STATUTORY INSTRUMENTS

2001 No. 2777

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 2001

Made - - - -	*31st July 2001*
Laid before Parliament	*1st August 2001*
Coming into force - -	*24th August 2001*

As regards England, Scotland and Wales, the Secretary of State concerned with health in England, and, as regards Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 58(1), (4) and (5) and 129(4) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said 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 consulting and taking into account the advice of the Committee on Safety of Medicines pursuant to sections 58(6) and 129(7) 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 Prescription Only Medicines (Human Use) Amendment Order 2001 and shall come into force on 24th August 2001.

(2) In this Order, "the principal Order" means the Prescription Only Medicines (Human Use) Order 1997(**3**).

(**1**) 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 article 5 of, and paragraph 1(1) of 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).

(**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 paragraph 1(1) of the Schedule 1 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. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2899 and 3231.

Amendment of article 1(5) of the principal Order

2. In article 1(5) of the principal Order, for "Schedules 1 to 3" there is substituted "Schedules 1, 2 and 5".

Amendment of Schedule 1 to the principal Order

3. 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 the restrictions on the sale and supply of prescription only medicines)—

(a) in relation to the substance Adrenaline, in column 3, after "External" there is inserted "(except ophthalmic)";

(b) in relation to the substance Fluconazole, in column 3, after "vaginal candidiasis" there is inserted "or associated candidal balanitis";

(c) in relation to the substance Hydrocortisone Acetate, in column 3, after "haemorrhoids" there is inserted "or in combination with Miconazole Nitrate, for athlete's foot and candidal intertrigo";

(d) in relation to the substance Stannous Fluoride, the entries in columns 2 and 3 are each numbered "(1)", and, after those entries there are inserted the following entries—

in column 2—

"(2) 0.4 per "; and

in column 3—

"(2) Dental gels for use in the prevention and treatment of dental caries and decalcification of the teeth";

(e) in relation to the substance Terbinafine Hydrochloride(**4**), in the entry in column 3, at the beginning there is inserted "Preparations, other than spray solutions, for"; the entries in columns 3 and 5 are each numbered "(1)" and after those entries there are inserted the following entries—

in column 3—

"(2) Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis"; and

in column 5—

"(2) Container containing not more than 30ml of medicinal product";

(f) 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 are inserted in columns 2, 3, 4 and 5 the corresponding entries in columns 2, 3, 4 and 5 in that Table—

Column 1 Substance	*Column 2 Maximum strength*	*Column 3 Use, pharmaceutical form or route of administration*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
Clobetasone Butyrate	0.05 per cent	Cream for use in adults and		Container or package

(**4**) This entry was inserted by S.I. 2000/1917.

Column 1 Substance	*Column 2 Maximum strength*	*Column 3 Use, pharmaceutical form or route of administration*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
		in children aged 12 years and over, for external use for the short term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis)		containing not more than 15g of medicinal product
Fenticonazole Nitrate		External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)		
Prochlorperazine Maleate	3mg	Buccal tablets for the treatment of nausea and vomiting in cases of previously diagnosed migraine only. For use in persons aged 18 years and over.	12mg (MDD)	Container or package containing not more than 8 tablets

; and

(g) there is inserted in column 1, at the appropriate place in the alphabetical order of the entries in that column, each of the following substances—

“Amisulpride”

“Balsalazide Sodium”

“Benserazide”

“Brimonidine Tartrate”

“Carbasalate Calcium”

“Cefdinir”

"Cerivastatin Sodium"
"Donepezil Hydrochloride"
"Fexofenadine Hydrochloride"
"Flutrimazole"
"Irbesartan"
"Levofloxacin"
"Mercaptamine Bitartrate"
"Modafinil"
"Naratriptan Hydrochloride"
"Pramipexole Hydrochloride"
"Reboxetine Mesilate"
"Sertindole"
"Temocapril Hydrochloride"
"Testosterone"
"Valsartan".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
30th July 2001 Department of Health

Bairbre de Brún
Minister of Health, Social Services and Public
31st July 2001 Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes a technical correction to article 1(5) of the Prescription Only Medicines (Human Use) Order 1997 and amends Schedule 1 to that 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) in order to provide—

(a) for the amendment of the conditions under which medicinal products containing Adrenaline, Fluconazole, Hydrocortisone Acetate, Stannous Fluoride and Terbinafine Hydrochloride may be sold or supplied otherwise than as prescription only medicines;

(b) that medicinal products containing Clobetasone Butyrate, Fenticonazole Nitrate and Prochlorperazine Maleate may be sold or supplied otherwise than as prescription only medicines on the conditions specified;

(c) for the insertion in Schedule 1 of the substances Amisulpride, Balsalazide Sodium, Benserazide, Brimonidine Tartrate, Carbasalate Calcium, Cefdinir, Cerivastatin Sodium, Donepezil Hydrochloride, Fexofenadine Hydrochloride, Flutrimazole, Irbesartan, Levofloxacin, Mercaptamine Bitartrate, Modafinil, Naratriptan Hydrochloride, Pramipexole Hydrochloride, Reboxetine Mesilate, Sertindole, Temocapril Hydrochloride, Testosterone, Valsartan.

An assessment of the cost to business of complying with this Order has been made, a copy of which 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.