2001 No. 2068

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment Order 2001

Made - - - - -	*10th May 2001*
Coming into force - -	*31st May 2001*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred on them by sections 51 and 129(4) of the Medicines Act 1968(**a**) or, as the case may be, the powers conferred by those provisions 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 taking into account the advice of the Committee on Safety of Medicines and 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 Order 2001 and shall come into force on 31st May 2001.

(2) In this Order—

(a) "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(**c**);

(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);

(c) "Table B of Schedule 1" means Table B (external use only) of Schedule 1 to the principal Order.

(**a**) 1968 c. 67; the expression "the appropriate Ministers", and the expression "the Health Ministers" which is relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142.

(**b**) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**c**) 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, 1999/852 and 2535, 2000/1092 and 2526.

Amendment of Article 1 of the principal Order

2. In article 1 of the principal Order (interpretation)—

(a) there is inserted in article 1(2)(a) immediately after the definition of "irrigation" the definition—

""Maximum amount released" means the maximum amount of the substance by weight released by a product during the period for which the product is to be applied continuously to the skin;"; and

(b) there is inserted in article 1(3)(a) immediately after the abbreviation of "gram" the abbreviation—

""hrca" for hours of continuous application".

Amendment of Schedule 1 to the principal Order

3. For article 1(1) of Schedule 1 to the principal Order there shall be substituted the following:—

"(1) a substance listed in column 1 of Table A where—

(a) the maximum strength of the substance in the medicinal product does not exceed the maximum strength, if any, specified in column 2 of Table A; and

(b) the maximum amount released of the substance by the product does not exceed the maximum amount released, if any, specified in column 2 of Table A;".

Amendment of Table A of Schedule 1 to the principal Order

4.—(1) In the heading of column 2 of Table A of Schedule 1 to the principal Order for the words "Maximum strength" there are substituted the words "Maximum strength or maximum amount released".

(2) In Table A of Schedule 1 to the principal Order—

(a) there is inserted in column 1, at the appropriate place in the alphabetical order of entries as they appear in that column, the entry "Gum Ammoniacum";

(b) against the entry in column 1 for "Cetylpyridinium Chloride"—

(i) in column 3, there are inserted the entries—

"(1) All preparations other than liquid preparations for oral administration

(2) Liquid preparations for oral administration"; and

(ii) in column 4, the entry "3 mg (MD)" is numbered "(1)" and, after that entry, there is inserted the entry "(2) 5 mg (MD)"; and

(c) against the entry in column 1 for "Nicotine"(**a**)—

(i) in column 2, for the entry "2 mg" there is substituted the entry "(1) 4 mg" and, after that entry, there are inserted the entries "(2) 1 mg", "(3) 15 mg in 16 hrca", and "(4) 21 mg in 24 hrca";

(ii) in column 3, there are inserted the entries—

"(1) Chewing gum

(2) Lozenges

(3) Transdermal patches for continuous application to the skin for a period of 16 hours

(4) Transdermal patches for continuous application to the skin for a period of 24 hours"; and

(iii) in column 3, for the entry "Chewing gum for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only" there is substituted the entry "In relation to any of the preparations (1), (2), (3) and (4), for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only".

(**a**) This entry was inserted by S.I. 1999/852.

Amendment of Table B of Schedule 1 to the principal Order

5. In Table B of Schedule 1 to the principal Order against the entry in column 1 for "Clotrimazole"(**a**), in column 3 there is subsituted for the entry "For treatment of tinea pedis (athlete's foot) only", the entry "Powders for the prevention of, or as an adjunct to the treatment of, tinea pedis (athlete's foot), and all preparations other than powders, for the treatment of tinea pedis".

Signed by Authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
10th May 2001 Department of Health

Bairbre de Brún
10th May 2001 Minister of Health, Social Services and Public Safety

(**a**) This entry was inserted by S.I. 1995/3216.

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 the interpretation provisions of the principal Order to add a definition for maximum amount released in relation to products which release a substance over a period of time and to add an abbreviation for hours of continuous application.

Article 3 amends Schedule 1 to the principal Order so that Column 2 of Table A (internal and external use) may also contain entries for maximum amount released in relation to products which release a substance over a period of time.

Article 4 amends Table A (internal and external use) of Schedule 1 to the principal Order (medicinal products, other than products the subject of a product licence of right, on general sale) by inserting an entry for Gum Ammoniacum, and amending the entries in respect of Cetylpyridinium Chloride to increase the maximum dose for liquid preparations for oral administration from 3 mg to 5 mg, and in respect of Nicotine to increase the maximum strength for chewing gum from 2 mg to 4 mg and to add Nicotine lozenges with a maximum strength of 1 mg and transdermal patches which release a maximum of 15 or 21 mgs of Nicotine during periods of 16 and 24 hours continuous application respectively.

Article 5 amends Table B (external use only) of Schedule 1 to the principal Order by amending the entries in respect of Clotrimazole to add Clotrimazole powder for prevention of, and as an adjunct to the treatment of, tinea pedis (athlete's foot).

Assessments of the cost to business of complying with this Order have 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 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

ISBN 0-11-029546-3

9 780110 295466

£1.75

Printed and published in the UK by The Stationery Office Limited
under the authority and superintendence of Carol Tullo, Controller of
Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.
E1139 6/2001 628592 19585