Summary of Community decisions on marketing authorisations in respect of medicinal products from 15 April 2005 to 15 May 2005

(Published pursuant to Article 12 or Article 34 of Council Regulation (EEC) No 2309/93) [1]

(2005/C 130/04)

— Modification of a marketing authorisation (Article 12 of Council Regulation (EEC) No 2309/93): Accepted

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
20.4.2005	Velcade	Janssen-Cilag International NV, Turnhoutseweg, 30 — B-2340 Beerse	EU/1/04/274/001	22.4.2005
20.4.2005	Viramune	Boehringer Ingelheim International GmbH, Binger Strasse 173 — D-55216 Ingelheim am Rhein	EU/1/97/055/001-002	22.4.2005
20.4.2005	Paxene	Norton Healthcare Limited, Albert Basin, Royal Docks, London E16 2QJ, United Kingdom	EU/1/99/113/001-004	22.4.2005
25.4.2005	Zeffix	Glaxo Group Ltd, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/99/114/001-003	27.4.2005
25.4.2005	HBVAXPRO	Sanofi Pasteur MSD, SNC, 8, rue Jonas Salk, F-69007 Lyon	EU/1/01/183/001-019	27.4.2005
25.4.2005	Humira	Abbott Laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom	EU/1/03/256/001-006	27.4.2005
25.4.2005	GONAL f	Serono Europe Limited, 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/95/001/001-035	27.4.2005
25.4.2005	Trudexa	Abbott Laboratories Ltd, Queenborough, Kent ME11 5EL, United Kingdom	EU/1/03/257/001-006	27.4.2005
27.4.2005	Viagra	Pfizer Limited, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/98/077/001-012	29.4.2005
27.4.2005	Keppra	UCB SA, Allée de la recherche, 60, B-1070 Bruxelles Researchdreef, 60, B-1070 Brussel	EU/1/00/146/001-027	29.4.2005
27.4.2005	Lantus	Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main	EU/1/00/134/012	29.4.2005
27.4.2005	Optisulin	Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main	EU/1/00/133/008	29.4.2005

[1] OJ L 214 of 24.8.1993, p. 1.

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
27.4.2005	Forsteo	Eli Lilly Nederland BV, Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/03/247/001-002	29.4.2005
27.4.2005	Neupopeg	Dompé Biotec SpA, Via San Martino, 12, I-20122 Milano	EU/1/02/228/001-002	29.4.2005
27.4.2005	Cellcept	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire AL7 3AY, United Kingdom	EU/1/96/005/001-006	29.4.2005
27.4.2005	Carbaglu	Orphan Europe, Immeuble 'Le Guillaumet', F-92046 Paris La Défense	EU/1/02/246/001-003	29.4.2005
28.4.2005	Herceptin	Roche Registration Limited, 40 Broadwater Road, Welwyn Garden City, Hertfordshire AL7 3AY, United Kingdom	EU/1/00/145/001	3.5.2005
28.4.2005	Emend	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-006	3.5.2005
28.4.2005	Emend	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262/001-006	3.5.2005
28.4.2005	Enbrel	Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/99/126/006-011	3.5.2005
28.4.2005	Rapamune	Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/01/171/001-012	3.5.2005
29.4.2005	Neulasta	Amgen Europe BV, Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227/001-002	3.5.2005
10.5.2005	Lyrica	Pfizer Ltd; Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	EU/1/04/279/001-025	13.5.2005
10.5.2005	Cancidas	Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/01/196/001-003	13.5.2005
13.5.2005	Apidra	Aventis Pharma Deutschland GmbH, Brueningstraße 50, D-65926 Frankfurt am Main	EU/1/04/285/001-028	18.5.2005

— **Withdrawal of a marketing authorisation (Article 12 of Council Regulation (EEC) No 2309/93)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
25.4.2005	Infanrix Hep B	GlaxoSmithKline Biologicals SA, rue de l'Institut 89, B-1330 Rixensart	EU/1/97/048/001-014	27.4.2005

— **Modification of a marketing authorisation (Article 34 of Council Regulation (EEC) No 2309/93): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
18.4.2005	Bayovac CSF E2	Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom Bayer AG, Geschäftsbereich Tiergesundheit, D-51368 Leverkusen	EU/2/00/025/001-004	20.4.2005
21.4.2005	Eurifel FeLV	Merial, 29 Avenue Tony Garnier, F-69007 Lyon	EU/2/00/019/001-003	27.4.2005
27.4.2005	Ibraxion	Merial, 29 avenue Tony Garnier, F-69007 Lyon	EU/2/99/017/001-006	29.4.2005
27.4.2005	Metacam	Boehringer Ingelheim Vetmedica GmbH, D-55216 Ingelheim am Rhein	EU/2/97/004/001 EU/2/97/004/003-010	29.4.2005

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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