STATUTORY INSTRUMENTS

1997 No. 2044

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 1997

Made - - - -	*26th August 1997*
Laid before Parliament	*26th August 1997*
Coming into force	
except for article 2(c)	*16th September 1997*
article 2(c)	*16th September 1998*

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 powers conferred on 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 Medicines Commission pursuant to sections 58(6) and 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 1997 and shall come into force on 16th September 1997 except for article 2(c) which shall come into force on 16th September 1998.

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

(**1**) 1968 c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by S.I.1969/388, Schedule 1.

(**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, the Transfer of Functions (Wales) Order 1969 (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. 1997/1830.

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) in the entry for "Carbenoxolone Sodium", there is substituted for "506mg" in column 5, "560mg";

(b) the entry for "Terfenadine" is amended by the deletion of the entries "120mg (MDD)" in column 4 and "Container or package containing not more than 1,200mg of Terfenadine" in column 5; and

(c) there are inserted in column 1 and, as the case may be, columns 2, 3 and 5, at the appropriate point in the alphabetical order of the entries as they appear in column 1, each of the entries set out in column 1 of Schedule 1 to this Order, together with the corresponding text in columns 2, 3 and 5 respectively of that Schedule.

Frank Dobson,
12th August 1997 Secretary of State for Health

Win Griffiths,
Parliamentary Under-Secretary of State,Welsh
20th August 1997 Office

Sam Galbraith,
Parliamentary Under-Secretary of State,The
26th August 1997 Scottish Office

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

L.S.

D. C. Gowdy,
20th August 1997. Permanent Secretary

SCHEDULE 1 Article 2(c)

ENTRIES INSERTED IN SCHEDULE 1 TO THE PRINCIPAL ORDER

Column 1 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Aspirin	(1) 325 mg	(1) Non-effervescent tablets and capsules (2) All preparations other than non-effervescent tablets or capsules		(1) The quantity sold or supplied in one container or package shall not exceed 32 The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100
Paracetamol	(1) 120 mg	(1) Non-effervescent tablets and capsules for use in children aged less than 12 years		(1) The quantity sold or supplied in one container or package shall not exceed 32 The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100

Column 1 Substance	*Column 2 Maximum strength*	*Column 3 Route of administration, use or pharmaceutical form*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
	(2) 500 mg	(2) Non-effervescent tablets and capsules for use in adults and children not less than 12 years (3) All preparations other than non-effervescent tablets and capsules		(2) The quantity sold or supplied in one container or package shall not exceed 32 The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order") which specifies descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail only in accordance with a prescription given by an appropriate practitioner and which may be administered only by or in accordance with the directions of such a practitioner). Under the principal Order products are included in a class of such medicines by reason of the substances contained in them, subject to their being excluded in specified circumstances.

Article 2 of this Order amends Schedule 1 to the principal Order, which lists substances which render a medicinal product a prescription only medicine except in the circumstances also listed. The entry for carbenoxolone sodium is amended with effect from 16th September 1997 as to the conditions under which that substance may be sold otherwise than as a prescription only medicine. The entry for terfenadine is amended so that with effect from 16th September 1997 all products containing that substance are prescription only medicines. With effect from 16th September 1998 medicinal products which contain the analgesics aspirin or paracetamol are included in that Schedule with

provisions to exempt certain products containing those substances and quantities of such products from being prescription only medicines.

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.