STATUTORY INSTRUMENTS

1998 No. 1178

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998

Made - - - -	*6th May 1998*
Laid before Parliament	*11th May 1998*
Coming into force	
except for article 2(d)(ii)	*1st June 1998*
article 2(d)(ii)	*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 (No. 2) Order 1998 and shall come into force on 1st June 1998, except for article 2(d)(ii) 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, amended by S.I. 1997/2044 and 1998/108.

Amendment of Schedule 1 to the principal Order

2. In Schedule 1 to the principal Order (which specifies substances which when 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 relation to the substance Domperidone Maleate, there are inserted the following entries—

in column 3

"For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,"

in column 4

"10mg (MD)

40mg (MDD)"

and in column 5

"Container or package containing not more than 100mg of Domperidone as Domperidone Maleate;"

(b) in relation to the substance Minoxidil, there are substituted for the entry in column 2 the entries—

"(1) 2.0 per cent

(2) 5.0 per cent"

and for the entry in column 3 the entries—

"(1) External

(2) External use for the treatment of alopecia androgenetica, in men aged 18 to 65 (but not in women);"

(c) in relation to the substance Nizatidine—

(i) there are inserted in the entry in column 3, after the word "prevention", the words "and treatment", and after the word "heartburn", the words "and meal-induced indigestion",

(ii) there is inserted in column 4, after the entry "75mg (MD)", the entry "150mg (MDD)", and

(iii) there is substituted in column 4 for the entry "Maximum of 4 such doses in any period of 14 days", the entry "For a maximum period of 14 days"; and

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

(i) "Pirenzepine Dihydrochloride Monohydrate"

"Quinapril Hydrochloride" and

(ii) "Phenolphthalein."

Amendment of Schedule 5 to the principal Order

3. In Part III of Schedule 5 to the principal Order there is inserted in the entry in column 2 of paragraph 9, after the words "Anhydrous Glucose", the words "Bretylium Tosylate".

Signed by the authority of the Secretary of State for Health

Jay
Minister of State,
1st May 1998 Department of Health

Peter Hain
Parliamentary Under Secretary of State, The
6th May 1998 Welsh Office

Sam Galbraith
Parliamentary Under Secretary of State, The
5th May 1998 Scottish Office

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

L.S.

D. C. Gowdy
6th May 1998. Permanent Secretary

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.

The amendments made by this Order are as follows—

amendments to the conditions under which Domperidone Maleate, Minoxidil and Nizatidine may be sold or supplied otherwise than as prescription only medicines;

the inclusion in Schedule 1 to the principal Order of products containing the substances Phenolphthalein, Pirenzepine Dihydrochloride Monohydrate and Quinapril Hydrochloride; and

the addition of Bretylium Tosylate to the list of substances in Part III of Schedule 5 to the principal Order which may be administered by ambulance paramedics.

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.