

Bendrijos sprendimų dėl leidimų prekiauti vaistais sąrašas nuo 2009 m. lapkričio 1 d. iki 2009 m. lapkričio 30 d.

(Paskelbtas pagal Europos Parlamento ir Tarybos reglamento (EB) Nr. 726/2004⁽¹⁾ 13 arba 38 straipsnį)

(2010/C 22/02)

— Leidimas prekiauti (Reglamento (EB) Nr. 726/2004 13 straipsnį) išduotas

Sprendimo data	Vaisto pavadinimas	INN (Tarptautinis nepatentuotas pavadinimas)	Leidimo prekiauti turėtojas	Irašo Bendrijos registre numeris	Vaisto forma	ATC kodas (Anatominis terapinis cheminis kodas)	Pranešimo data
2009 11 4	Repaglinide Krka	repaglinidas	KRKA, d. d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA	EU/1/09/579/001-018	Tabletė	A10B X02	2009 11 6
2009 11 4	Copalia HCT	amlodipino besilatas/ valsartanas/hidro- chlorotiazidas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/575/001-060	Plėvele dengta tabletė	C09DX01	2009 11 6
2009 11 4	Dafiro HCT	amlodipino besilatas/ valsartanas/hidro- chlorotiazidas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/574/001-060	Plėvele dengta tabletė	C09DX01	2009 11 6
2009 11 26	Multaq	dronedaronas	Sanofi-Aventis 174 avenue de France 75013 Paris FRANCE	EU/1/09/591/001-004	Plėvele dengta tabletė	Netaikoma	2009 12 1
2009 11 26	Irbesartan/Hydrochlorothiazide Teva	Irbesartanas/hidro- chlorotiazidas	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/583/001-072	Plėvele dengta tabletė	C09D A04	2009 12 1

⁽¹⁾ OL L 136, 2004 4 30, p. 1.

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2009 11 30	Sildenafil Teva	sildenafilis	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/584/001-018	Plėvele dengta tabletė	G04BE03	2009 12 2
2009 11 30	Nevirapine Teva	nevirapinas	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND	EU/1/09/598/001-004	Tabletė	J05AG01	2009 12 2
2009 11 30	Hirobriz Breezhaler	indakaterolio maleatas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/594/001-010	Inhaliaciniai milteliai, kieta kapsulė	Netaikoma	2009 12 2
2009 11 30	Onbrez Breezhaler	indakaterolio maleatas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/593/001-010	Inhaliaciniai milteliai, kieta kapsulė	Netaikoma	2009 12 2
2009 11 30	Oslif Breezhaler	indakaterolio maleatas	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/09/586/001-010	Inhaliaciniai milteliai, kieta kapsulė	Netaikoma	2009 12 2
2009 11 30	Zutectra	Žmogaus hepatito B imunoglobulinas	Biotest Pharma GmbH Landsteinerstr. 5 63303 Dreieich DEUTSCHLAND	EU/1/09/600/001	Injekcinis tirpalas	J06BB04	2009 12 2

— Leidimas prekiauti (Reglamento (EB) Nr. 726/2004 13 straipsnį) pakeistas

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 4	Intelence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	2009 11 6
2009 11 4	Optisulin	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/00/133/001-032	2009 11 6
2009 11 4	Lantus	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/00/134/001-037	2009 11 6
2009 11 4	Ketek	Aventis Pharma S.A. 20 avenue Raymond Aron 92160 Antony FRANCE	EU/1/01/191/001-005	2009 11 6
2009 11 4	Osseor	Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/287/001-006	2009 11 6
2009 11 4	Protelos	Les Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/04/288/001-006	2009 11 6
2009 11 5	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU UNITED KINGDOM	EU/1/04/276/001-020 EU/1/04/276/024-036	2009 11 10
2009 11 5	Tyverb	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/440/001-002	2009 11 9
2009 11 5	Pre-pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/478/001	2009 11 9
2009 11 5	Celsentri	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/07/418/001-010	2009 11 9
2009 11 5	Invega	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/07/395/001-095	2009 11 9

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 5	Foscan	Biolitec Pharma Ltd United Drug House Magna Drive Dublin 24 IRELAND	EU/1/01/197/003-005	2009 11 9
2009 11 6	Fosavance	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/05/310/001-009	2009 11 10
2009 11 9	Januvia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/383/001-018	2009 11 11
2009 11 11	Celvapan	Baxter AG Industriestraße 67 1221 Wien ÖSTERREICH	EU/1/08/506/001	2009 11 12
2009 11 11	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA	EU/1/07/385/001-002 EU/1/07/385/004	2009 11 12
2009 11 11	Pandemrix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/452/001	2009 11 12
2009 11 11	Insuman	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/97/030/028-195	2009 11 13
2009 11 11	PegIntron	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/00/131/001-050	2009 11 13
2009 11 11	Soliris	Alexion Europe S.A.S. 25 boulevard de l'Amiral Bruix 75016 Paris FRANCE	EU/1/07/393/001	2009 11 13
2009 11 11	Rebetol	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/107/001-005	2009 11 13
2009 11 12	Intence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	2009 11 17

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 12	IntronA	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/127/001-044	2009 11 17
2009 11 12	ViraferonPeg	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/00/132/001-050	2009 11 17
2009 11 19	IntronA	Schering Plough Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/99/127/031-039	2009 11 23
2009 11 19	Clopidogrel Pharma	Teva Teva Pharma B.V. Computerweg 10 3542 DR Utrecht NEDERLAND HCS bvba, H. Kennisstraat 53 2650 Edegem BELGIË	EU/1/09/561/001-009	2009 11 23
2009 11 20	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square The Forbury, Reading Berkshire RG1 3EB UNITED KINGDOM	EU/1/07/392/001-002	2009 12 18
2009 11 20	Bondronat	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/96/012/004 EU/1/96/012/009-013	2009 11 24
2009 11 20	Ebixa	H. Lundbeck A/S Ottliavej 9 2500 Valby DANMARK	EU/1/02/219/001-003 EU/1/02/219/005-049	2009 11 24
2009 11 20	Mycamine	Astellas Pharma Europe B.V. Elisabethhof 19 2353 EW Leiderdorp NEDERLAND	EU/1/08/448/001-002	2009 11 24
2009 11 20	NeoRecormon	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/97/031/019-046	2009 11 24
2009 11 20	MabCampath	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/01/193/001-002	2009 11 24

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 20	Somavert	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/02/240/001-004	2009 11 24
2009 11 20	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/03/267/001-010	2009 11 24
2009 11 20	Xeristar	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/04/297/001-008	2009 11 24
2009 11 20	Regranex	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/99/101/001	2009 11 24
2009 11 20	Ziagen	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/99/112/001-002	2009 11 24
2009 11 20	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/296/001-009	2009 11 24
2009 11 20	Angiox	The Medicines Company UK Ltd 115 L Milton Park Abingdon Oxfordshire OX14 4SA UNITED KINGDOM	EU/1/04/289/001-002	2009 11 24
2009 11 20	Agenerase	Glaxo Group Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/00/148/001-004	2009 11 24
2009 11 20	RoActemra	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/08/492/001-006	2009 11 24
2009 11 23	Nexavar	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/06/342/001	2009 11 25
2009 11 23	Noxafil	SP Europe Rue de Stalle 73 1180 Bruxelles BELGIQUE Stallestraat 73 1180 Brussel BELGIË	EU/1/05/320/001	2009 11 25

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 23	Pritor	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/98/089/001-022	2009 11 25
2009 11 23	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/05/315/001-002	2009 11 26
2009 11 23	Exjade	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/356/001-009	2009 11 25
2009 11 23	Cervarix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/07/419/001-012	2009 11 25
2009 11 23	Trizivir	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/00/156/002-003	2009 11 25
2009 11 23	Telzir	Glaxo Group Ltd. Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/282/001-002	2009 11 25
2009 11 23	Azilect	Teva Pharma GmbH Kandelstrasse 10 79199 Kirchzarten DEUTSCHLAND	EU/1/04/304/001-007	2009 11 25
2009 11 23	Invega	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/07/395/001-095	2009 11 25
2009 11 23	Puregon	Organon N.V. Kloosterstraat 6 Postbus 20 5340 BH Oss NEDERLAND	EU/1/96/008/001-041	2009 11 25
2009 11 23	Kinzalmono	Bayer Schering Pharma AG 13342 Berlin DEUTSCHLAND	EU/1/98/091/001-014	2009 11 25
2009 11 23	Micardis	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/98/090/001-020	2009 11 26
2009 11 23	Kaletra	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/01/172/001-007	2009 11 25

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 24	Synagis	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/99/117/001-002	2009 11 26
2009 11 24	alli	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/401/007-010	2009 11 26
2009 11 25	Kivexa	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/298/001-003	2009 11 27
2009 11 26	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/99/126/001-021	2009 12 1
2009 11 26	Enbrel	Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/99/126/001-021	2009 12 1
2009 11 26	Diacomit	Biocodex 7 avenue Gallieni 94250 Gentilly FRANCE	EU/1/06/367/001-012	2009 12 1
2009 11 26	Intelence	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/08/468/001	2009 12 1
2009 11 26	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn DEUTSCHLAND	EU/1/07/412/021-026	2009 12 1
2009 11 27	Pandemrix	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 1330 Rixensart BELGIQUE	EU/1/08/452/001	2009 11 30
2009 11 27	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina 1 53100 Siena SI ITALIA	EU/1/07/385/001-002 EU/1/07/385/004	2009 11 30
2009 11 30	Velcade	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIË	EU/1/04/274/001-002	2009 12 2

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 30	Champix	Pfizer Ltd Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/06/360/001-013	2009 12 2
2009 11 30	Adcirca	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/08/476/001-006	2009 12 2
2009 11 30	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE	EU/1/07/384/003-004	2009 12 2
2009 11 30	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron 92165 Antony Cedex FRANCE	EU/1/95/002/003-004	2009 12 2

— **Leidimas prekiauti (Reglamento (EB) Nr. 726/2004 13 straipsnį) panaikintas**

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 11	Irbesartan BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/375/001-033	2009 11 13
2009 11 11	Irbesartan HCT BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/369/001-028	2009 11 13
2009 11 12	Clopidogrel BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/08/464/001-019	2009 11 17
2009 11 26	Paxene	Norton Healthcare Limited Albert Basin Royal Docks London E16 2QJ UNITED KINGDOM	EU/1/99/113/001-004	2009 12 10

— Leidimas prekiauti (Reglamento (EB) Nr. 726/2004 38 straipsnį) išduotas

Sprendimo data	Vaisto pavadinimas	INN (Tarptautinis nepatentuotas pavadinimas)	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Vaisto forma	ATC kodas (Anatominis terapinis cheminis kodas)	Pranešimo data
2009 11 4	Zolvix	monepantel	Novartis Healthcare A/S Lyngbyvej 172 2100 Copenhagen DANMARK	EU/2/09/101/001-010	Oral solution	QP52AX09	2009 11 6

— **Leidimas prekiauti (Reglamento (EB) Nr. 726/2004 38 straipsnį) pakeistas**

Sprendimo data	Vaisto pavadinimas	Leidimo prekiauti turėtojas	Įrašo Bendrijos registre numeris	Pranešimo data
2009 11 18	Dexdomitor	Orion Corporation Orionintie 1 FI-02200 Espoo SUOMI/FINLAND	EU/2/02/033/001-002	2009 11 20
2009 11 19	Improvac	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/2/09/095/001-003	2009 11 23
2009 11 20	Metacam	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein DEUTSCHLAND	EU/2/97/004/026 EU/2/97/004/033-034	2009 11 24
2009 11 23	Halocur	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/99/013/001-002	2009 11 25

Pageidaujantys susipažinti su konkrečių vaistų viešo įvertinimo ataskaita ir su sprendimais dėl jų gali kreiptis į Europos vaistų agentūrą:

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