S T A T U T O R Y I N S T R U M E N T S

2001 No. 3942

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001

Made- - - -	*9th December 2001*
Laid before Parliament	*10th December 2001*
Coming into force	*31st December 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 58(1), (4) and (5), 59 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 Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 and shall come into force on 31st December 2001.

(2) In this Order, "the principal Order" means the Prescription Only Medicines (Human Use) Order 1997**(c)**;

Amendment of Schedule 1 to the principal Order

2. In Schedule 1 to the principal Order (which specifies substances which if included in medicinal products make those products prescription only medicines and exemptions from restrictions on the sale and supply of prescription only medicines)—

(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; section 58 was amended by section 1 of the Prescription by Nurses etc. Act 1992 (c.28) and by section 63 of the Health and Social Care Act 2001 (c.15).

(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. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231, 2001/2777 and 2889.

(a) in relation to the substance Cetirizine Hydrochloride, the entry in column 5 is deleted;

(b) in relation to the substance Flurbiprofen—

(i) in column 2, there is inserted "8.75 mg";

(ii) in column 3, there is inserted "Throat lozenges";

(iii) in column 4, there is inserted "43.75 mg (MDD)"; and

(iv) in column 5, there is inserted "Container or package containing not more than 140 mg of Flurbiprofen";

(c) in relation to the substance Loratadine, the entry in column 5 is deleted;

(d) in relation to the substance Terbinafine—

(i) in column 2, there is inserted "1.0 per cent";

(ii) in column 3, there is inserted "External use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel"; and

(iii) in column 5, there is inserted "Container or package containing not more than 30 grams of medicinal product";

(e) there is inserted in column 1, at the appropriate place in the alphabetical order of the entries as they appear in that column, the entries set out in column 1 in the Table below, and, against those entries, there is inserted in columns 2, 3, 4 and 5 the corresponding text in columns 2, 3, 4 and 5 below:

Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration, use, or pharmaceutical form	Treatment limitations	Maximum quantity
Diphenoxylate Hydrochloride	2.5 mg	In combination with Atropine Sulphate for short term use as an adjunctive therapy to appropriate rehydration in acute diarrhoea For use in persons aged 16 years and over Tablets	25 mg (MDD)	Container or package containing not more than 20 tablets
Dolasetron Mesilate				
Ropinirole Hydrochloride				

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

9th December 2001

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

6th December 2001

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order").

Article 2 amends Schedule 1 to the principal Order (which specifies substances which, if included in medicinal products, make them prescription only medicines, and exemptions from the restrictions in section 58(2) on sale and supply of prescription only medicines):

(a) in respect of the entries for Cetirizine Hydrochloride and Loratadine to provide that medicinal products containing these substances may be sold or supplied otherwise than as prescription only medicines without any restriction on the maximum quantity in a container or package;

(b) in respect of the entries for Flurbiprofen and Terbinafine to provide that medicinal products containing these substances may be sold or supplied otherwise than as prescription only medicines on the conditions specified;

(c) to insert an entry for Diphenoxylate Hydrochloride and to provide that medicinal products containing Diphenoxylate Hydrochloride may be sold or supplied otherwise than as a prescription only medicine with Atropine Sulphate on the conditions specified;

(d) to insert entries for the substances Dolasetron Mesilate and Ropinirole Hydrochloride.

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 10–202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

£1.75

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