

MINISTRY OF HEALTH

No. 37/2008/QĐ-BYT

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

Hanoi, November 20, 2008

DECISION

PROMULGATION OF LIST OF RARE MEDICINES ONLY AVAILABLE ON REQUEST

THE MINISTRY OF FINANCE

Pursuant to the Government's Decree No. 188/2007/ND-CP dated December 27, 2007, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to the Law on Pharmacy No. 34/2005/QH11 dated June 14, 2005;

Pursuant to the Prime Minister's Decision No. 151/2007/QĐ-TTg dated September 12, 2007 of the Prime Minister on import of medicines that have not had registration numbers in Vietnam;

At the request of Director of Drug Administration of Vietnam,

DECIDES THAT:

Article 1. The list of rare medicines is promulgated together with this Decision.

Article 2. This Decision takes effect after 15 days from the day on which it is published on the Official Gazette.

Article 3. The Chief of the Ministry Office, the Chief Inspector, Director of Drug Administration of Vietnam, heads of units affiliated to the Ministry, Director of Services of Health are responsible for the implementation of this Decision./.

**PP THE Minister
DEPUTY MINISTER**

Cao Minh Quang

LIST

RARE MEDICINES ONLY AVAILABLE ON REQUEST

(Promulgated together with the Decision No. 37/2008/QĐ-BYT dated November 20, 2008 of the Minister of Health)

I. PURPOSE

In consideration of the conditions of medical facilities nationwide which are in the need for some medicines that are not available in Vietnam serving a limited number of patients or some medical techniques that have not been widely applied in Vietnam. In order to enable patients to have the medicines they need, the Ministry of Health promulgates a List of rare medicines.

II. RULES AND CRITERIA FOR COMPILING THE LIST OF RARE MEDICINES:

1. Rules:

- The use of the List of rare medicines shall be instructed in relevant documents.
- The list of rare medicines shall be adjusted periodically.

2. Criteria for selection:

A medicine in the List of rare medicine has to satisfy all of the criteria below:

- The medicine is not available in Vietnam (with regard to formula, concentration, and route of administration). There is not any similar medicine registered in Vietnam or there is a similar medicine that has a registration number but it is not sold or its supply is not sufficient.
- The medicine is used for a number of limited patients (inpatients or outpatients).
- The medicine is requested by medical facilities.
- The medicine is not on the list of Medicines not recommended by WHO.
- The medicine has been manufactured and used in one of member States of International Conference Harmonization (including: USA, Europe, Japan) or in one of the member State of Pharmaceutical Inspection Cooperation Scheme (PICs).

III. LIST OF RARE MEDICINES

No.	Active ingredient	Route of administration and/or dosage form and/or concentration
1	Acenocoumarol	Oral administration: Various forms
2	Acetazolamide	Injection: Powder for solution for injection Oral administration: Various forms
3	Acetylcysteine	Injection: Solution for infusion
4	Aciclovir	Injection: Powder for solution for infusion
5	Acitretin	Oral administration: Various forms
6	Altretamin	Oral administration: Various forms
7	Amitriptyline chlorhydrate	Oral administration: Various forms: Orally administered solution
8	Amphotericin B	Injection: Solution for injection
9	Anetholtrihion	Oral administration: Various forms
10	Anti-D immunoglobuline human	Injection: Powder for solution for injection
11	Apomorphine	Oral administration: Various forms
12	Aprotinin	Injection: Solution for infusion
13	Atenolol	Injection: Solution for infusion
14	Atropin	Injection: Solution for injection 1mg/ml Eye drops: 1% solution
15	Azathioprin	Oral administration: Various forms
16	Bacteries BCG	Injection: Solution for injection
17	Betamethasone	Oral administration: oral drops Injection: Solution for injection; mixture for injection

18	Betaxolol	Eye drops
19	Bromocriptin	Oral administration: Various forms
20	Buspirone chlorhydrate	Oral administration: Various forms
21	Busulfan	Oral administration: Various forms
22	Coagulation factor II, VII, VIII, IX, X	Injection: various forms (as a single substance or combined with other elements)
23	Calcipotriol	Topical administration: Topical cream
24	Calcium chloride	Injection: 10% solution for infusion
25	Carbidopa	Oral administration: breakable tablets
26	Cefoxitin	Injection: Powder for solution for intravenous injection
27	Celiprolol	Oral administration: Various forms
28	Cethexonium bromide	Eye drops
29	Chlorpromazine	Injection: Solution for injection Oral administration: oral drops
30	Cibenzoline	Oral administration: Various forms
31	Clofazimine	Oral administration: Various forms
32	Clomipramine	Oral administration: Various forms
33	Clonazepam	Oral administration: Various forms Injection: Solution for injection
34	Clonidine	Injection: Solution for injection Oral administration: Various forms
35	Codeine	Oral administration: Syrup
36	Cholestyramine	Oral administration: Powder pack
37	Colistin (Colimycin)	Injection: Solution for injection Oral administration: Various forms
38	Corticotropin	Hypothalamus hormone diagnosis
39	Cortivazol	Injection: mixture for injection
40	Cromolyn sodium (Cromoglicate de Na)	Injection, oral administration, spray, intravitreal administration
41	Cyclopentolate	Eye drops: diagnostic solution
42	Dacarbazine	Injection: Powder for solution for infusion
43	Dantrolene	Oral administration: tablets Injection: Lyophilized powder for solution for injection
44	Dapsone	Oral administration: tablets (as a single substance or combined with other elements)
45	Desmopressin	Spray
46	Dexamethasone + Oxytetracycline + Polymyxin + Nystatin	Topical administration: Ear spray
47	Dexchlorpheniramine maleate	Injection: Solution for injection
48	Diethylcarbamazine	Oral administration: Various forms

49	Digitoxin	Oral administration: Various forms
50	Digoxin	Injection: Solution for intravenous injection Oral administration: Orally administered solution
51	Dihydroergotamin	Oral administration: tablets
52	Diltiazem	Injection: Solution for injection
53	Dimercaprol	Injection: Solution for intramuscular injection (as a single substance or combined with other elements)
54	Dinoproston	Suppository: sterile vaginal gel, pre-filled syringe
55	Dipyridamol	Injection: Solution for injection Oral administration: Various forms
56	Dorzolamide	Eye drops: eye ointment, intravitreal solution
57	Droperidol	Injection: Solution for injection
58	Ephedrine	Injection: Solution for injection
59	Eptifibatide	Injection: Solution for injection
60	Ergotamin	Oral administration: tablets (as a single substance or combined with other elements)
61	Erythromycin lactobionate	Injection: Powder for solution for infusion
62	Esmolol chlorhydrate	Injection: Solution for injection
63	Estradiol	Transdermal patch
64	Etoposide	Oral administration: Various forms
65	Exemestan	Oral administration: Various forms
66	Fibrinogen	Injection: Powder for solution for injection (as a single substance or combined with other elements)
67	Filgrastim	Injection: Solution for injection
68	Flecainide acetate	Solution for injection; Oral administration: Various forms
69	Fludrocortison acetate + lidocain chlorhydrat + polymyxin	Ear drops
70	Fluindioin	Oral administration: Various forms
71	Flunitrazepam	Oral administration: Various forms
72	Fluorescein	Eye drops Injection: Solution for intravenous injection
73	Recombinant follitropin alpha/ Follitropin beta	Injection: subcutaneous injection, intravenous injection
74	Fosfomycin trometamol	Oral administration: granules for oral solution
75	Fosphenytoin	Injection: Solution for injection
76	Fuller 's Earth (Clay)	Oral administration: Various forms
77	Fusidic Acid	Oral administration: Various forms
78	Glatiramer	Injection: Powder for solution for injection

79	Glucose 1-phosphat di Natri tetrahydrat	Injection: Solution for infusion
80	Halofantrin hydrochloride	Oral administration: tablets
81	Haloperidol	Oral administration: oral drops
82	Calcium heparinate	Injection: Solution for injection
83	Human Chorionic Gonadotropin (HCG)	Injection: intramuscular injection, lyophilized powder tube
84	Human Menotropin Gonadotropin (HMG)	Injection: intramuscular injection, lyophilized powder tube
85	Snake antivenom serum (various type)	Injection: Solution for injection
86	Hydralazine	Injection: Solution for injection Oral administration: Various forms
87	Hydroxycarbamide	Oral administration: Various forms
88	Hydroxychloroquine	Oral administration: Various forms
89	Hydroxyzine	Injection: Solution for injection; Oral administration: Various forms
90	Indometacin	Suppository
91	Interferon bêta-1a	Injection: Various forms
92	Interferon bêta-1b	Injection: Various forms
93	Iohexol	Injection: Solution for injection (for diagnosis)
94	Iopamidol	Injection: Solution for injection
95	Ipratropi bromide	Nose spray
96	Isoprenaline	Injection: Solution for injection Oral administration: Various forms
97	Isosorbide	Injection: Solution for intravenous injection
98	Ivermectin	Oral administration: Various forms
99	Josamycin	Oral administration: Various forms
100	Potassium chloride	Injection: Solution for injection Oral administration: Orally administered solution
101	Potassium iodide	Oral administration: Orally administered solution
102	Labetalol	Injection: Solution for injection Oral administration: Various forms
103	Lauromacrogol 400 (Polidocanol, Aetoxisclerol)	Injection: Solution for injection
104	L-Cystin; Soufre precipit ...	Oral administration: tablets for solution
105	Leucovorin	Injection: intravenous injection; Oral administration: Various forms
106	Levonorgestrel	Intrauterine suppository
107	Linsidomin	Injection: Lyophilized powder for solution for

		injection
108	Lorazepam	Oral administration: Various forms
109	Loxapin	Injection: Solution for injection Oral administration: Various forms
110	Levothyroxine	Oral administration: tablets
111	Magnesi sulfate	Injection: Solution for intravenous injection
112	Magnesium chloride	Injection: 10% solution for injection
113	Mangan glycerophosphate + Ammoni dihydrogenophosphate	Oral administration: Effervescent tablet
114	Mechlorethamine	Injection: Various forms
115	Mecophenolate mofetil	Injection: Solution for intravenous injection
116	Medroxyprogesteron	Oral administration: Various forms
117	Mefloquine	Oral administration: Various forms
118	Meladine (Methoxsalen)	Topical administration
119	Melphalane	Oral administration: Various forms
120	Mercaptopurine	Oral administration: Various forms
121	Mesalazine	Oral administration: Various forms Rectal enema, rectal suppository; emulsion
122	Methylethylmercurine	Oral administration: Orally administered solution Injection: Solution for injection
123	Metoclopramide	Oral drops: 0.1 mg per drop
124	Mexiletine	Injection: Various form; Oral administration: Various forms
125	Milrinone	Injection: Solution for intravenous injection
126	Mitoxantrone	Injection: Solution for injection
127	Molsidomin	Oral administration: tablets
128	Montelukast	Oral administration: 5mg tablets
129	Morniflumate	Rectal suppository
130	Morphine sulfate	Oral administration: Extended-release capsule
131	Nalbuphine	Injection: Solution for injection
132	Naloxone	Injection: Solution for injection
133	Sodium bicarbonate	Injection: 1.4%, 8.4% solution for injection
134	Sodium calcium edetate (E.D.T.A)	Injection: Solution for injection
135	Sodium chloride (NaCl)	Injection: 0.9% solution for injection in 250ml/500ml/1000ml plastic bag; 20% solution for injection in 10ml tube; 10% solution
136	Sodium thiosulfate	Injection: 25% solution for injection
137	Nelfinavir	Oral administration: Various forms
138	Nicardipine	Oral administration: Various forms Injection: Solution for intravenous injection

139	Nilutamid	Oral administration: Various forms
140	Nitroglycerin	Transdermal patch Injection: Solution for injection Spray solution Sublingual tablets
141	Nitroprussiat	Injection: Powder for solution for injection
142	Octreotid	Injection: Solution for injection
143	Oxybuprocain	Eye drops
144	Papaverin	Injection: Solution for injection
145	Acid Para-aminobenzoic	Oral administration: Various forms
146	Paroxetin	Oral administration: Various forms
147	Pemirolast	Eye drops
148	Penicillamin	Oral administration: Various forms
149	Permethrin	Topical administration: Various forms
150	Phenylephrin	Eye drops: solution
151	Phenytoin	Injection: Solution for injection
152	Phloroglucinol	Injection: Solution for injection
153	Phytomenadion	Oral administration: oral emulsion, tablets
154	Pilocarpine	1%, 2% eye drop solution
155	Podophyllotoxin	Topical administration: Topical solution
156	Polystyrene sulfonate	Oral administration: powder for oral solution Rectal enema: mixture
157	Praziquantel	Oral administration: Various forms
158	Prednisolon + Naphazolin	Nose spray
159	Pristinamycin	Oral administration: Various forms
160	Procain chlohydrate	Injection: Solution for injection
161	Procarbazine	Oral administration: Various forms
162	Promegeston	Oral administration: Various forms
163	Propafenon	Oral administration: Various forms
164	Propranolol	Injection: Solution for injection
165	Protamine	Injection: Solution for injection
166	Quinidine	Oral administration: Various forms
167	Quinine	Injection: Solution for injection Oral administration: as a single substance or combined with Thiamin
168	Raubasine dihydroergocristine	Injection: Solution for injection
169	Retinol	Eye drops: eye ointment
170	Salbutamol	Injection: Solution for injection Suppository
171	Selegiline	Oral administration: Various forms
172	Somatropin	Injection: Lyophilized powder for solution for

		injection
173	Sotalol	Injection: Solution for intravenous injection Oral administration: Various forms
174	Sufentanil	Injection: Solution for injection
175	Sulfamethoxazol 400mg + Trimethoprim 80mg	Injection: Solution for infusion
176	Sulfasalazin	Oral administration: Various forms
177	Sulproston	Injection: Lyophilized powder for solution for injection
178	Sumatriptan	Injection: Solution for injection
179	Sunitinib	Oral administration: Various forms
180	Terbutaline	Injection: Solution for injection
181	Tetracaine	Eye drops: solution
182	Tetracosactide	Injection: mixture intravenous injection, intramuscular injection
183	Tetrazepam	Oral administration: Various forms
184	Tiapride	Injection: Solution for injection
185	Tioguanin (6-Thioguanin)	Oral administration: Various forms
186	Topiramate	Oral administration: Various forms
187	Topotecane	Injection: Powder for solution for infusion
188	Triclabendazole	Oral administration: Various forms
189	Trientine	Injection: Various form; Oral administration: Various forms
190	Trihexyphenidyl	Oral administration: solution, tablets
191	Tropatepine	Oral administration: Various forms
192	Trospium	Oral administration: Various forms
193	Urapidil	Injection: Solution for injection
194	Valaciclovir	Oral administration: Various forms
195	Valproic Acid	Injection: Powder for solution for injection
196	Sterile vaseline	Sterile vaseline (used for surgery and endotracheal intubation)
197	Verapamil	Injection: Solution for injection; Oral administration: Various forms
198	Vigabatrin	Oral administration: Various forms
199	Warfarin	Oral administration: Various forms
200	Methylene blue	Injection: Solution for injection
201	Zidovudin	Injection: Solution for injection; Oral administration: Various forms
202	Zopiclon	Oral administration: Various forms

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