Jersey R & O 1/2000

Medicines (Jersey) Law 1995

MEDICINES (PRESCRIPTION ONLY) (AMENDMENT No. 2) (JERSEY) ORDER 2000

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. In Article 9(3)(b)(ii) of the Medicines (Prescription Only) (Jersey) Order 1997,[2] as amended[3] (in this Order called "the principal Order"), there shall be inserted before the words "an aerosol for the relief of asthma" the words "a preparation of insulin,".

2.-(1) In Part I of the First Schedule to the principal Order, in column 1, the word "Desmopressin" shall be deleted in the second place where it occurs.

(2) In Part I of the First Schedule to the principal Order, there shall be substituted for the entries relating to minoxodil, in the columns (and under the headings) respectively indicated in Schedule 1 to this Order, the entries specified in Schedule 1 to this Order.

(3) In Part I of the First Schedule to the principal Order, there shall be inserted –

(a) in their appropriate alphabetical order; and

(b) in the columns (and under the headings) respectively indicated in Schedule 2 to this Order,

the entries specified in Schedule 2 to this Order.

1 Recueil des Lois, Volume 1994–1995, pages 507 and 569.
2 No. 9140.
3 No. 9326.

(4) In Part I of the First Schedule to the principal Order, in column 1, there shall be inserted in their appropriate alphabetical order the substances specified in Schedule 3 to this Order.

3. For Part IV of the First Schedule to the principal Order, there shall be substituted the Part set out in Schedule 4 to this Order.

4. In Part I of the Second Schedule to the principal Order, in column 2 of paragraph 4 (which relates to certified midwives), beneath the words "Pentazocine hydrochloride" there shall be inserted the word "Phytomenadrone".

5. In Part III of the Second Schedule to the principal Order, in column 2 of paragraph 1 (which relates to state registered chiropodists), beneath the second entry relating to "Lignocaine hydrochloride" there shall be inserted the words "Mepivacaine hydrochloride".

6. This Order may be cited as the Medicines (Prescription Only) (Amendment No. 2) (Jersey) Order 2000 and shall come into force on the first day of February 2000.

By Order of the Health and Social Services Committee,

C.M. NEWCOMBE

Deputy Greffier of the States.

12th January 2000.

SCHEDULE 1

(Article 2(2))

Entry to be substituted in Part I of First Schedule to principal Order in columns (and under headings) indicated

Prescription Only Medicine	**Circumstances In Which Substances Are Not Prescription Only Medicines**		
Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Minoxidil	(1) 2.0 per cent	External	
	(2) 5.0 per cent	External, for the treatment of alopecia androgenetica in men who have attained the age of 18 years but have not attained the age of 65 years	

SCHEDULE 2

(Article 2(3))

Entries to be inserted in Part 1 of First Schedule to principal Order in columns (and under headings) indicated

Prescription Only Medicine	**Circumstances In Which Substances Are Not Prescription Only Medicines**		
Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Diphenhydramine Hydrochloride		All preparations except liquid-filled capsules	
Ibuprofen Lysine		Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza	
		Internal	(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)
Phytomenadine	Any use except the prevention or treatment of haemorrhagic disorders	

SCHEDULES 3

(Article 2(4))

Substances to be inserted in Column 1 of Part 1 of First Schedule to principal Order

Aloxiprin
Hydrocyanic Acid
Levocabastine Hydrochloride
Lornoxicam
Nebivolol Hydrochloride
Nilutamide
Nisoldipine
Phenolphthalein
Pirenzepine Dihydrochloride Monohydrate
Propiverine Hydrochloride
Quinapril Hydrochloride
Strychnine Nitrate
Sulphabenzamide
Tacalcitol Monohydrate

SCHEDULE 4

New Part IV to be substituted in First Schedule to principal Order

(Article 3)

PART IV

(Article 3(4))

OTHER MEDICINAL PRODUCTS THAT ARE NOT PRESCRIPTION ONLY MEDICINES

1. A medicinal product shall not be a prescription only medicine by reason that it contains the substance aciclovir, where –

(a) the maximum strength of the aciclovir in the medicinal product does not exceed 5 per cent;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 2 g of the medicinal product; and

(c) the medicinal product is indicated only for external application for the treatment of herpes simplex virus infections of the lips and face (Herpes labialis).

2. A medicinal product shall not be a prescription only medicine by reason that it contains the substance acrivastine, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 240 mg of acrivastine; and

(b) the container or package is labelled to show a maximum daily dose of 24 mg of acrivastine.

3. A medicinal product shall not be a prescription only medicine by reason that it contains the substance aloxiprin, where –

(a) the medicinal product is in the form of non-effervescent tablets or capsules;

(b) the maximum strength of the medicinal product in each tablet or capsule does not exceed 620 mg;

(c) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied in one container or package does not exceed thirty-two; and

(d) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied to a person at any one time does not exceed one hundred.

4. A medicinal product shall not be a prescription only medicine by reason that it contains the substance aloxiprin, where it is not in the form of a non-effervescent tablet or capsule.

5. A medicinal product shall not be a prescription only medicine by reason that it contains the substance aspirin, where –

(a) the medicinal product is in the form of non-effervescent tablets or capsules;

(b) the maximum strength of the medicinal product in each tablet or capsule does not exceed 75 mg;

(c) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied in one container or package does not exceed one hundred; and

(d) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied to a person at any one time does not exceed one hundred.

6. A medicinal product shall not be a prescription only medicine by reason that it contains the substance aspirin, where –

(a) the medicinal product is in the form of non-effervescent tablets or capsules;

(b) the maximum strength of the medicinal product in each tablet or capsule does not exceed 325 mg;

(c) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied in one container or package does not exceed thirty-two; and

(d) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied to a person at any one time does not exceed one hundred.

7. A medicinal product shall not be a prescription only medicine by reason that it contains the substance azelastine hydrochloride, where –

(a) the medicinal product is in non-aerosol, aqueous form for nasal administration;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 36 doses each of which contains not more than 140 mcg of azelastine hydrochloride;

(c) the container or package is labelled to show a maximum dose of 140 mcg per nostril and a maximum daily dose of 280 mcg per nostril of azelastine hydrochloride; and

(d) the medicinal product is indicated only for the treatment of seasonal allergic rhinitis, in persons aged not less than 12 years.

8. A medicinal product shall not be a prescription only medicine by reason that it contains the substance beclomethasone dipropionate, where –

(a) the medicinal product is in non-aerosol form for nasal administration;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 5,600 mcg of beclomethasone diopropionate;

(c) the container or package is labelled to show a maximum dose of 100 mcg per nostril and a maximum daily dose of 200 mcg per nostril of beclomethasone dipropionate; and

(d) the medicinal product is indicated only for the prevention of treatment of allergic rhinitis, in persons aged not less than 12 years.

9. A medicinal product shall not be a prescription only medicine by reason that it contains the substance budesonide, where –

(a) the medicinal product is in non-aerosol, aqueous form for nasal administration;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 10 mg of the medicinal product;

(c) the container or package is labelled to show a maximum dose, and a maximum daily dose, of 200 mcg per nostril of budesonide; and

(d) the medicinal product is indicated only for the prevention of treatment of seasonal allergic rhinitis, in persons aged not less than 12 years.

10. A medicinal product shall not be a prescription only medicine by reason that it contains the substance carbenoxolone sodium, where –

(a) the medicinal product is in the form of granules;

(b) the maximum strength of the carbenoxolone sodium in the medicinal product does not exceed one per cent, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 560 mg of carbenoxolone sodium;

(d) the container or package is labelled to show a maximum dose of 20 mg and a maximum daily dose of 80 mg of carbenoxolone sodium; and

(e) the medicinal product is indicated only for treatment by mouthwash, in persons aged not less than 12 years.

11. A medicinal product shall not be a prescription only medicine by reason that it contains the substance cetirizine, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 100 mg of cetirizine; and

(b) the container or package is labelled to show a maximum daily dose of 10 mg of cetirizine.

12. A medicinal product shall not be a prescription only medicine by reason that it contains the substance cimetidine, where –

(a) the container or package in which the medicinal product is sold or supplied is labelled to show a maximum dose of 200 mg and a maximum daily dose of 800 mg of cimetidine for a maximum period of 14 days; and

(b) the medicinal product is indicated for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity and for the prophylaxsis of meal-induced heartburn.

13. A medicinal product shall not be a prescription only medicine by reason that it contains the substance cimetidene, where –

(a) the medicinal product is for the prophylactic management of nocturnal heartburn; and

(b) the container or package in which the medicinal product is sold or supplied is labelled to show a maximum dose of 100 mg of cimetidine to be taken once daily at night for a maximum period of 14 days.

14. A medicinal product shall not be a prescription only medicine by reason that it contains the substance diclofenac diethylammonium, where –

(a) the maximum strength of the diclofenac diethylammonium in the medicinal product does not exceed 1.16 per cent, calculated in terms of weight in weight;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 30 g of the medicinal product;

(c) the container or package is labelled to show a maximum period of use of 7 days; and

(d) the medicinal product is indicated for external application for the local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localized forms of soft tissue rheumatism, in persons aged not less than 12 years.

15. A medicinal product shall not be a prescription only medicine by reason that it contains the substance domperidone maleate, where –

(a) the medicinal product is sold in a container, or package, containing not more than 100 mg of domperidone maleate;

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

(c) the medicinal product is indicated for use for the relief of postprandial symptoms of excessive fullness, nausea, epigastric bloating and belching, accompanied by epigastric discomfort and heartburn.

16. A medicinal product shall not be a prescription only medicine by reason that it contains the substance famotidine, where –

(a) the container or package in which the medicinal product is sold or supplied is labelled to show a maximum dose of 10 mg and a maximum daily dose of 20 mg of famotidine for a maximum period of 14 days; and

(b) the medicinal product is indicated for –

(i) the short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion or hyperacidity; or

(ii) the prevention of the symptoms of heartburn, dyspepsia, indigestion, acid indigestion or hyperacidity where they are associated with the consumption of food or drink, including the prevention of sleep disturbance because of those symptoms.

17. A medicinal product shall not be a prescription only medicine by reason that it contains the substance felbinac, where –

(a) the maximum strength of the felbinac in the medicinal product does not exceed 3.17 per cent, calculated in terms of weight in weight;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 30 mg of the medicinal product;

(c) the container or package is labelled to show a maximum period of use of 7 days; and

(d) the medicinal product is indicated for external application for the relief of symptoms associated with soft tissue injury such as strains, sprains and contusions, in persons aged not less than 12 years.

18. A medicinal product shall not be a prescription only medicine by reason that it contains the substance fluconazole, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 150 mg of the medicinal product;

(b) the container or package is labelled to show a maximum dose of 150 mg of fluconazole; and

(c) the medicinal product is indicated for oral administration for the treatment of vaginal candidiasis, in persons aged not less than 16 years but less than 60 years.

19. A medicinal product shall not be a prescription only medicine by reason that it contains the substance flunisolide, where –

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

(b) the maximum strength of the flunisolide in the medicinal product does not exceed 0.025 per cent, calculated in terms of weight in volume;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 240 metered doses of the medicinal product;

(d) the container or package is labelled to show a maximum dose of 50 mcg per nostril and a maximum daily dose of 100 mcg per nostril of flunisolide in the case of persons aged not less than 16 years, and a maximum dose of 25 mcg per nostril and a maximum daily dose of 75 mcg per nostril in the case of children aged not less than 12 years but less than 16 years; and

(e) the medicinal product is indicated for the prevention and treatment of seasonal allergenic rhinitus, including hay fever, in persons aged not less than 12 years.

20. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hydrocortisone, where –

(a) the maximum strength of the hydrocortisone in the medicinal product does not exceed 0.5 per cent, calculated in terms of weight in weight;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 15 g of the medicinal product; and

(c) the medicinal product is indicated for external use in combination with nystatin of a maximum strength of 3.0 per cent, for intertrigo, in persons aged not less than 10 years.

21. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hydrocortisone, where –

(a) the medicinal product is in the form of a cream, ointment or spray;

(b) the maximum strength of the hydrocortisone in the medicinal product does not exceed 1.0 per cent, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing –

(i) where the medicinal product is in the form of a cream or ointment, not more than 15 g of the medicinal product; or

(ii) where the medicinal product is in the form of a spray, not more than 30 ml of the medicinal product;

(d) the medicinal product is indicated for external use, either alone or in conjunction with crotamiton in irritant dermatitis, contact allergic dermatitis, insect bite reactions or mild to moderate eczema, and either in combination with clotrimazole or miconazole nitrate for athlete's foot and candidal intertrigo or in combination with lignocaine for anal and perianal itch associated with haemorrhoids; and

(e) the medicinal product is indicated for use in persons aged not less than 10 years.

22. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hydrocortisone acetate, where –

(a) the medicinal product is in the form of a cream or ointment, or suppositories;

(b) the maximum strength of the hydrocortisone acetate in the medicinal product is equivalent to 1.0 per cent of hydrocortisone, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing –

(i) where the medicinal product is in the form of a cream or ointment, not more than 15 g of the medicinal product; or

(ii) where the medicinal product is in the form of suppositories, not more than 12 suppositories;

(d) the medicinal product is indicated for external use, in irritant dermatitis, contact allergic dermatitis, insect bite reactions, or mild to moderate eczema, and in combination with one or more of the following, namely benzyl benzoate bismuth oxide, bismuth subgallate, peru balsam pramoxine hydrochloride and zinc oxide, for haemorrhoids; and

(e) the medicinal product is indicated for use in persons aged not less than 10 years.

23. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hydrocortisone sodium succinate, where –

(a) the medicinal product is in the form of pellets;

(b) the maximum strength of the hydrocortisone sodium succinate in the medicinal product is equivalent to 2.5 mg of hydrocortisone, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing the equivalent of 50 mg of hydrocortisone; and

(d) the medicinal product is indicated for external use for aphthous ulceration of the mouth, in persons aged not less than 12 years.

24. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hydroxyzine hydrochloride, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 750 mg of the medicinal product;

(b) the container or package is labelled to show a maximum dose of 25 mg, and to show a maximum daily dose of 75 mg in the case of persons aged not less than 12 years and a maximum daily dose of 50 mg in the case of children aged not less than 6 years but less than 12 years; and

(c) the medicinal product is indicated for the management of pruritus associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in persons aged not less than 6 years.

25. A medicinal product shall not be a prescription only medicine by reason that it contains the substance hyoscine butylbromide, where –

(a) the route of administration of the medicinal product is internal and is otherwise than by means of an inhaler;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 240 mg of the medicinal product; and

(c) the container or package is labelled to show a maximum dose of 20 mg and a maximum daily dose of 80 mg of the medicinal product.

26. A medicinal product shall not be a prescription only medicine by reason that it contains the substance ketoconazole, where –

(a) the medicinal product is in the form of a shampoo;

(b) the maximum strength of the ketoconazole in the medicinal product does not exceed 2 per cent, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 120 ml of the medicinal product and containing in the medicinal product not more than 2,400 mg of ketoconazole;

(d) the container or package is labelled to show a maximum frequency of application of once every three days; and

(e) the medicinal product is indicated for the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp.

27. A medicinal product shall not be a prescription only medicine by reason that it contains the substance ketoprofen, where –

(a) the maximum strength of the ketoprofen in the medicinal product does not exceed 2.5 per cent, calculated in terms of weight in weight;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 30 grams of the medicinal product; and

(c) the medicinal product is indicated only for treatment by external topical application, for rheumatic and muscular pain, in persons aged not less than 12 years, for a maximum period of 7 days.

28. A medicinal product shall not be a prescription only medicine by reason that it contains the substance levocabastine hydrochloride, where –

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

(b) the maximum strength of the medicinal product does not exceed the equivalent of 0.05 per cent levocabastine;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 10 ml of the medicinal product; and

(d) the medicinal product is indicated for the symptomatic treatment of seasonal allergic rhinitis.

29. A medicinal product shall not be a prescription only medicine by reason that it contains the substance levocabastine hydrochloride, where –

(a) the medicinal product is in the form of aqueous eye drops;

(b) the maximum strength of the medicinal product does not exceed the equivalent of 0.05 per cent levocabastine;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 4 ml of the medicinal product; and

(d) the medicinal product is indicated for the symptomatic treatment of seasonal allergic conjunctivitis.

30. A medicinal product shall not be a prescription only medicine by reason that it contains the substance loratadine, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 100 mg of loratadine; and

(b) the container or package is labelled to show a maximum daily dose of 10 mg of loratadine.

31. A medicinal product shall not be a prescription only medicine by reason that it contains the substance mebendazole, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 800 mg of mebendazole;

(b) the container or package is labelled to show a maximum dose of 100 mg of mebendazole; and

(c) the medicinal product is indicated for oral use in the treatment of enterobiasis, in persons aged not less than 2 years.

32. A medicinal product shall not be a prescription only medicine by reason that it contains the substance nedocromil sodium, where –

(a) the maximum strength of the nedocromil sodium in the medicinal product does not exceed 2.0 per cent, calculated in terms of weight in volume;

(b) the medicinal product is sold in a container, or package, containing not more than 3 ml of the medicinal product; and

(c) the medicinal product is indicated for the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis.

33. A medicinal product shall not be a prescription only medicine by reason that it contains the substance nizatidine, where –

(a) the container or package in which the medicinal product is sold or supplied is labelled to show a maximum dose of 75

mg of nizatidine and a maximum of 4 such doses in any period of 14 days; and

(b) the medicinal product is indicated only for the prevention of the symptoms of food-related heartburn, in persons aged not less than 16 years.

34. A medicinal product shall not be a prescription only medicine by reason that it contains the substance nystatin, where –

(a) the maximum strength of the nystatin in the medicinal product does not exceed 3.0 per cent, calculated in terms of weight in weight;

(b) the medicinal product is sold in a container, or package, containing not more than 15 g of the medicinal product; and

(c) the medicinal product is indicated for external use in combination with hydrocortisone of a maximum strength of 0.5 per cent for intertrigo, in persons aged not less than 10 years.

35. A medicinal product shall not be a prescription only medicine by reason that it contains the substance oxethazaine, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 400 ml of oxethazaine; and

(b) the container or package is labelled to show a maximum dose of 10 ml and a maximum daily dose of 30 ml of oxethazaine.

36. A medicinal product shall not be a prescription only medicine by reason that it contains the substance paracetamol, where –

(a) the medicinal product is in the form of non-effervescent tablets or capsules;

(b) the maximum strength of the medicinal product in each tablet or capsule does not exceed 500 mg;

(c) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied in one container or package does not exceed thirty-two;

(d) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied to a person at any one time does not exceed one hundred; and

(e) the medicinal product is indicated for use by administration to persons aged not less than 12 years.

37. A medicinal product shall not be a prescription only medicine by reason that it contains the substance paracetamol, where –

(a) the medicinal product is in the form of non-effervescent tablets or capsules;

(b) the maximum strength of the medicinal product in each tablet or capsule does not exceed 120 mg;

(c) the quantity (of tablets or capsules, or of any combination of tablets and capsules) that is sold or supplied in one container or package does not exceed thirty-two; and

(d) the quantity (of tablets and capsules, or of any combination of tablets and capsules) that is sold or supplied to a person at any one time does not exceed one hundred.

38. A medicinal product shall not be a prescription only medicine by reason that it contains the substance piroxicam, where –

(a) the maximum strength of the piroxicam in the medicinal product does not exceed 0.5 per cent;

(b) the medicinal product is sold or supplied in a container, or package, containing not more than 30 mg of the medicinal product;

(c) the container or package is labelled to show a maximum period of use of 7 days; and

(d) the medicinal product is indicated for external application for the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries, in persons aged not less than 12 years.

39. A medicinal product shall not be a prescription only medicine by reason that it contains the substance pyrantel embonate, where –

(a) the medicinal product is sold or supplied in a container, or package, containing not more than 750 mg of the medicinal product;

(b) the container or package is labelled to show a maximum daily dose (to be taken as a single dose) of pyrantel embonate of 750 mg in the case of persons aged not less than 12 years, of 500 mg in the case of children aged not less than 6 years but less than 12 years, and of 250 mg in the case of children aged not less than 2 years but less than 6 years; and

(c) the medicinal product is indicated for the treatment of enterobiasis, in persons aged not less than 2 years.

40. A medicinal product shall not be a prescription only medicine by reason that it contains the substance ranitidine hydrochloride, where –

(a) the container or package in which the medicinal product is sold or supplied is labelled to show a maximum dose equivalent to 75 ml and a maximum daily dose equivalent to 300 ml of ranitidine for a maximum period of use of 14 days; and

(b) the medicinal product is indicated for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, or the prevention of those symptoms when associated with the consumption of food and drink.

41. A medicinal product shall not be a prescription only medicine by reason that it contains the substance sodium cromoglycate, where –

(a) the medicinal product is in the form of aqueous eye drops;

(b) the maximum strength of the sodium cromoglycate in the medicinal product does not exceed 2 per cent, calculated in terms of weight in volume;

(c) the medicinal product is sold or supplied in a container containing not more than 10 ml of the medicinal product; and

(d) the medicinal product is indicated for treatment of acute seasonal allergic conjunctivitis.

42. A medicinal product shall not be a prescription only medicine by reason that it contains the substance sodium cromoglycgate, where –

(a) the medicinal product is in the form of an eye ointment;

(b) the maximum strength of the sodium cromoglycate in the medicinal product is 4 per cent, calculated in terms of weight in weight;

(c) the medicinal product is sold or supplied in a container, or package, containing not more than 5 g of the medicinal product; and

(d) the medicinal product is indicated for the treatment of acute seasonal allergic conjunctivitis or perennial allergic conjunctivitis.