Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 December 2006 to 31 December 2006

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2007/C 18/03)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
13.12.2006	Glucomed	See Annex I	See Annex I	14.12.2006
13.12.2006	Agopton	See Annex II	See Annex II	14.12.2006

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
19.12.2006	Cetirizine Nordic Drugs	See Annex III	See Annex III	21.12.2006
19.12.2006	Cetirizine Dermapharm	See Annex IV	See Annex IV	21.12.2006
19.12.2006	Cetirizine Apex	See Annex V	See Annex V	21.12.2006

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT, MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use
Belgium	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use
Cyprus	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Czech Republic	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use
Denmark	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Estonia	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Finland	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
France	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Germany	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Greece	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Hungary	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use
Ireland	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use
Italy	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Lithuania	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Luxemburg	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
The Netherlands	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Poland	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Portugal	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Slovakia	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Spain	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Sweden	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
United Kingdom	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Iceland	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Glucomed	625 mg	Tablet	Oral use
Norway	—	Navamedic ASA Vollsveien 13 C N-1327 Lysaker	Flexove	625 mg	Tablet	Oral use

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Takeda Pharma Ges.m.b.H. Seidengasse 33-35 A-1070 Vienna	AGOPTON	15 mg	Capsule	Oral use
		AGOPTON	30 mg	Capsule	Oral use
		AGOPTON Rapid	15 mg	Oro-dispersible tablet	Oral use
		AGOPTON Rapid	30 mg	Oro-dispersible tablet	Oral use
Belgium	Sanofi-Synthelabo SA NV Dobbelenberg 5, Avenue de la Metrologie B-1130 Brussels	DAKAR	15mg	Capsule	Oral use
		DAKAR	30 mg	Capsule	Oral use
		NIBITOR	30 mg	Capsule	Oral use
Denmark	Wyeth ab Box 1822 S-171 24 Solna	LANZO	15 mg	Capsule	Oral use
		LANZO	30 mg	Capsule	Oral use
Finland	Wyeth AB Box 1822 S-171 24 Solna	LANZO	30 mg	Capsule	Oral use
		LANZO	15 mg	Oro-dispersible tablet	Oral use
		LANZO	30 mg	Oro-dispersible tablet	Oral use
France	Laboratoires Takeda SA 15, quai de Dion Bouton F-92816 Puteaux Cedex	OGAST	15 mg	Capsule	Oral use
		OGAST	30 mg	Capsule	Oral use
	Sanofi-Aventis 46 quai de la Râpée F-75601 Paris Cedex 12	LANZOR	15 mg	Capsule	Oral use
		LANZOR	30 mg	Capsule	Oral use
Germany	Takeda Pharma GmbH Viktoriaallee 3-5 D-52066 Aachen	AGOPTON	15 mg	Capsule	Oral use
		AGOPTON	30 mg	Capsule	Oral use
		LANZOR	15 mg	Capsule	Oral use
		LANZOR	30 mg	Capsule	Oral use
Greece	Vianex S.A. Tatoiou Street EL-146 71 Nea Erythrea, Athens	LAPRAZOL	15 mg	Capsule	Oral use
		LAPRAZOL	30 mg	Capsule	Oral use
		LAPRAZOL FasTab	15 mg	Oro-dispersible tablet	Oral use
		LAPRAZOL FasTab	30 mg	Oro-dispersible tablet	Oral use
Hungary	Gedeon Richter Gyomrói út 19-21 H-1103 Budapest	LANSONE	30 mg	Capsule	Oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	John Wyeth & Brother Limited Trading as Wyeth Pharmaceuticals Huntercombe Lane South Taplow, Maidenhead Berkshire SL6 0PH United Kingdom	ZOTON	15 mg	Capsule	Oral use
		ZOTON	30 mg	Capsule	Oral use
		ZOTON FasTab	15 mg	Oro-dispersible tablet	Oral use
		ZOTON FasTab	30 mg	Oro-dispersible tablet	Oral use
	Cyanamid of Great Briain Ltd. Fareham Road GOSPORT Hampshire PO13 0AS United Kingdom	ZOTON	30mg	Gastro-resistant granules for oral suspension	Oral use
Italy	Takeda Italia Farmaceutici S.p.A. Via Elio Vittorini 129 I-00144 Roma	LANSOX	15 mg	Capsule	Oral use
		LANSOX	30 mg	Capsule	Oral use
		LANGAST	15 mg	Capsule	Oral use
		LANGAST	30 mg	Capsule	Oral use
		LANSOX	15 mg	Oro-dispersible tablet	Oral use
		LANSOX	30 mg	Oro-dispersible tablet	Oral use
	Sigma-Tau S.p.A. Via Pontina km. 30,400 I-00040 Pomezia, Roma	LIMPIDEX	15 mg	Capsule	Oral use
		LIMPIDEX	30 mg	Capsule	Oral use
		LIMPIDEX	15 mg	Oro-dispersible tablet	Oral use
		LIMPIDEX	30 mg	Oro-dispersible tablet	Oral use
	Wyeth Lederle S.p.A. Via Nettunense, 90 I-04011 Aprilia (LT)	ZOTON	15 mg	Capsule	Oral use
		ZOTON	30 mg	Capsule	Oral use
		ZOTON	15 mg	Oro-dispersible tablet	Oral use
		ZOTON	30 mg	Oro-dispersible tablet	Oral use
Luxembourg	Sanofi-Synthelabo SA NV Dobbelenberg, 5, Avenue de la Metrologie B-1130 Brussels	DAKAR	15 mg	Capsule	Oral use
		DAKAR	30 mg	Capsule	Oral use
Netherlands	Sanofi-Synthelabo B.V./Aventis Pharma B.V. Kampenringweg 45 D-E (toren D en E) 2803 PE Gouda Nederland	PREZAL	15 mg	Capsule	Oral use
		PREZAL	30 mg	Capsule	Oral use
Portugal	Seber Portuguesa Farmacêutica, SA Rua Norberto de Oliveira, 1 a 5 P-2620-111 Póvoa de Santo Adrião	OGASTO	15 mg	Capsule	Oral use
		OGASTO	30 mg	Capsule	Oral use
		OGASTO	15 mg	Oro-dispersible tablet	Oral use
		OGASTO	30 mg	Oro-dispersible tablet	Oral use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Almirall Prodesfarma, S.A. General Mitre, 151 E-08022 Barcelona	OPIREN	15 mg	Capsule	Oral use
		OPIREN	30 mg	Capsule	Oral use
		BAMALITE	15 mg	Capsule	Oral use
		BAMALITE	30 mg	Capsule	Oral use
		OPIREN Flas	15 mg	Oro-dispersible tablet	Oral use
		OPIREN Flas	30 mg	Oro-dispersible tablet	Oral use
		BAMALITE Flas	15 mg	Oro-dispersible tablet	Oral use
		BAMALITE Flas	30 mg	Oro-dispersible tablet	Oral use
Sweden	Wyeth AB Box 1822 S-171 24 Solna	LANZO	15 mg	Capsule	Oral use
		LANZO	30 mg	Capsule	Oral use
		LANZO	15 mg	Oro-dispersible tablet	Oral use
		LANZO	30 mg	Oro-dispersible tablet	Oral use
United Kingdom	John Wyeth & Brother Limited Trading as Wyeth Pharmaceuticals Huntercombe Lane South Taplow, Maidenhead Berkshire SL6 0PH United Kingdom	ZOTON	15 mg	Capsule	Oral use
		ZOTON	30 mg	Capsule	Oral use
		ZOTON	30 mg	Gastro-resistant granules for oral suspension	Oral use
		ZOTON FasTab	15 mg	Oro-dispersible Tablet	Oral use
		ZOTON FasTab	30 mg	Oro-dispersible Tablet	Oral use
Iceland	Wyeth AB Box 1822 S-171 24 Solna	LANZO	15 mg	Capsule	Oral use
		LANZO	30 mg	Capsule	Oral use
		ZOTON	15 mg	Capsule	Oral use
		ZOTON	30 mg	Capsule	Oral use
		LANZO	15 mg	Oro-dispersible tablet	Oral use
		LANZO	30 mg	Oro-dispersible tablet	Oral use
Norway	Wyeth AB Box 1822 S-171 24 Solna	LANZO	15 mg	Capsule	Oral use
		LANZO	30 mg	Capsule	Oral use
		LANZO	15 mg	Oro-dispersible tablet	Oral use
		LANZO	30 mg	Oro-dispersible tablet	Oral use

ANNEX III

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

CETIRIZINE DIHYDROCHLORIDE NORDIC DRUGS 10 mg AND ASSOCIATED NAMES

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Denmark	Nordic Drugs AB Geijersgatan 4 C S-200 61 Limhamn	Gardex	10 mg	Film coated tablet	Oral
Finland	Nordic Drugs AB Geijersgatan 2A Box 30035 S-200 61 Limhamn	Gardex 10 mg tabletti, kalvopäällysteinen	10 mg	Film coated tablet	Oral
Netherlands	Nordic Drugs AB Box 30035 S-200 61 Limhamn	Cetirizine dihydrochloride Nordic Drugs 10 mg	10 mg	Film coated tablet	Oral
Norway	Nordic Drugs AB, Box 30035 S-200 61 Limhamn	Acura	10 mg	Film coated tablet	Oral
Sweden	Nordic Drugs AB Box 300 35 S-200 61 Limhamn	Acura	10 mg	Film coated tablet	Oral

ANNEX IV

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

CETIRIZINE DIHYDROCHLORIDE DERMAPHARM 10 mg AND ASSOCIATED NAMES

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Austria	Dermapharm GmbH Türkenstr. 25/12 A-1090 Wien	Cetiderm 10 mg Filmtabletten	10 mg	Film coated tablet	Oral
Belgium	Dermapharm AG Luise-Ullrich-Str. 6 D-82031 Grünwald	Cetirizine dihydrochloride Dermapharm 10 mg filmomhulde tabletten	10 mg	Film coated tablet	Oral
Germany	Dermapharm AG Luise-Ullrich-Str. 6 D-82031 Grünwald	Cetiderm 10 mg Filmtabletten	10 mg	Film coated tablet	Oral
Netherlands	Dermapharm AG Luise-Ullrich-Str. 6 D-82031 Grünwald	Cetirizine dihydrochloride Dermapharm 10 mg tabletten	10 mg	Film coated tablet	Oral

ANNEX V

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

CETIRIZINE DIHYDROCHLORIDE APEX 10 mg AND ASSOCIATED NAMES

Member State	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Belgium	Docpharma N.V. Ambachtenlaan 13 H B-3001 Heverlee	Doccetiri	10 mg	Film coated tablet	Oral
Luxembourg	Docpharma N.V. Ambachtenlaan 13 H B-3001 Heverlee	Doccetiri-10	10 mg	Film coated tablet	Oral
Netherlands	Apex Pharmaceuticals Ltd. 2nd Floor, Devlin House 36 Saint George Street Mayfair W1S 2FW London United Kingdom	Cetirizine dihydrochloride-APEX 10 mg	10 mg	Film coated tablet	Oral