STATUTORY INSTRUMENTS

2002 No. 933

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Amendment Order 2002

Made - - - - 11th March 2002

Coming into force - - 1st April 2002

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(**1**) or, as the case may be, the powers 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 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 2002 and shall come into force on 1st April 2002.

(2) In this Order, "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(**3**).

Amendments of the principal Order

2. The principal Order is amended as follows—

(a) in paragraph (2)(a) of article 1 (interpretation), after the definition of "irrigation" there shall be inserted the following definition—

(**1**) 1968 c. 67; the expression "the appropriate Ministers", and the expression "the Health Ministers" which are 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.

(**2**) 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).

(**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, 1999/852 and 2535, 2000/1092 and 2526, and 2001/2068 and 4111.

""marketing authorization" means a marketing authorization granted by—

(a) the European Commission in accordance with Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**4**); or

(b) the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**);"; and

(b) for article 2 (which specifies classes of medicines on a general sale list), there is substituted the following article—

"**General sale list**

2. There are hereby specified classes of medicinal products which in the opinion of the Ministers can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist, namely, medicinal products which are not prescription only medicines but which are—

(a) medicinal products in respect of which a marketing authorization has been granted, which in the marketing authorization are classified as being general sale list medicines;

(b) medicinal products in respect of which no marketing authorization has been granted, other than products the subject of a product licence of right, which fall within the class specified in Schedule 1 but which do not fall within a class specified in Schedule 3;

(c) medicinal products which are products the subject of a product licence of right and which fall within the class specified in Schedule 2 but which do not fall within a class specified in Schedule 3; and

(d) medicinal products which are for sale or supply either for oral administration as a food or for external use as a cosmetic, other than products which are eye drops or eye ointments or which contain either—

(i) Vitamin A, Vitamin A acetate or Vitamin A palmitate with a maximum daily dose equivalent to more than 7500 international units of Vitamin A or 2250 micrograms of retinol, or

(ii) Vitamin D with a maximum daily dose of more than 400 units of antirachitic activity.".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

11th March 2002

(**4**) OJ No. L 214, 24.8.1993, p.1.
(**5**) S.I. 1994/3144, amended by S.I. 1998/3105, 2000/292, 2001/795 and 2002/236.

Bairbre de Brún
Minister of Health, Social Services and Public Safety

7th March 2002

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 article 2 of the principal Order (which specifies classes of medicinal products on a general sale list) to provide that medicinal products which have been granted a marketing authorization will be available on general sale if so classified in their marketing authorization. Medicinal products for which no marketing authorization has been granted, or for which there is a product licence of right, will continue to be classified as general sale if they fall within the class specified in Schedule 1 or 2 and are not specified in Schedule 3.

A Regulatory Impact Assessment in relation to this Order has 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.