

Kopsavilkums par Kopienas lēmumiem attiecībā uz zāļu tirdzniecības atļaujām no 1.10.2007. līdz 30.10.2007.

(Publicēts atbilstīgi 13. pantam vai 38. pantam Eiropas Parlamenta un Padomes Regulā (EK) Nr. 726/2004 ⁽¹⁾)

(2007/C 288/04)

— Tirdzniecības atļaujas izmaiņas (13. pants Regulā (EK) Nr. 726/2004): Pieņemts

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
2.10.2007.	ADROVANCE	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/06/364/001-009	4.10.2007.
2.10.2007.	Fuzeon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/03/252/001-003	4.10.2007.
3.10.2007.	Aclasta	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/308/001-002	5.10.2007.
4.10.2007.	Thyrogen	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/99/122/001-002	8.10.2007.
4.10.2007.	FOSAVANCE	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/05/310/001-009	11.10.2007.
9.10.2007.	Arixtra	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/206/001-008	11.10.2007.
9.10.2007.	AZILECT	Teva Pharma GmbH Kandelstraße 10 D-79199 Kirchzarten	EU/1/04/304/001-007	11.10.2007.
9.10.2007.	Quixidar	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/02/207/001-008	11.10.2007.
9.10.2007.	Humira	Abbott Laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/03/256/001-010	11.10.2007.

⁽¹⁾ OV L 136, 30.4.2004., 1. lpp.

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9.10.2007.	Myozyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/06/333/001-003	11.10.2007.
15.10.2007.	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/05/315/001	19.10.2007.
15.10.2007.	Levemir	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/04/278/004-006	18.10.2007.
15.10.2007.	Ionsys	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/05/326/001	18.10.2007.
15.10.2007.	Foscan	Biolitec Pharma Ltd United Drug House Magna Drive Dublin 24 Ireland	EU/1/01/197/003-005	18.10.2007.
15.10.2007.	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/99/126/013-015	18.10.2007.
15.10.2007.	Elaprase	Shire Human Genetic Therapies AB Rinkebyvägen 11B S-182 36 Danderyd	EU/1/06/365/001-003	18.10.2007.
15.10.2007.	Zevalin	Bayer Schering Pharma AG D-13342 Berlin	EU/1/03/264/001	18.10.2007.
15.10.2007.	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/98/085/001-034	18.10.2007.
15.10.2007.	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174, avenue de France F-75013 Paris	EU/1/98/086/001-034	23.10.2007.
18.10.2007.	Zenapax	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/99/098/001-002	23.10.2007.
18.10.2007.	Cialis	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland Lilly ICOS Limited St Bride's House 10 Salisbury Square London EC4Y 8EH United Kingdom	EU/1/02/237/001-008	22.10.2007. 24.10.2007.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
19.10.2007.	Zometa	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/01/176/001-006	23.10.2007.
19.10.2007.	Invirase	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/96/026/001-002	23.10.2007.
19.10.2007.	Viracept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/97/054/001 EU/1/97/054/003-005	23.10.2007.
19.10.2007.	Keppra	UCB Pharma SA Allée de la Recherche, 60/ Researchdreef, 60 B-1070 Bruxelles/Brussel	EU/1/00/146/001-030	23.10.2007.
19.10.2007.	Cellcept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/96/005/001-006	23.10.2007.
19.10.2007.	Fasturtec	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/00/170/001-002	23.10.2007.
22.10.2007.	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/05/315/001	24.10.2007.
22.10.2007.	Fabrazyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/01/188/001-006	24.10.2007.
22.10.2007.	Zevalin	Bayer Schering Pharma AG D-13342 Berlin	EU/1/03/264/001	24.10.2007.
23.10.2007.	ACOMPLIA	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/06/344/001-011	25.10.2007.
23.10.2007.	Tritanrix HepB	GlaxoSmithKline Biologicals s.a. rue de l'Institut, 89 B-1330 Rixensart	EU/1/96/014/001-003	25.10.2007.
23.10.2007.	Vasovist	Bayer Schering Pharma AG D-13342 Berlin	EU/1/05/313/001-009	25.10.2007.
23.10.2007.	Telzir	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	EU/1/04/282/001-002	25.10.2007.
23.10.2007.	Zimulti	Sanofi-Aventis 174, avenue de France F-75013 Paris	EU/1/06/345/001-011	25.10.2007.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
23.10.2007.	Hepsera	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/03/251/001-002	25.10.2007.
24.10.2007.	Hycamtin	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	EU/1/96/027/001 EU/1/96/027/003-005	26.10.2007.
24.10.2007.	Competact	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/06/354/001-009	26.10.2007.
24.10.2007.	Tamiflu	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/02/222/001-004	26.10.2007.
24.10.2007.	Avastin	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/04/300/001-002	26.10.2007.
24.10.2007.	Tygacil	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/06/336/001	26.10.2007.
24.10.2007.	FOSAVANCE	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/05/310/001-009	26.10.2007.
24.10.2007.	SUTENT	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/06/347/001-006	26.10.2007.
24.10.2007.	Kaletra	Abbott Laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/01/172/001-005	26.10.2007.
29.10.2007.	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU United Kingdom	EU/1/04/276/033-035	31.10.2007.
29.10.2007.	Zonegran	Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/04/307/001-013	31.10.2007.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
29.10.2007.	Luminity	Bristol-Myers Squibb Pharma Belgium Sprl Chaussée de la Hulpe, 185/ Terhulpsessesteenweg, 185 B-1170 Bruxelles/Brussel	EU/1/06/361/001-002	31.10.2007.
29.10.2007.	Nexavar	Bayer HealthCare AG D-51368 Leverkusen	EU/1/06/342/001	31.10.2007.
30.10.2007.	Noxafil	SP Europe Rue de Stalle, 73/Stallestraat, 73 B-1180 Bruxelles/Brussel	EU/1/05/320/001	5.11.2007.
30.10.2007.	Posaconazole SP	SP Europe Rue de Stalle, 73/Stallestraat, 73 B-1180 Bruxelles/Brussel	EU/1/05/321/001	5.11.2007.
30.10.2007.	Remicade	Centocor B.V. Einsteinweg 101 2333 CB Leiden Nederland	EU/1/99/116/001-003	1.11.2007.
30.10.2007.	Helixate NexGen	Bayer HealthCare AG D-51368 Leverkusen	EU/1/00/144/001-003	2.11.2007.
30.10.2007.	KOGENATE Bayer	Bayer HealthCare AG D-51368 Leverkusen	EU/1/00/143/001-009	2.11.2007.
30.10.2007.	PegIntron	Schering Plough Europe Rue de Stalle, 73/Stallestraat, 73 B-1180 Bruxelles/Brussel	EU/1/00/131/001-050	5.11.2007.
30.10.2007.	ViraféronPeg	Schering Plough Europe Rue de Stalle, 73/Stallestraat, 73 B-1180 Bruxelles/Brussel	EU/1/00/132/001-050	5.11.2007.
30.10.2007.	Epivir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN United Kingdom	EU/1/96/015/001-005	1.11.2007.
30.10.2007.	Rebetol	Schering Plough Europe Rue de Stalle, 73/Stallestraat, 73 B-1180 Bruxelles/Brussel	EU/1/99/107/001-005	5.11.2007.
30.10.2007.	Nonafact	Sanquin Plesmanlaan 125 1066 CX Amsterdam Nederland	EU/1/01/186/001-002	1.11.2007.
31.10.2007.	Xyrem	UCB Pharma Ltd 208 Bath Road Slough Berkshire SL1 3WE United Kingdom	EU/1/05/312/001	7.11.2007.
31.10.2007.	Ammonaps	Swedish Orphan International AB Drottninggatan 98 S-111 60 Stockholm	EU/1/99/120/001-004	7.11.2007.
31.10.2007.	Aldurazyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/03/253/001-003	7.11.2007.

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
31.10.2007.	Fuzeon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/03/252/001-003	7.11.2007.
31.10.2007.	ADROVANCE	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/06/364/001-009	7.11.2007.
31.10.2007.	Tracleer	Actelion Registration Ltd BSI Building 13th Floor 389 Chiswick High Road London W4 4AL United Kingdom	EU/1/02/220/001-005	7.11.2007.
31.10.2007.	Alimta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/290/001-002	7.11.2007.
31.10.2007.	BYETTA	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/06/362/001-004	7.11.2007.

— Tirdzniecības atļaujas apturēšanas atcelšana (20. pants Regulā (EK) Nr. 726/2004)

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
15.10.2007.	Viracept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/97/054/001 EU/1/97/054/003-005	18.10.2007.

— Tirdzniecības atļaujas izmaiņas (38. pants Regulā (EK) Nr. 726/2004): Pieņemts

Lēmuma datums	Zāļu nosaukums	Tirdzniecības atļaujas turētājs	Ieraksta numurs Kopienas reģistrā	Paziņojuma datums
9.10.2007.	Poulvac FluFend H5N3 RG	Fort Dodge Animal Health Ltd Flanders Road Hedge End Southampton SO30 4QH United Kingdom	EU/2/06/060/001-002	11.10.2007.
15.10.2007.	Purevax FeV	Merial 29, Avenue Tony Garnier F-69007 Lyon	EU/2/00/019/005-007	18.10.2007.
29.10.2007.	ProteqFlu Te	Merial 29, Avenue Tony Garnier F-69007 Lyon	EU/2/03/038/005	31.10.2007.

Ja vēlaties apskatīt publisko novērtējuma ziņojumu par attiecīgajām zālēm un ar tām saistītos lēmumus, lūdzam sazināties ar

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