release preparation: equivalent of 30 mg of Dextromethorphan (MD), equivalent of 75 mg of Dextromethorphan (MDD);</p> <p>(b) in any other case: equivalent of 15 mg of Dextromethorphan (MD), equivalent of 75 mg of Dextromethorphan (MDD).</p>
Ibuprofen		<p>Rheumatic and muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of cold and influenza:</p> <p>(1) Internal</p>	<p>(1) (a) In the case of a controlled release preparation: 600 mg (MD), 1200 mg (MDD);</p> <p>(b) in any other case: 400 mg (MD), 1200 mg (MDD).</p>
	(2) 5.0 per cent.	(2) External	

SCHEDULE 2

PARAGRAPHS INSERTED IN SCHEDULE 3 TO THE PRESCRIPTION ONLY MEDICINES ORDER

PART I

Article 6(b)

PARAGRAPH INSERTED IN PART II OF SCHEDULE 3 TO THE PRESCRIPTION ONLY MEDICINES ORDER

Column 1	Column 2	Column 3
<i>Persons exempted</i>	<i>Prescription only medicines to which the exemption applies</i>	<i>Conditions</i>
7. Persons employed as qualified first-aid personnel on offshore installations.	7. All prescription only medicines.	7. The supply shall be only so far as is necessary for the treatment of persons on the installation.

PART II

Article 6(c)

PARAGRAPH INSERTED IN PART III OF SCHEDULE 3 TO THE PRESCRIPTION ONLY MEDICINES ORDER

Column 1	Column 2	Column 3
<i>Persons exempted</i>	<i>Prescription only medicines to which the exemption applies</i>	<i>Conditions</i>
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescription only medicines that are for parenteral administration.	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.

SCHEDULE 3

Article 8(b)

PARAGRAPH INSERTED IN PART II OF SCHEDULE 1 TO THE PHARMACY AND GENERAL SALE EXEMPTION ORDER

Column 1	Column 2	Column 3
<i>Persons exempted</i>	<i>Medicinal products to which the exemption applies</i>	<i>Conditions</i>
13. Persons employed as qualified first-aid personnel on offshore installations.	13. All medicinal products.	13. The supply shall be only so far as is necessary for the treatment of persons on the installation.

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 POM Order) which specifies descriptions and classes of prescription only medicines subject to section 58(2) of the Medicines Act 1968, that is to say, 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 direction of such a practitioner.

The Order also further amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 (the Pharmacy and General Sale Exemption Order) which specifies exemptions from the general requirements as to retail sale or supply set out in sections 52 and 53 of the Medicines Act 1968.

The amendments made by this Order are as follows:—

—Articles 2 and 6(b) and (c) and Schedule 2 amend the POM Order to provide an exemption from the provisions of section 58(2) in respect of qualified first-aid personnel on “offshore installations” (such as oil rigs). Articles 7 and 8(b) and Schedule 3 make comparable exemptions for such persons from the provisions of sections 52 and 53.

—Article 3 amends article 4 of the POM Order which specifies exemptions from the provisions of section 58(2) so as to exempt certain products containing the substance mebendazole from being prescription only medicines.

—Article 4 amends Part I of Schedule I to the POM Order which lists substances which render medicinal products prescription only medicines except in circumstances also listed.

—Article 5 deletes entries from Part IV of the POM Order which lists the name and product licence number of medicinal products that are not prescription only medicines.

—Article 6(a) amends the list of prescription only medicines in Part I of Schedule 3 to the POM Order which a person lawfully conducting a retail pharmacy business may sell or supply to the order of a registered ophthalmic optician. Article 8(a) makes a comparable amendment to the Pharmacy and General Sale Exemption Order to the list of medicinal products which a registered ophthalmic optician may sell or supply on his own behalf.