Jersey R & O 2/2001

Medicines (Jersey) Law 1995

MEDICINES (PRESCRIPTION ONLY) (AMENDMENT No. 3) (JERSEY) ORDER 2001

THE HEALTH AND SOCIAL SERVICES COMMITTEE, in pursuance of Articles 57 and 111 of the Medicines (Jersey) Law 1995,[1] and after consultation with the Medicines Advisory Council and having otherwise complied with Article 111 of that Law, orders as follows -

1.-(1) In this Order "the principal Order" means the Medicines (Prescription Only) (Jersey) Order 1997,[2] as amended.[3]

(2) Unless the context otherwise requires, a reference in this Order to an enactment, or to an Act or subordinate legislation of the United Kingdom, is a reference to that enactment, Act or subordinate legislation as amended from time to time and includes a reference to that enactment, Act or subordinate legislation as extended or applied under another enactment, including another provision of this Order.

2. In Article 2 of the principal Order there shall be inserted after the definition "soaps" the following definition -

> " 'state registered paramedic' means a person who is registered in the register established and maintained under section 60 and paragraph 1(a) of Schedule 3 to the Health Act, 1999 of the United Kingdom;".

3. In Part I of the First Schedule to the principal Order -

(a) there shall be inserted in column 1, at the appropriate place in the alphabetical order of the entries in that column, the substance "Levocarnitine", and, in column 3, in relation to

[1] Recueil des Lois, Volume 1994-1995, pages 507 and 569.
[2] No. 9140.
[3] Nos. 9326 and 1/2000.

that substance, there shall be inserted the entry "For dietary supplementation";

(b) in relation to the substance Ibuprofen the entries in columns 2, 3 and 4 shall be revoked;

(c) 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"; and

(d) 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 -

"Acamprosate"

"Aceclofenac"

"Alendronate Sodium"

"Altretamine"

"Apraclonidine Hydrochloride"

"Bicalutamide"

"Calcipotriol Hydrate"

"Cefprozil"

"Didanosine"

"Exemestane"

"Ferumoxsil"

“Imidapril Hydrochloride”

“Lercanidipine Hydrochloride”

“Meloxicam”

“Moexipril Hydrochloride”

“Moxonidine”

“Omeprazole Magnesium”

“Pantoprazole Sodium”

“Penciclovir”

“Quinagolide Hydrochloride”

“Ranitidine Bismuth Citrate”

“Rimexolone”

“Sevoflurane”

“Sparfloxacin”

“Tamsulosin Hydrochloride”

“Terbinafine Hydrochloride”

“Ticlopidine Hydrochloride”

“Tiludronate Disodium”

“Topiramate”

“Toremifene”

“Valaciclovir Hydrochloride”

“Venlafaxine Hydrochloride”.

4. In Part IV of the First Schedule to the principal Order -

(a) in paragraph 7(d) -

(i) after "rhinitis" there shall be inserted "or perennial allergic rhinitis", and

(ii) the number "12" shall be revoked and the number "5" substituted;

(b) the following paragraph shall be inserted after paragraph 14 -

"14A. A medicinal product shall not be a prescription only medicine by reason that it contains the substance Domperidone, where -

(a) the medicinal product is indicated for the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn;

(b) the medicinal product is sold or supplied in a container or package containing not more than 200 mg of Domperidone; and

(c) the container or package is labelled to show a maximum dose of 10 mg of Domperidone and a maximum daily dose of 40 mg of Domperidone.";

(c) in paragraph 15 the number "100" shall be revoked and the number "200" substituted;

(d) in paragraph 17(b) "30 mg" shall be revoked and "50 g" substituted;

(e) the following paragraph shall be inserted after paragraph 25 -

"25A. A medicinal product shall not be a prescription only medicine by reason that it contains the substance Ibuprofen, where -

(a) the medicinal product is indicated for the relief of rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza; and either

(b) the route of the administration of the medicinal product is internal; and -

(i) in the case of a prolonged release preparation the container or package is labelled to show a maximum dose of 600 mg and a maximum daily dose of 1200 mg; or

(ii) in any other case the container or package is labelled to show a maximum dose of 400 mg and a maximum daily dose of 1200 mg; or

(c) the route of administration of the medicinal product is external; and

(i) the maximum strength of the Ibuprofen in the medicinal product does not exceed 5%; or

(ii) (A) the maximum strength of the Ibuprofen in the medicinal product does not exceed 10%; and

(B) the medicinal product is sold or supplied in a container or package containing not more than 50 g of medicinal product which is labelled

to show a maximum dose of 125 mg and a maximum daily dose of 500 mg.";

(f) in paragraph 36(e) there shall be inserted after "administration" the words "wholly or mainly";

(g) in paragraph 37(b) the number "120" shall be revoked and the number "250" substituted; and

(h) the following paragraphs shall be added after paragraph 42 -

"43. A medicinal product shall not be a prescription only medicine by reason of the fact that it contains Terbinafine Hydrochloride where -

(a) the maximum strength of the Terbinafine Hydrochloride in the medicinal product does not exceed 1%;

(b) the medicinal product is indicated for external use for the treatment of tinea pedis and tinea cruris; and

(c) the medicinal product is sold or supplied in a container or package containing not more than 15 g of medicinal product.

44. A medicinal product shall not be a prescription only medicine by reason of the fact that it contains Triamcinolone Acetonide where -

(a) the medicinal product is in the form of a non-pressurised nasal spray;

(b) the medicinal product is indicated for the treatment of symptoms of seasonal allergic rhinitis in persons aged 18 years and over for a maximum period of 3 months;

(c) the container or package is labelled to show a maximum dose of 110 mcg per nostril and a maximum daily dose of 110 mcg per nostril; and

(d) the medicinal product is sold or supplied in a container or package containing not more than 3.375 mg of Triamcinolone Acetonide".

5. In Part III of the Second Schedule to the principal Order -

(a) in entry 6 of column 1 there shall be inserted after "Secretary of State" the words "of the United Kingdom, or persons who are state registered paramedics."; and

(b) in entry 6 of column 2 -

(i) after sub-paragraph (b) there shall be inserted -

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

(ii) 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".

6. This Order may be cited as the Medicines (Prescription Only) (Amendment No. 3) (Jersey) Order 2001 and shall come into force on the first day of February 2001.

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By Order of the Health and Social Services Committee,

C.M. NEWCOMBE

Greffier of the States.

10th January 2001.

Explanatory Note

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Medicines (Prescription Only) (Amendment No. 3) (Jersey) Order 2001

Health and Social Services Committee

This Order further amends the Medicines (Prescription Only) (Jersey) 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 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 Schedule 1 to the principal Order, products are included in a class of medicines by reason of the substances contained in them, subject to their being excluded in specified circumstances. Schedule 2 to the principal Order lists the persons exempt from the restrictions on the sale or supply of prescription only medicines imposed by Article 57(2) of the Medicines (Jersey) Law, 1995, and the conditions under which those exemptions are operative.

The amendments made by this Order are as follows -

Amendment of the conditions under which products containing the substance Felbinac may be sold or supplied otherwise than as a prescription only medicine (to increase from 30 g to 50 g the maximum amount of medicinal product that may be contained in a container or package);

Amendment of the conditions under which medicinal products containing Azelastine Hydrochloride, Domperidone Maleate, Paracetamol and Triamcinolone Acetonide may be sold or supplied otherwise than as prescription only medicines;

An exemption from the restrictions on sale and supply of prescription only medicines for products containing the substance Ibuprofen where they are for external use, of maximum strength 10 per cent, have a maximum pack size of 50 grams, and are for administration at a maximum dose of 125 mg and a maximum daily dose of 500 mg;

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An amendment 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;

The inclusion in Schedule 1 to the principal Order of the substance Levocarnitine with an exemption where products are for use for dietary supplementation;

The inclusion in Schedule 1 of the substance Terbinafine Hydrochloride, with an exemption for products which are for external use for the treatment of tinea pedis or tinea cruris, with a maximum pack size of 15 grams and a maximum strength of 1 per cent;

The inclusion in Schedule 1 to the principal Order of the substances Acamprosate, Aceclofenac, Alendronate Sodium, Altretamine, Apraclonidine Hydrochloride, Bicalutamide, Calcipotriol Hydrate, Cefprozil, Didanosine, Exemestane, Ferumoxsil, Imidapril Hydrochloride, Lercanidipine Hydrochloride, Meloxicam, Moexipril Hydrochloride, Moxonidine, Omeprazole Magnesium, Penciclovir, Quinagolide Hydrochloride, Ranitidine Bismuth Citrate, Rimexolone, Sevoflurane, Sparfloxacin, Tamsulosin Hydrochloride, Ticlopidine Hydrochloride, Tiludronate Disodium, Topiramate, Toremifene, Valaciclovir Hydrochloride and Venlafaxine Hydrochloride.

The amendment of Part III of the Second Schedule to the principal Order to extend the exemption from the prohibition to state registered paramedics, and to add to the list of medicines which may be administered by paramedics, medicines containing the substances Ergometrine Maleate 500 mcg per ml with Oxytocin 5 iu per ml, and medicines containing the substances Benzylpenicillin, Frusemide, Metoclopramide, Morphine Sulphate and Streptokinase.

The Order was made on 10th January 2001 and comes into force on 1st February 2001.

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