STATUTORY INSTRUMENTS

2000 No. 2899

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000

Made - - - -	*26th October 2000*
Laid before Parliament	*26th October 2000*
Coming into force - -	*16th November 2000*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects 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 (No. 2) Order 2000 and shall come into force on 16th November 2000.

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

Amendment of article 5 of the principal Order

2. In article 5(4) of the principal Order, after sub-paragraph (b), there is added—

(**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).

(**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 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, 1999/3463 and 2000/1917.

", provided that, where the entry in column 3 contains a condition to the effect that the product is to be wholly or mainly for use in a specified class of persons, the product satisfies that condition where it is sold or supplied wholly or mainly for use in persons of that class".

Amendment of article 12C of, and Schedule 7 to, the principal Order

3.—(1) In article 12C of the principal Order(**4**), after paragraph (2)(c), there is inserted—

"(cc) where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business within the meaning of section 69, the individual who administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing, on behalf of the body with which an arrangement has been made as referred to in paragraph (1)(a), for the purpose of the administration of prescription only medicines under the Patient Group Direction; and".

(2) In the heading of Part III of Schedule 7(**4**) to the principal Order, for "**BY WHOM SUPPLIES MAY BE MADE**" there is substituted "**BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED**".

Amendment of Schedule 1 to the principal Order

4. 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 Azelastine Hydrochloride, in column 3, after "seasonal allergic rhinitis", there is inserted "or perennial allergic rhinitis", and for "12 years" there is substituted "5 years";

(b) in relation to the substance Domperidone, 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 of Domperidone (MD)

40mg of Domperidone (MDD)"; and

in column 5—

"Container or package containing not more than 200mg of Domperidone";

(c) in relation to the substance Domperidone Maleate(**5**), in column 5, for "100mg" there is substituted "200mg";

(d) in relation to the substance Ibuprofen(**6**), in column 5, for "100g" there is substituted "50g";

(e) in relation to the substance Lodoxamide Trometamol—

(i) in column 2, there is inserted "equivalent of 0.1 per cent Lodoxamide"; and

(ii) in column 3, there is inserted "For the treatment of ocular signs and symptoms of allergic conjunctivitis, in adults and in children aged 4 years and over";

(**4**) The article and Schedule 7 were inserted by S.I. 2000/1917.
(**4**) The article and Schedule 7 were inserted by S.I. 2000/1917.
(**5**) This entry was amended by S.I. 1998/1178 and 2081.
(**6**) This entry was amended by S.I. 2000/1917.

(f) in relation to the substance Paracetamol(**7**)—

(i) in column 2, in the entry numbered "(1)", for "120mg" there is substituted "250mg";

(ii) in column 3, in the entry numbered "(1)", there is inserted after "capsules", "wholly or mainly"; and

(iii) in column 3, in the entry numbered "(2)", there is inserted after "capsules", "wholly or mainly";

(g) in relation to the substance Triamcinolone Acetonide, the entries in columns 2, 3 and 5 are each numbered "(1)", and, after those entries, there are inserted the following entries—

in column 3—

"(2) In the form of a non-pressurised nasal spray, for the treatment of symptoms of seasonal allergic rhinitis in persons aged 18 years and over";

in column 4—

"(2) 110mcg per nostril (MD)

110mcg per nostril (MDD)

For a maximum period of 3 months"; and

in column 5—

"(2) Container or package containing not more than 3.575mg of Triamcinolone Acetonide"; and

(h) 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—

"Cabergoline"

"Cefprozil"

"Indapamide"

"Lansoprazole"

"Lercanidipine Hydrochloride"

"Meloxicam"

"Pantoprazole Sodium"

"Penciclovir"

"Tamsulosin Hydrochloride"

"Ticlopidine Hydrochloride"

"Tiludronate Disodium"

"Toremifene".

Amendment of Schedule 5 to the principal Order

5. In paragraph 9 of Part III of Schedule 5 to the principal Order—

(a) in column 1, there is added, at the end, "or persons who are state registered paramedics";

(b) in column 2, after sub-paragraph (b), there is inserted—

"(bb) medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient"; and

(**7**) This entry was inserted by S.I. 1997/2044.

(c) in column 2, in sub-paragraph (c), there is inserted, at the appropriate place in the alphabetical order of the entries in that sub-paragraph, the following entries—

"Benzylpenicillin"

"Frusemide"

"Metoclopramide"

"Morphine Sulphate"

"Streptokinase".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
24th October 2000 Department of Health

Bairbre de Brún
Minister of Health, Social Services and Public
26th October 2000 Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order") and provides—

(a) in articles 2 and 4, for the amendment of Schedule 1 to the principal 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), to amend the conditions under which medicinal products containing Azelastine Hydrochloride, Domperidone Maleate, Ibuprofen, Paracetamol and Triamcinolone Acetonide may be sold or supplied otherwise than as prescription only medicines;

(b) in article 4, for the amendment of Schedule 1 to the principal Order to provide that medicinal products containing Domperidone and Lodoxamide Trometamol may be sold or supplied otherwise than as prescription only medicines on the conditions specified;

(c) in article 4, for the insertion in Schedule 1 to the principal Order of the substances Cabergoline, Cefprozil, Indapamide, Lansoprazole, Lercanidipine Hydrochloride, Meloxicam, Pantoprazole Sodium, Penciclovir, Tamsulosin Hydrochloride, Ticlopidine Hydrochloride, Tiludronate Disodium and Toremifene;

(d) in article 3, for the amendment of article 12C of the principal Order (exemption from the restrictions in section 58(2), for the supply or administration of prescription only medicines under a Patient Group Direction by a person lawfully conducting a retail pharmacy business) to provide that prescription only medicines may only be administered under the Direction where they are administered by a designated individual belonging to one of the classes of individual specified in Part III of Schedule 7 to the principal Order; and the amendment of Part III of Schedule 7 to the principal Order, to correct the heading of that Part;

(e) in article 5, for the amendment of paragraph 9 of Part III of Schedule 5 to the principal Order (exemption from the restrictions in section 58(2)(b), for administration by paramedics), to extend the exemption to state registered paramedics, and to add to the list of medicines which may be administered by paramedics, medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, and medicines containing the substances Benzylpenicillin, Frusemide, Metoclopramide, Morphine Sulphate and Streptokinase.

An assessment to 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 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.