

- 35.** Sections 56 and 57 are revoked.
- 36.** Sections 59 and 60 are revoked.
- 37.** Section 62 is revoked.
- 38.** Sections 64 to 66 are revoked.
- 39.** Subdivision 6 of Division V, comprising sections 68 to 76, is revoked.

**40.** Section 80 is amended by deleting the word “public” preceding the word “telephone”.

**41.** The following is substituted for section 81:

“**81.** Every tourist information office must also offer the public an area large enough to park at least five automobiles, if no public parking is available within a 100-metre radius of the establishment.”.

**42.** The following is substituted for section 82:

“**82.** The days on which a tourist information office is open and its business hours must be posted in public view outside the establishment.”.

**43.** Section 83 is amended

(1) by deleting the words “or a camping establishment” in the part preceding paragraph 1; and

(2) by striking out paragraph 7.

**44.** Section 86 is amended

(1) by deleting the words “or camping establishment” in the part preceding paragraph 1; and

(2) by substituting the following for paragraphs 1 and 2:

“(1) in every sleeping-accommodation unit, for an establishment in the “small hotels”, “medium-sized hotels”, “large hotels”, “tourist homes” or “bed and breakfast establishments” or “teaching establishments” subclass;

(2) in the area for receiving and registering customers, for an establishment in the “youth hostels” subclass.”.

**45.** This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*, except section 7, paragraph 1 of section 8 in respect of camping establishments, para-

graph 1 of section 11 and paragraph 2 of that section in respect of camping establishments, sections 12, 15 and 16, paragraph 2 of section 17, section 20, paragraph 2 of section 21, sections 25 to 27, paragraph 3 of section 28 and sections 39 and 43, which will come into force on 1 November 1997.

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Gouvernement du Québec

### O.C. 776-97, 11 juin 1997

An Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32)

#### Basic prescription drug insurance plan

Regulation to amend the Regulation respecting the basic prescription drug insurance plan

WHEREAS under subparagraph 3 of the first paragraph of section 78 of the Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32), the Government may, after consulting the Régie de l'assurance-maladie du Québec, make regulations to determine the cases, conditions and therapeutic indications in and for which the cost of certain medications included in the list drawn up by the Minister under section 60 of the Act is covered by the basic plan; the conditions may vary according to whether the coverage is provided by the Board or under a group insurance contract or an employee benefit plan;

WHEREAS under section 79 of the Act, such a regulation is not subject to the requirements concerning publication and the date of coming into force contained in sections 8 and 17 of the Regulations Act (R.S.Q., c. R-18.1);

WHEREAS the Government made the Regulation respecting the basic prescription drug insurance plan by Order in council 1519-96 dated 4 December 1996;

WHEREAS it is expedient to amend the Regulation;

WHEREAS in accordance with section 78 of the Act respecting prescription drug insurance and amending various legislative provisions, the Régie de l'assurance-maladie du Québec has been consulted on the amendments;

IT IS ORDERED, therefore, upon the recommendation of the Minister of Health and Social Services:

THAT the Regulation to amend the Regulation respecting the basic prescription drug insurance plan, attached to this Order in Council, be made.

MICHEL CARPENTIER,  
*Clerk of the Conseil exécutif*

## Regulation to amend the Regulation respecting the basic prescription drug insurance plan

An Act respecting prescription drug insurance and amending various legislative provisions (1996, c. 32, s. 78, 1<sup>st</sup> par., subpar. 3)

**1.** The Regulation respecting the basic prescription drug insurance plan, made by Order in Council 1519-96 dated 4 December 1996 and amended by the Regulations made by Orders in Council 1532-96 dated 6 December 1996, 364-97 dated 19 March 1997, 431-97 dated 26 March 1997 and 582-97 dated 30 April 1997, is further amended by substituting the following for subparagraphs 1 to 77 of the second paragraph of section 2.1:

“(1) ACYCLOVIR, tab.:

(a) in immunocompromised persons, for curative and preventive treatment of severe herpes virus infections;

(b) in immunocompetent persons:

i. for early treatment of zona, that is, within 48 to 72 hours following the appearance of lesions;

ii. for suppressive treatment of recurrent herpes, that is, 6 episodes or more per year;

iii. for curative treatment of severe herpes virus infections;

iv. for early curative treatment of varicella-zoster infections in persons 13 years of age or older and in children over 12 months of age suffering from chronic skin diseases or pulmonary disorders or receiving a long-term salicylate-based therapy;

(2) ACYCLOVIR, top. cr., top. oint.:

for local treatment of herpes virus infections in immunocompromised persons;

(3) ALENDRONATE:

(a) for treatment of persons having had osteoporosis-related fractures;

(b) for treatment of symptomatic Paget’s disease;

(c) for treatment of persons unable to tolerate etidronate;

(4) CALCIUM ALGINATE FIBRE:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

(5) ALUMINUM HYDROXIDE:

as a phosphate binder in persons suffering from severe renal failure;

(6) ANETHOL TRITHIONE:

for treatment of persons suffering from severe xerostomia;

(7) BISACODYL:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

(8) BUTORPHANOL TARTRATE, nasal sol.:

for non-prophylactic treatment of migraine episodes or Horton’s syndrome in persons for whom treatment with other opiate analgesics or other drug therapies is ineffective or poorly tolerated;

(9) CALCIUM ACETATE:

as a phosphate binder in persons suffering from severe renal failure;

(10) CALCIUM CARBONATE:

(a) as a calcium supplement for persons suffering from hypoparathyroidism, lactase deficiency or malabsorption;

(b) as a phosphate binder in persons suffering from severe renal failure;

(11) CALCIUM GLUCONATE/CALCIUM GLUCOHEPTONATE:

(a) as a calcium supplement for children suffering from bovine protein or lactose intolerance;

(b) as a calcium supplement for persons suffering from hypoparathyroidism, lactase deficiency or malabsorption and unable to take tablets;

## (12) CAPSAICIN, top. cr.:

for treatment of pain caused by episodes of herpes zoster infection or related to peripheral neuropathies;

## (13) CARBOXYMETHYLCELLULOSE SODIUM:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production, where preservatives are not tolerated or are contraindicated;

## (14) CARVEDILOL:

for treatment of stable symptomatic congestive heart failure in persons receiving a diuretic and an angiotensin converting enzyme inhibitor;

## (15) SODIUM CHLORIDE, dres.:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (16) SODIUM CITRATE/SODIUM LAURYL SULFOACETATE:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (17) CLINDAMYCIN PHOSPHATE, vag. cr.:

for treatment of bacterial vaginosis during the first term of pregnancy;

## (18) CLINDAMYCIN PHOSPHATE, top. sol.:

for treatment of acne vulgaris in persons for whom topical erythromycin is ineffective or poorly tolerated;

## (19) DESMOPRESSIN ACETATE, tab.:

for treatment of diabetes insipidus in persons unable to use a desmopressin nasal spray or nasal solution;

## (20) DICLOFENAC SODIUM, oph. sol.:

for treatment of ocular inflammation in persons for whom ophthalmic corticosteroids are not indicated;

## (21) DIPHENHYDRAMINE HYDROCHLORIDE:

for adjuvant treatment of certain psychiatric disorders and of Parkinson's disease;

## (22) DIPYRIDAMOLE:

(a) for prevention of thromboembolic accidents in persons having valvular or vascular prostheses or having undergone bypass surgery with a vein graft;

(b) for prevention of thromboembolic accidents in persons for whom the conventional therapy is ineffective or contraindicated;

## (23) DOCUSATE CALCIUM:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (24) DOCUSATE SODIUM:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (25) DORNASE ALFA:

(a) during initial treatment in persons over 5 years of age suffering from cystic fibrosis and whose forced vital capacity is more than 40 percent of the predicted value. The maximum initial duration of authorization will be 3 months;

(b) during maintenance treatment in persons for whom the physician provides evidence of a beneficial clinical effect. The authorization will have a maximum duration of one year;

## (26) DORZOLAMIDE HYDROCHLORIDE:

(a) for adjuvant treatment of glaucoma where treatment with a beta-blocker produces insufficient control of ocular tension;

(b) for treatment of glaucoma where a beta-blocker is not tolerated or is contraindicated;

## (27) EPOETIN ALFA:

(a) for treatment of symptomatic anemia related to severe chronic renal failure (during the dialysis stage or before the dialysis stage begins);

(b) for treatment of non-hemolytic symptomatic anemia necessitating regular transfusions in persons having no iron, folic acid or vitamin B12 deficiency and where the anemia persists despite treatment of the underlying causes. In such cases, the maximum initial duration of authorization will be 3 months;

(28) ESTRADIOL-17 $\beta$ :

for persons unable to take oral estrogens because of thromboembolic disorders or unable to tolerate oral estrogens;

(29) ESTRADIOL-17 $\beta$ /NORETHINDRONE ACETATE:

for persons unable to take oral estrogens because of thromboembolic disorders or unable to tolerate oral estrogens or progestogens;

## (30) FAMCICLOVIR:

(a) for early treatment of zona, that is, within 48 to 72 hours following the appearance of lesions;

(b) for curative treatment of severe infectious episodes of recurrent genital herpes;

(c) for suppressive treatment of recurrent genital herpes;

## (31) FENTANYL, skin patch:

for relief of pain in persons unable to tolerate oral morphine preparations or unable to swallow because of a digestive pathology;

## (32) FILGRASTIM:

(a) for treatment of persons undergoing cycles of moderately or highly myelosuppressive chemotherapy ( $\geq 40$  percent risk of febrile neutropenia);

(b) for treatment of persons at risk of developing severe neutropenia during chemotherapy;

(c) in subsequent cycles of chemotherapy, for treatment of persons having suffered from severe neutropenia (neutrophil count below  $0.5 \times 10^9/L$ ) during the first cycles of chemotherapy and for whom a reduction in the antineoplastic dose is inappropriate;

(d) during chemotherapy undergone by children suffering from solid tumours;

(e) for treatment of persons suffering from medullary aplasia (neutrophil count below  $0.5 \times 10^9/L$ ) and awaiting curative treatment by means of a bone marrow transplant or with antithymocyte serum;

(f) for treatment of persons suffering from congenital or hereditary neutropenia whose neutrophil count is below  $0.5 \times 10^9/L$ ;

(g) for treatment of HIV-infected persons suffering from neutropenia secondary to antiretroviral drugs, or secondary to ganciclovir in the case of persons who are unable to tolerate foscarnet and whose neutrophil count remains below  $0.5 \times 10^9/L$ , despite temporary stopping of medication or reduction of dosage;

(h) to stimulate bone marrow in the donor in the case of an allograft, or in the recipient in the case of an autograft;

## (33) FLUCONAZOLE, oral susp.:

(a) for treatment of oropharyngeal candidiasis in persons for whom the conventional therapy is ineffective or poorly tolerated;

(b) for treatment of esophageal candidiasis;

## (34) NUTRITIVE FORMULAS — CASEIN-BASED (INFANTS AND CHILDREN):

(a) for infants and children allergic to complete milk proteins. In such cases, the maximum initial duration of authorization will be up to the age of 9 months. The results of re-exposure to milk must be provided in order for utilization to continue;

(b) for infants and children suffering from galactosemia and requiring a lactose-free diet;

maximum initial duration of authorization: 3 months;

(c) for infants and children suffering from persistent diarrhea or other severe gastrointestinal problems;

maximum initial duration of authorization: 3 months;

## (35) NUTRITIVE FORMULAS — POLYMERIZED GLUCOSE:

to increase the caloric content of other nutritive formulas;

maximum initial duration of authorization: 3 months;

## (36) NUTRITIVE FORMULAS — FRACTIONATED COCONUT OIL:

for persons unable to effectively digest or absorb long-chain fatty foods;

## (37) NUTRITIVE FORMULAS — SKIM MILK/COCONUT OIL:

for persons unable to effectively digest or absorb long-chain fatty foods;

## (38) NUTRITIVE FORMULAS — MONOMERIC:

(a) for total oral feeding, and for enteral feeding of persons requiring liquid nutritive formulas as a source of nutrition, in presence of esophageal dysfunction or dysphagia, maldigestion or malabsorption;

(b) for children suffering from Crohn's disease;

(c) for persons suffering from cystic fibrosis;

maximum initial duration of authorization: 3 months;

## (39) NUTRITIVE FORMULAS — POLYMERIC WITH RESIDUES:

(a) for total oral feeding, and for enteral feeding of persons requiring liquid nutritive formulas as a source of nutrition, in presence of esophageal dysfunction or dysphagia, maldigestion or malabsorption;

(b) for children suffering from Crohn's disease;

(c) for persons suffering from cystic fibrosis;

maximum initial duration of authorization: 3 months;

## (40) NUTRITIVE FORMULAS — LOW-RESIDUE POLYMERIC:

(a) for total oral feeding, and for enteral feeding of persons requiring liquid nutritive formulas as their source of nutrition, in presence of esophageal dysfunction or dysphagia, maldigestion or malabsorption;

(b) for children suffering from Crohn's disease;

(c) for persons suffering from cystic fibrosis;

maximum initial duration of authorization: 3 months;

## (41) NUTRITIVE FORMULAS — PROTEINS/ CARBOHYDRATES &amp; LIPIDS (INFANTS AND CHILDREN):

for infants and children requiring a product low in mineral content;

maximum initial duration of authorization: 3 months;

## (42) GANCICLOVIR, caps.:

for maintenance treatment of cytomegalovirus (CMV) retinitis in immunocompromised persons;

## (43) GRANISETRON HYDROCHLORIDE:

(a) during the first day of a highly emetic chemotherapy or radiotherapy treatment;

(b) in children during highly emetic chemotherapy or radiotherapy;

(c) during chemotherapy or radiotherapy undergone by persons for whom the conventional antiemetic therapy is ineffective or poorly tolerated;

## (44) MINERAL OIL:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (45) HYDROXYPROPYL METHYLCELLULOSE:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (46) HYDROXYPROPYL METHYLCELLULOSE/ DEXTRAN 70:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (47) IDARUBICIN (hydrochloride):

for treatment of acute myelocytic leukemia in adults;

## (48) INDOMETHACIN, oph. sol.:

for treatment of ocular inflammation in persons for whom ophthalmic corticosteroids are not indicated;

## (49) INSULIN LISPRO:

for persons suffering from type I diabetes not controlled by intensive insulin therapy with other insulin preparations;

## (50) INTERFERON BETA 1-B:

for treatment of persons suffering from cyclic remitting multiple sclerosis who are capable of walking, even if they require assistance, and who have had 2 or more episodes of the disease within the last 2 years;

The physician must provide, at the beginning of treatment and with each subsequent request, the following information: number of episodes per year, result on EDSS scale, and adjuvant treatments;

The maximum initial duration of authorization is 6 months. When submitting subsequent requests, the physician must provide evidence of a beneficial effect (absence of deterioration);

(51) KETOROLAC TROMETHAMINE:

for treatment of ocular inflammation in persons for whom ophthalmic corticosteroids are not indicated;

(52) LACTULOSE:

(a) for treatment of hepatic encephalopathy;

(b) for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

(53) MAGNESIUM GLUCOHEPTONATE, oral sol.:

for treatment of persons suffering from hypomagnesemia;

(54) MAGNESIUM GLUCONATE, oral sol.:

for treatment of persons suffering from hypomagnesemia;

(55) MAGNESIUM HYDROXIDE:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

(56) MAGNESIUM HYDROXYDE/ALUMINUM HYDROXYDE:

as a phosphate binder in persons suffering from severe renal failure;

(57) MEGESTROL ACETATE:

(a) for hormone therapy in the treatment of cancer;

(b) for hormone replacement therapy in persons unable to tolerate oral progestogens or for whom oral progestogens are contraindicated;

(58) METRONIDAZOLE, vag. gel:

for treatment of bacterial vaginosis during the second and third terms of pregnancy;

for treatment of bacterial vaginosis in persons unable to tolerate metronidazole administered orally;

(59) MIDAZOLAM:

(a) in palliative care, for persons having an obstruction of the upper respiratory tract or uncontrollable symptoms requiring titrated sedation;

(b) in palliative care, for non-prophylactic treatment of generalized convulsive seizures and of myoclonia where the intravenous route is not advisable;

(60) MIDODRINE HYDROCHLORIDE:

for treatment of orthostatic hypotension in persons for whom the conventional treatment is insufficient or contraindicated;

(61) MINOCYCLINE HYDROCHLORIDE:

for treatment of acne or other superficial skin infections in persons for whom tetracycline would be indicated but is ineffective or poorly tolerated;

(62) MULTIVITAMINS:

for persons suffering from cystic fibrosis;

(63) ONDANSETRON HYDROCHLORIDE:

(a) during the first day of a highly emetic chemotherapy or radiotherapy treatment;

(b) during highly emetic chemotherapy or radiotherapy undergone by children;

(c) during chemotherapy or radiotherapy undergone by persons for whom the conventional antiemetic treatment is ineffective or poorly tolerated;

(64) CARBOXYMETHYLCELLULOSE DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

(65) ACTIVATED CHARCOAL/SILVER DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

(66) COLLAGEN/ALGINATE DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (67) HYDROCOLLOIDAL DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (68) HYDROCOLLOIDAL/ALGINATE DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (69) HYDROGEL DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (70) SEMIPERMEABLE DRESSING:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (71) PARAFFIN/MINERAL OIL:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (72) PENTOXIFYLLINE:

for non-prophylactic treatment of persons suffering from venous insufficiency and having cutaneous ulcers;

## (73) SODIUM PHOSPHATE MONOBASIC/SODIUM PHOSPHATE DIBASIC:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (74) PILOCARPINE HYDROCHLORIDE, tab.:

for treatment of xerostomia occurring during radiotherapy;

## (75) POLYSORBATE 80/VITAMIN A:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (76) HYDROPHILIC POLYURETHANE, dres.:

for treatment of persons suffering from serious burns or severe cutaneous ulcers;

## (77) POLYVINYL ALCOHOL:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (78) POLYVINYL ALCOHOL/POLYETHYLENE GLYCOL 6000:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;;

## (79) POLYVINYL ALCOHOL/POVIDONE:

for treatment of keratoconjunctivitis sicca or other severe conditions accompanied by markedly reduced tear production;

## (80) PSYLLIUM MUCILAGE:

(a) for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

(b) for treatment of chronic diarrhea;

## (81) SENNOSIDES A &amp; B:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

## (82) SOMATROPIN:

(a) for treatment of children suffering from delayed growth due to insufficient secretion of endogenous growth hormone, where they meet the following criteria:

— untermated growth, a growth rate for the child's bone age below the 25<sup>th</sup> percentile (calculated over at least a one-year period), and a serum level of somatropin below 8 ng/mL (measured in two pharmacological tests) or between 8 and 10 ng/mL in tests repeated twice at a 6-month interval. The one-year observation period does not apply to young children suffering from hypoglycemia secondary to growth hormone deficiency;

— excluded are children carrying a Turner's syndrome or suffering from achondroplasia or delayed growth of a genetic or familial type;

— excluded are children whose bone age has reached 15 years for girls and 16 years for boys;

— excluded are children whose growth rate, evaluated on two consecutive visits (at a 3-month interval), falls below 4 cm per year during treatment;

(b) for treatment of children suffering from delayed growth related to chronic renal failure until they undergo a kidney transplant, where they meet the following criteria:

— untermiated growth, a glomerular filtration rate  $\leq 75$  mL/min./1.73m<sup>2</sup>, and a HSDS  $\leq$  a standard deviation of  $-2$  (HSDS = height compared to the average of normal values for the child's age and sex) or a  $\Delta$ HSDS  $<$  a standard deviation of 0 where the child's height is below the 10<sup>th</sup> percentile (based on minimum observation periods of 6 months for children over the age of one and 3 months for children under the age of one);

— excluded are children who have had a pseudotumour, a malignant tumour (a child with a tumour that has been stable for more than 12 months may be eligible) or an epiphysiolysis;

— excluded are children in whom, during treatment, an ossification of the conjugative cartilages is observed, and children who have reached their final predicted height;

— excluded are children in whom, during treatment, complications such as hip problems, a pseudotumour, uncontrolled hyperparathyroidism or a malignant tumour are observed;

— excluded are children in whom, during treatment, no response (no increase in  $\Delta$ HSDS in the first 12 months of treatment) is observed, and children whose growth rate, evaluated on two consecutive visits (at a 3-month interval), falls below 2 cm per year despite an adjustment in the dosage;

#### (83) SOMATREM:

(a) for treatment of children suffering from delayed growth due to insufficient secretion of endogenous growth hormone, where they meet the following criteria:

— untermiated growth, a growth rate for the child's bone age below the 25<sup>th</sup> percentile (calculated over at least a one-year period), and a serum level of somatropin below 8 ng/mL (measured in two pharmacological tests) or between 8 and 10 ng/mL in tests repeated twice at a 6-month interval. The one-year observation period does not apply to young children suffering from hypoglycemia secondary to growth hormone deficiency;

— excluded are children carrying a Turner's syndrome or suffering from achondroplasia or delayed growth of a genetic or familial type;

— excluded are children whose bone age has reached 15 years for girls and 16 years for boys;

— excluded are children whose growth rate, evaluated on two consecutive visits (at a 3-month interval), falls below 4 cm per year during treatment;

(b) for treatment of children suffering from delayed growth related to chronic renal failure until they undergo a kidney transplant, where they meet the following criteria:

— untermiated growth, a glomerular filtration rate  $\leq 75$  mL/min./1.73m<sup>2</sup>, and a HSDS  $\leq$  a standard deviation of  $-2$  (HSDS = height compared to the average of normal values for the child's age and sex) or a  $\Delta$ HSDS  $<$  a standard deviation of 0 where the child's height is below the 10<sup>th</sup> percentile (based on minimum observation periods of 6 months for children over the age of one and 3 months for children under the age of one);

— excluded are children who have had a pseudotumour, a malignant tumour (a child with a tumour that has been stable for more than 12 months may be eligible) or an epiphysiolysis;

— excluded are children in whom, during treatment, an ossification of the conjugative cartilages is observed, and children who have reached their final predicted height;

— excluded are children in whom, during treatment, complications such as hip problems, a pseudotumour, uncontrolled hyperparathyroidism or a malignant tumour are observed;

— excluded are children in whom, during treatment, no response (no increase in  $\Delta$ HSDS in the first 12 months of treatment) is observed, and children whose growth rate, evaluated on two consecutive visits (at a 3-month interval), falls below 2 cm per year despite an adjustment in the dosage;

#### (84) SORBITOL:

for treatment of constipation related to a medical condition and not responding to non-pharmacological measures;

#### (85) TOCOPHERYL dl-ALFA ACETATE:

for prevention and treatment of neurological manifestations associated with malabsorption of vitamin E;



(86) BOTULINUM TOXIN TYPE A:

for treatment of cervical dystonia, blepharospasm, strabismus and other severe spasticity conditions;

(87) TRETINOIN, top. cr., top. gel, top. sol.:

for treatment of acne;

(88) VALACYCLOVIR HYDROCHLORIDE:

(a) for early treatment of zona, that is, within 48 to 72 hours following the appearance of lesions;

(b) for curative treatment of severe infectious episodes of recurrent genital herpes.”

**2.** This Regulation comes into force on 1 July 1997.