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STATUTORY INSTRUMENTS

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**1999 No. 2535**

**MEDICINES**

**The Medicines (Products Other Than Veterinary Drugs)  
(General Sale List) Amendment (No. 2) Order 1999**

*Made* - - - - *8th September 1999*

*Coming into force* - - *30th September 1999*

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 the powers conferred on them by sections 51 and 129(4) of the Medicines Act 1968(1) or, as the case may be, those conferred by those 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 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 may be cited as the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment (No. 2) Order 1999 and shall come into force on 30th September 1999.

(2) In this Order—

- (a) “the principal Order” means the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(3);
- (b) “Table A of Schedule 1” means Table A (internal or external use) of 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);

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(1) 1968 c. 67; section 1(1)(a) of the 1968 Act, as amended by S.I. 1969/388, contains a definition of “the Health Ministers” and section 1(2) contains a definition of “the appropriate Ministers”, both of which are relevant to the powers being exercised in the making of this Order.

(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, 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. 1984/769, amended by S.I. 1985/1540, 1987/910, 1989/969, 1990/1129, 1992/1535, 1994/2410, 1995/3216, 1997/2043, 1998/2170 and 1999/852.

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- (c) any reference to an entry in Table A of Schedule 1 which comprises the name of a substance is a reference to such an entry as it occurs in column 1 of that Table.

### **Amendment of Schedule 1 to the principal Order**

2.—(1) Table A of Schedule 1 is amended as follows—

- (a) against the entry for “Ibuprofen”(4), there is inserted in column 3, in the entry numbered “(2)”, before the words “rheumatic pain”, the word “backache”;
- (b) against the entry for “Lignocaine Hydrochloride”(5), there is inserted—
- (i) in column 2, after the entry numbered “(2)”, the words “(3) 2.0 per cent”; and
- (ii) in column 3, after the entry numbered “(2)”, the words “(3) External, except local ophthalmic use; for use in adults and in children aged 12 years and over; all preparations except sprays”; and
- (c) against the entry for “Zinc Sulphate”, there is substituted for the entry in column 2 “(2) 0.25 per cent”, the entry “(2) 1.0 per cent”.

(2) In Table A of Schedule 1, there is inserted in column 1, at the appropriate place in the alphabetical order of the entries as they appear in that column, the entry set out in column 1 below, and, against that entry, there is inserted in columns 2, 3 and 4 the corresponding text in columns 2, 3 and 4 below:

Column 1	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Ranitidine Hydrochloride	75mg	Tablets; for the short term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity	150mg (MDD).

Signed by authority of the Secretary of State for Health

6th September 1999

*Hunt*  
Parliamentary Under Secretary of State,  
Department of Health

8th September 1999

*David Hanson*  
Parliamentary Under Secretary of State, The  
Welsh Office

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(4) Entry inserted by S.I. 1995/3216.

(5) Entry inserted by S.I. 1994/2410.

8th September 1999

*John Reid*  
Secretary of State, The Scotland Office

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

L.S.

8th September 1999

*D. C. Gowdy*  
Permanent Secretary

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## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 (“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).

Article 2 amends Schedule 1 to the principal Order (medicinal products, other than products the subject of a product licence of right, on general sale) by amending Table A (internal or external use)—

- (a) in respect of the entry for Ibuprofen, by inserting a reference to external use for the treatment of backache;
- (b) in respect of the entry for Lignocaine Hydrochloride, by inserting a reference to products of maximum strength 2.0 per cent, for external use except local ophthalmic use, for use in adults and in children aged 12 years and over, and in any type of preparation except sprays;
- (c) in respect of the entry for Zinc Sulphate, to increase the maximum strength, for external use, from 0.25 per cent to 1.0 per cent; and
- (d) in respect of Ranitidine Hydrochloride, to insert an entry for products of maximum strength 75 mg, for the short term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity with a maximum daily dose of 150 mg.

An assessment of the cost to business of complying with this Order has been made, copies of which have been placed in the libraries of both Houses of Parliament. Further copies may be obtained from the Department of Health, Medicines Control Agency, Information Centre, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.