STATUTORY INSTRUMENTS

1998 No. 108

MEDICINES

The Prescription Only Medicines (Human Use) Amendment Order 1998

Made - - - -	*23rd January 1998*
Laid before Parliament	*23rd January 1998*
Coming into force except for articles 2 and 3(e)(ii)	*13th February 1998*
articles 2 and 3(e)(ii)	*13th August 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 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 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 1998 and shall come into force on 13th February 1998, except for article 2 and article 3(e)(ii) which shall come into force on 13th August 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.

Amendment of article 3 of the principal Order

2. In article 3 of the principal Order (medicinal products on prescription only), in paragraph (c) the words ", other than preparations of insulin for parenteral administration" are deleted.

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

(a) in relation to the substance Hydrocortisone, there are inserted in the entry in column 3, after the word "Clotrimazole", the words "or Miconazole Nitrate";

(b) in relation to the substance Mebeverine Hydrochloride, there are substituted for the entry in column 3 the following entries—

"(a) For the symptomatic relief of irritable bowel syndrome

(b) For uses other than the symptomatic relief of irritable bowel syndrome"

and for the entry in column 4 the following entries—

"(a) 135 mg (MD)

405 mg (MDD)

(b) 100 mg (MD)

300 mg (MDD)";

(c) in relation to the substance Ranitidine Hydrochloride, there are added at the end of the entry in column 3 the words "or the prevention of these symptoms when associated with consuming food and drink";

(d) in relation to the substance Sodium Cromoglycate, there are inserted in entry (b) in column 3, after the words "acute seasonal allergic conjunctivitis", the words "or perennial allergic conjunctivitis"; and

(e) 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) "Estramustine Sodium Phosphate"

"Mizolastine"

"Niceritrol"

"Piroxicam Beta-cyclodextrin"

"Torasemide"; and

(ii) "Insulin".

Amendment of Schedule 3 to the principal Order

4. In Schedule 3 to the principal Order (descriptions and classes of prescription only medicines in relation to which appropriate nurse practitioners are appropriate practitioners) the following entries are inserted at the appropriate point in the alphabetical order of the entries in that Schedule—

"Co-danthramer Capsules NPF"

"Co-danthramer Capsules, Strong NPF"

"Co-danthrusate Oral Suspension NPF".

Amendment of Schedule 5 to the principal Order

5.—(1) At the end of Part I of Schedule 5 to the principal Order (exemptions for certain persons from the provisions of section 58(2) of the Medicines Act 1968) there are inserted the entries set out in the Schedule to this Order.

(2) In Part III of Schedule 5 to the principal Order for the three substances listed in column 2 of paragraph 1 there is substituted the following list—

"Bupivacaine hydrochloride

Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride

Lignocaine hydrochloride

Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride

Prilocaine hydrochloride."

Signed by authority of the Secretary of State for Health

Jay
Minister of State,
16th January 1998 Department of Health

Ron Davies
23rd January 1998 Secretary of State for Wales

Sam Galbraith
Parliamentary Under Secretary of State, Minister
20th January 1998 of State, The Scottish Office

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

L.S.

D. C. Gowdy
19th January 1998. Permanent Secretary

THE SCHEDULE

Article 5(1)

ENTRIES INSERTED IN PART I OF SCHEDULE 5 TO THE PRINCIPAL ORDER

Column 1 *Persons exempted*	Column 2 *Prescription only medicines to which the exemption applies*	Column 3 *Conditions*
10. State registered chiropodists who hold a certificate of competence in the use of the medicines specified in Column 2 issued by or with the approval of the Chiropodists Board.	**10.** The following prescription only medicines— (a) Co-dydramol 10/500 tablets; (b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight; (c) Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume; and (d) Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	**10.** The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.

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—

the ending of the exemption under which insulin for parenteral administration could be sold or supplied otherwise than as a prescription only medicine (article 2);

amendments to the conditions under which Hydrocortisone, Mebeverine Hydrochloride, Ranitidine Hydrochloride and Sodium Cromoglycate may be sold or supplied otherwise than as prescription only medicines (article 3);

the inclusion in Schedule 1 to the principal Order of products containing the substances Estramustine Sodium Phosphate, Insulin, Mizolastine, Niceritrol, Piroxicam Beta-cyclodextrin and Torasemide (article 3);

the inclusion in Schedule 3 to the principal Order of the substances Co-danthramer Capsules NPF, Co-danthramer Capsules, Strong NPF and Co-danthrusate Oral Suspension NPF, enabling them to be prescribed by appropriate nurse practitioners (article 4); and

the inclusion in Part I of Schedule 5 to the principal Order of a list of substances which may be sold or supplied by chiropodists who hold the appropriate certificate of competence (article 5 and the Schedule) and the amendment of the list of substances in Part III of the said Schedule 5 which may be administered by state registered chiropodists with a certificate in the use of analgesics.

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.