
STATUTORY INSTRUMENTS

1992 No. 1534

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1992

| | | |
|-------------------------------|---------|-----------------------|
| <i>Made</i> | - - - - | <i>29th June 1992</i> |
| <i>Laid before Parliament</i> | | <i>29th June 1992</i> |
| <i>Coming into force</i> | - - | <i>20th July 1992</i> |

The Secretary of State concerned with health in England, the Secretaries of State respectively 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 the powers conferred upon them by sections 1(2), 58(1), 129(4) and 132(1) 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 make the following Order:—

Citation, commencement and interpretation

1.—(1) This Order, which may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1992, shall come into force on 20th July 1992.

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

Amendment of article 3 of the principal Order

2. In article 3(1)(a) of the principal Order (medicinal products on prescription only), for the words “and (1D)” there are substituted the words “, (1D) and (1E),”.

-
- (1) 1968 c. 67; see the meaning assigned to “the appropriate Ministers” by sections 1(2) and 132(1) and to “the Ministers” by section 1(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 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).
- (3) S.I. 1983/1212, as amended by S.I. 1984/756, 1986/586, 1987/674 and 1250, 1988/2017, 1989/1852 and 1991/962.

Amendment of article 4 of the principal Order

3. In article 4 of the principal Order (medicinal products that are not prescription only), the following paragraph is inserted after paragraph (1D):—

“(1E) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it consists of or contains the substance carbenoxolone sodium where—

- (a) it is in the form of granules;
- (b) its maximum strength does not exceed one per cent calculated in terms of weight in weight;
- (c) it is sold or supplied in a container or package containing not more than 560mg;
- (d) its container or package is labelled to show a maximum daily dose of 80mg and a maximum dose of 20mg; and
- (e) it is indicated only for treatment, by mouthwash, in adults and in children over the age of 12 years.”.

Amendment of Part I of Schedule 1 to the principal Order

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

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

Cisapride
Clozapine
Dopexamine Hydrochloride
Doxorubicin Hydrochloride
Esmolol Hydrochloride
Felbinac
Fluconazole
Foscarnet Sodium
Idarubicin Hydrochloride
Itraconazole
Mefloquine Hydrochloride
Mesna
Milrinone
Noscapine
Noscapine Hydrochloride
Olsalazine Sodium
Omeprazole
Podophyllotoxin
Propafenone
Ramipril
Simvastatin
Sulfametopyrazine

- (b) in the entry in Column 3 relating to “Clotrimazole” for the words “External: (1) cream (2) powder (3) solution” there are substituted the words “External, but in the case of vaginal use only external use for the treatment of vaginal candidiasis”; and
- (c) in the entries in Column 3 relating to “Econazole”, “Econazole Nitrate”, “Isoconazole Nitrate”, “Miconazole” and “Miconazole Nitrate” for the words “External (except vaginal use)” there are substituted the words “External, but in the case of vaginal use only external use for the treatment of vaginal candidiasis”.

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

5. In Table A of Part IV of Schedule 1 to the principal Order (medicinal products specified by name and product licence number which are not prescription only medicines) immediately after the entry “Efcortelan P Ointment 1° 0004/0326” the following entry is inserted—

“Eurax HC Cream 0001/5010R”.

Signed by authority of the Secretary of State for Health

29th June 1992

Brian Mawhinney
Minister,
Department of Health

29th June 1992

David Hunt
Secretary of State for Wales

29th June 1992

Fraser of Carmyllie
Minister, Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

29th June 1992.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

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

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this

L.S.

29th day of June 1992.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

L.S.

29th day of June 1992.

W. J. Hodges
Permanent Secretary

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 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 directions of such a practitioner.

The amendments made by this Order are as follows:—

Article 2 amends article 3 of the principal Order consequentially on the changes made to article 4 of the principal Order.

Article 3 amends article 4 of the principal Order so as to exempt certain products containing Carbenoxolone Sodium 1% from being prescription only medicines.

Article 4 amends Part I of Schedule 1 to the principal Order which lists substances which render medicinal products prescription only medicines except in circumstances also listed.

Article 5 adds an entry to Part IV of Schedule 1 to the principal Order which lists specific medicinal products which are not prescription only medicines.