

STATUTORY INSTRUMENTS

1985 No. 1540

MEDICINES

**The Medicines (Products Other Than Veterinary Drugs)
(General Sale List) Amendment Order 1985**

Made - - - - - 3rd October 1985
Coming into Operation 1st November 1985

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 powers conferred by sections 51 and 129(4) of the Medicines Act 1968 (a) and now vested in them (b) 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 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 (Products Other Than Veterinary Drugs) (General Sale List) Amendment Order 1985, amends the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 (c) (hereinafter referred to as “the principal order”) and shall come into operation on 1st November 1985.

(2) In this order, unless the context otherwise requires, a reference to adding an entry to a column in a Table in a Schedule to the principal order shall be construed as a reference to inserting that entry at the appropriate point in the alphabetical order of the entries in column 1 of that Table.

Amendment of Article 1 of the principal order

2. In Article 1(2)(a) of the principal order (interpretation) there are inserted—

(a) immediately after the definition of “the Act” the following definition:—

(a) 1968 c.67.

(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) and 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. 1984/769.

““aspirin equivalent” means, in relation to a quantity of aloxiprin, the quantity of aspirin which is equal in weight to 81.25 per cent of that quantity of aloxiprin;”

- (b) immediately after the definition of “dosage unit” the following definition:—

““enema” means a preparation to be administered into the rectum as an aqueous or oily solution or suspension;”

- (c) immediately after the definition of “food” the following definition:—

““irrigation” means to bathe by means of the application of a fluid in a continuous stream;”.

Amendment of Schedule 1 to the principal order

3.—(1) Schedule 1 to the principal order (which specifies the class of medicinal products, other than products the subject of a product licence of right, on general sale by virtue of Article 2(a) of the principal order) is amended in accordance with the following paragraphs of this article.

(2) In Table A (internal or external use) there are added to column 1 and, as the case may be, columns 2 and 3, those entries set out in columns 1, 2 and 3 respectively in Part I of Schedule 1 to this order.

(3) In Table B (external use only) there are added to column 1 and, as the case may be, columns 2 and 3, those entries set out in columns 1, 2 and 3 respectively in Part II of Schedule 1 to this order.

Amendment of Schedule 2 to the principal order

4.—(1) Schedule 2 to the principal order (which specifies the class of medicinal products, the subject of a product licence of right, on general sale by virtue of Article 2(b) of the principal order) is amended in accordance with the following paragraph of this article.

(2) In Table A (internal or external use)—

- (a) there is added to column 1 the entry “Alexitol Sodium”,
(b) there are deleted from column 1 the entries “Pennyroyal” and “Sodium Polyhydroxyaluminium Monocarbonate Hexitol Complex”, and
(c) there are deleted from column 1 the entry “Salicylamide” and from columns 3 and 4 the entries relating to Salicylamide.

Amendment of Schedule 3 to the principal order

5. In Schedule 3 to the principal order (which specifies classes of medicinal products which are not on the general sale list) the word “or”, occurring in paragraph (c), is deleted and after paragraph (d) there are added the following paragraphs—

- “(e) for use as enemas, or
(f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum.”.

Signed by authority of the Secretary of State for Social Services.

R. W. Whitney,
Parliamentary Under-Secretary of State,
Department of Health and Social Security.

18th September 1985.

Signed with the authority of the Secretary of State for Wales

Wyn Roberts,
Parliamentary Under-Secretary of State for
Wales.

23rd September 1985.

George Younger,
Secretary of State for Scotland.

3rd October 1985.

In witness whereof the official seal of the Minister of Agriculture, Fisheries
and Food is hereunto affixed on 22nd September 1985.



Michael Jopling,
Minister of Agriculture, Fisheries
and Food.

Sealed with the official seal of the Department of Health and Social Services
for Northern Ireland this 12th day of September 1985.



Maurice N. Hayes,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern
Ireland this 12th day of September 1985.



W. H. Jack,
Permanent Secretary.

SCHEDULE 1

Article 3

PART I

ENTRIES ADDED TO TABLE A IN SCHEDULE 1 TO THE PRINCIPAL ORDER
(INTERNAL OR EXTERNAL USE)

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|--------------------------------------|---|-------------------------------------|
| Substance | Maximum strength | Use, pharmaceutical form or route of administration | Maximum dose and maximum daily dose |
| Celery Oil Charcoal, Medicinal Dichloroxylenol | (1) 0.5 per cent (2) 5.0 per cent | (1) Internal (2) External | |

PART II

ENTRIES ADDED TO TABLE B IN SCHEDULE 1 TO THE PRINCIPAL ORDER
(EXTERNAL USE ONLY)

| Column 1 | Column 2 | Column 3 |
|---|------------------|---|
| Substance | Maximum strength | Use, pharmaceutical form or route of administration |
| Alum Aluminium Sulphate Amber Oil Disodium Edetate Eugenol Formaldehyde Solution Octaphonium Chloride Oleic Acid | 1.3 per cent | Dentifrice |

EXPLANATORY NOTE

(This Note is not part of the Order.)

This order amends the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 (referred to as “the principal order”) which specifies classes of medicinal products which can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist (the general sale list) and classes of such products which can with reasonable safety be sold by means of automatic machines (the automatic machines section of the general sale list).

The amendments made by this order are as follows:

Article 2 adds a definition of the expression “aspirin equivalent” which occurs in a reference to the substance Aloxiprin in Table A in Schedules 1 and 2 to the principal order. This article also adds definitions of the expressions “enema” and “irrigation” which occur by virtue of the amendments made by this order to Schedule 3.

Article 3 adds certain substances to Tables A and B in Schedule 1 to the principal order (which lists substances used in medicinal products other than products the subject of a product licence of right, on general sale).

Article 4 deletes certain substances from Table A in Schedule 2 to the principal order (which lists substances used in medicinal products, the subject of a product licence of right, on general sale).

Article 4 also deletes the entry in Table A in Schedule 2 to the principal order relating to the substance listed as Sodium Polyhydroxyaluminium Monocarbonate Hexitol Complex and adds an entry in that Table for Alexitol Sodium, which is the British Approved Name for that substance, used in the list of names prepared in accordance with section 100 of the Medicines Act 1968.

Article 5, by amendments to Schedule 3 to the principal order, excludes from the general sale list and the automatic machines section of the general sale list medicinal products which are promoted, recommended or marketed for use as enemas or for the irrigation of wounds or the irrigation of the bladder, vagina or rectum.

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