STATUTORY INSTRUMENTS

1998 No. 2081

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998

Made - - - -	*27th August 1998*
Laid before Parliament	*27th August 1998*
Coming into force - -	*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. 3) Order 1998 and 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**).

Amendment of article 8 of the principal Order

2. In paragraph 4(b)(i) of article 8 of the principal Order (exemptions for emergency sale or supply), before the words "an aerosol" there are inserted the words "a preparation of insulin,".

(**1**) 1968 c. 67; section 58(1), (4) and (5) of the 1968 Act has been amended by section 1 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28). Section 1(1)(a) of the 1968 Act, as amended by the Transfer of Functions (Wales) Order 1969 (S.I.1969/388), contains a definition of "the Health Ministers" and section 1(2) of the 1968 Act contains a definition of "the appropriate Ministers", both of which are relevant to the powers being exercised in the making of this Order.

(**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; 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, 1998/108 and 1998/1178.

Amendment of Schedule 1 to the principal Order

3. 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 Aspirin(**4**), there is substituted for the entry "(1) 325 mg" in column 2, "(1) 500 mg";

(b) in relation to the substance Astemizole, the entries in columns 3, 4 and 5 are deleted;

(c) in relation to each of the substances Beclomethasone Dipropionate and Budesonide–

(i) there are substituted for the entry "For use in adults and children not less than 12 years" in column 3, the entry "For use in persons aged 18 years and over", and

(ii) there is inserted in column 4, after the entry "200 mcg per nostril (MDD)", the entry "For a maximum period of 3 months";

(d) in relation to the substance Domperidone Maleate(**5**), there is substituted for the entry "10 mg (MD) 40 mg (MDD)" in column 4, the following entry

"10 mg of Domperidone as Domperidone Maleate (MD)

40 mg of Domperidone as Domperidone Maleate (MDD)";

(e) in relation to the substance Felbinac, there is substituted for the entry "For the relief of symptoms associated with soft tissue injury such as strains, sprains and contusions" in column 3, the entry–

"For the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions";

(f) in relation to the substance Flunisolide–

(i) there are substituted for the entry "For use in adults and children not less than 16 years" in column 3, the entry "For use in persons aged 18 years and over",

(ii) there is inserted in column 4, after the entry "100 mcg per nostril (MDD)", the entry "For a maximum period of 3 months", and

(iii) the entries under the letter "(b)" in columns 3, 4 and 5 are deleted;

(g) in relation to the substance Ketoconazole–

(i) there is inserted in column 3, before the entry "For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp", the entry "External",

(ii) there are inserted in the entries in columns 3, 4 and 5, at the beginning of each of the first entries, the letter "(a)", and

(iii) there is inserted in column 3, after the entry "In the form of a shampoo", the entry "(b) For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo";

(h) in relation to the substance Nedocromil Sodium there are inserted the following entries–

in column 2

"2.0 per cent",

in column 3

"For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis", and

(**4**) Entry inserted by S.I. 1997/2044.
(**5**) Entry amended by S.I. 1998/1178.

in column 5

"Container or package containing not more than 3 ml of medicinal product"; and

(i) there are inserted in column 1, and, as the case may be, columns 2, 3, 4 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 the Schedule to this Order, together with the corresponding text in columns 2, 3, 4 and 5 respectively of that Schedule.

Amendment of Schedule 5 to the principal Order

4. In Schedule 5 to the principal Order (exemptions for certain persons from the provisions of section 58(2) of the Medicines Act 1968)–

(a) in Part I there is inserted in the list in column 2 of paragraph 4, after the substance Pentazocine Hydrochloride, "Phytomenadione", and

(b) in Part III there is inserted in the list in column 2 of paragraph 1, after the substance Lignocaine hydrochloride with adrenaline**(6)**, "Mepivacaine hydrochloride".

Signed by authority of the Secretary of State for Health

Paul Boateng
Parliamentary Under Secretary of State,
21st August 1998 Department of Health

Jon Owen Jones
Parliamentary Under Secretary of State, The
27th August 1998 Welsh Office

Sam Galbraith
25th August 1998 Minister for Health, The Scottish Office

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

D.C. Gowdy
24th August 1998. Permanent Secretary

(**6**) Entry inserted by S.I. 1998/108.

THE SCHEDULE Article 3(i)

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*
Aloxiprin	(1) 620 mg	(1) Non-effervescent tablets and 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
		(2) All preparations other than non-effervescent tablets or capsules		
Diphenhydramine Hydrochloride		All preparations except liquid-filled capsules		
Hydrocyanic Acid				
Ibuprofen Lysine		Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache,		

Column 1 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
		dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza		
		Internal	(a) (a) In the case of a prolonged release preparation 600 mg (MD) 1,200 mg (MDD) (b) in any other case 400 mg (MD) 1,200 mg (MDD)	
Levocabastine Hydrochloride	Equivalent of 0.05 per cent Levocabastine	(1) Nasal sprays For the symptomatic treatment of seasonal allergic rhinitis		(1) Container or package containing not more than 10 ml of medicinal product
		(2) Aqueous eye drops For the symptomatic treatment of seasonal allergic conjunctivitis		(2) Container or package containing not more than 4 ml of medicinal product
Nilutamide				
Phytomenadione		Any use except the prevention		

Column 1 Substance	*Column 2 Maximum strength*	*Column 3 Route of administration, use or pharmaceutical form*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
		or treatment of haemorrhagic disorders		
Strychnine Nitrate				
Sulfabenzamide				

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).

The amendments made by this Order are as follows–

the amendment to the emergency supply rules in article 8 to enable pharmacists to supply more than 5 days' supply of insulin where only packs containing more than that amount are available (article 2);

amendments to the conditions under which Aspirin, Beclomethasone Dipropionate, Budesonide, Domperidone Maleate, Felbinac, Flunisolide, Ketoconazole, and Nedocromil Sodium may be sold or supplied otherwise than as prescription only medicines (article 3);

the revocation of the conditions under which Astemizole may be sold or supplied otherwise than as a prescription only medicine (article 3);

the inclusion in Schedule 1 to the principal Order of products containing the substances Aloxiprin, Diphenhydramine Hydrochloride, Hydrocyanic Acid, Ibuprofen Lysine, Levocabastine Hydrochloride, Nilutamide, Phytomenadione, Strychnine Nitrate and Sulfabenzamide, and the conditions for their sale or supply otherwise than as prescription only medicines on the terms set out in the Schedule to this Order (article 3);

the addition of Phytomenadione to the list of substances in Part I of Schedule 5 to the principal Order which may be sold or supplied by midwives (article 4); and

the addition of Mepivacaine Hydrochloride to the list of substances in Part III of Schedule 5 to the principal Order which may be administered by registered chiropodists (article 4).

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.