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

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

(2006/C 46/04)

— 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
9.1.2006	Actilyse	See Annex I	See Annex I	10.1.2006
24.1.2006	Ionsys	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse	This Decision is addressed to the Member States	25.1.2006
24.1.2006	Exubera	Aventis/Pfizer EEIG, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	This Decision is addressed to the Member States	25.1.2006
31.1.2006	Macugen	Pfizer Limited, Sandwich, Kent CT13 9NJ, United Kingdom	This Decision is addressed to the Member States	1.2.2006

[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, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, CONTENT AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Boehringer Ingelheim Austria GmbH	Actilyse	20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Belgium	n.v. Boehringer Ingelheim s.a.	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Cyprus	Cyprus Pharm. Organization Ltd.	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Czech Republic	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Denmark	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Estonia	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Finland	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
France	Boehringer Ingelheim, France	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Germany	Boehringer Ingelheim Pharma KG	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Greece	Boehringer Ingelheim Hellas AE	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Hungary	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Ireland	Boehringer Ingelheim Ltd, Royaume-Uni	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml

Member State	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	Boehringer Ingelheim Italia spa	Actilyse	20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Latvia	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Lituania	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Povder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Luxembourg	n.v. Boehringer Ingelheim s.a., Belgique	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Malta	Boehringer Ingelheim Ltd., Royaume-Uni	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Netherlands	Boehringer Ingelheim b.v.	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Poland	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for infusion	Intravenous use	1 mg/ml
Portugal	Boehringer Ingelheim, Lda	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Slovakia	Boehringer Ingelheim International GmbH	Actilyse	20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Slovenia	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml
Spain	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Sweden	Boehringer Ingelheim International GmbH	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
United Kingdom	Boehringer Ingelheim Ltd.	Actilyse	10, 20, 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Iceland	Boehringer Ingelheim International GmbH	Actilyse	50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml or 2 mg/ml
Norway	Boehringer Ingelheim International GmbH	Actilyse	10, 20 50 mg	Powder and solvent for solution for injection and infusion	Intravenous use	1 mg/ml