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Information and Notices

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[1] Text with EEA relevance

(Continued overleaf)

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II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Authorisation for State aid pursuant to Articles 87 and 88 of the EC Treaty
Cases where the Commission raises no objections

(Text with EEA relevance)

(2009/C 73/01)

Date of adoption of the decision	23.12.2008
Reference number of the aid	N 143/08
Member State	Slovakia
Region	Stredné Slovensko
Title (and/or name of the beneficiary)	ZSNP, a.s.
Legal basis	Zákon č. 587/2004 Z. z. o Environmentálnom fonde a o zmene a doplnení niektorých zákonov v znení neskorších predpisov; Vyhláška Ministerstva životného prostredia Slovenskej republiky č. 157/2005 Z. z., ktorou sa vykonáva zákon č. 587/2004 Z. z. o Environmentálnom fonde a o zmene a doplnení niektorých zákonov; Zákon č. 231/1999 Z. z. o štátnej pomoci v znení neskorších predpisov
Type of measure	Individual aid
Objective	Environmental protection
Form of aid	Soft loan
Budget	Overall budget: SKK 65,8 million
Intensity	12 %
Duration	—
Economic sectors	Manufacturing industry
Name and address of the granting authority	Environmentálny fond Bukureštská 4 813 26 Bratislava SLOVENSKÁ REPUBLIKA
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/community_law/state_aids/

Date of adoption of the decision	24.2.2009
Reference number of the aid	N 77/09
Member State	Hungary
Region	—
Title (and/or name of the beneficiary)	Limited amounts of compatible aid
Legal basis	Art. 23/A, 23/C and 23/D. of the Government Decree 85/2004. (IV. 19.) on the Procedure regarding State Aid defined by Article 87 (1) of the EC Treaty and on the Regional Aid Map
Type of measure	Individual aid
Objective	Aid to remedy serious disturbances in the economy
Form of aid	*Ad hoc* contracts
Budget	—
Intensity	—
Duration	22.2.2009-31.12.2010
Economic sectors	All sectors
Name and address of the granting authority	All competent aid granting authorities in the Hungary
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/community_law/state_aids/

Date of adoption of the decision	24.2.2009
Reference number of the aid	N 78/09
Member State	Hungary
Region	—
Title (and/or name of the beneficiary)	Temporary aid scheme for granting aid in the form of loans with subsidised interest rate
Legal basis	Art. 23/B, Art. 23/C and Art. 23/D of the Government Decree 85/2004. (IV. 19.) on the Procedure regarding State Aid defined by Article 87 (1) of the EC Treaty and on the Regional Aid Map
Type of measure	Individual aid
Objective	Aid to remedy serious disturbances in the economy
Form of aid	*Ad hoc* contracts
Budget	—
Intensity	—
Duration	23.2.2009-31.12.2010

Economic sectors	All sectors
Name and address of the granting authority	All competent aid granting authorities in Hungary
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/community_law/state_aids/

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Euro exchange rates [1]

26 March 2009

(2009/C 73/02)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,3607	AUD	Australian dollar	1,9349
JPY	Japanese yen	133,63	CAD	Canadian dollar	1,6707
DKK	Danish krone	7,4488	HKD	Hong Kong dollar	10,4579
GBP	Pound sterling	0,9316	NZD	New Zealand dollar	2,3497
SEK	Swedish krona	10,8765	SGD	Singapore dollar	2,0349
CHF	Swiss franc	1,5266	KRW	South Korean won	1 810,75
ISK	Iceland króna		ZAR	South African rand	12,7498
NOK	Norwegian krone	8,8175	CNY	Chinese yuan renminbi	9,2191
BGN	Bulgarian lev	1,9558	HRK	Croatian kuna	7,4682
CZK	Czech koruna	27,233	IDR	Indonesian rupiah	15 797,73
EEK	Estonian kroon	15,6466	MYR	Malaysian ringgit	4,8909
HUF	Hungarian forint	302	PHP	Philippine peso	65,53
LTL	Lithuanian litas	3,4528	RUB	Russian rouble	45,4005
LVL	Latvian lats	0,7095	THB	Thai baht	47,627
PLN	Polish zloty	4,5675	BRL	Brazilian real	3,0426
RON	Romanian leu	4,2655	MXN	Mexican peso	19,2525
TRY	Turkish lira	2,255	INR	Indian rupee	68,246

[1] *Source:* reference exchange rate published by the ECB.

Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 February 2009 to 28 February 2009

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council [1]*)*

(2009/C 73/03)

— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004): Accepted

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
4.2.2009	Nplate	Romiplostim	Amgen Europe B.V. Minervum 7061 4817 ZK Breda NEDERLAND	EU/1/08/497/001-002	Powder for solution for injection	B02BX04	6.2.2009
6.2.2009	Zarzio	Filgrastim	Sandoz GmbH Biochemiestraße 10 6250 Kundl ÖSTERREICH	EU/1/08/495/001-008	Solution for injection or infusion	L03AA02	10.2.2009
6.2.2009	Filgrastim Hexal	Filgrastim	HEXAL AG Industriestraße 25 83607 Holzkirchen DEUTSCHLAND	EU/1/08/496/001-008	Solution for injection or infusion	L03AA02	10.2.2009
17.2.2009	FIRMAGON	Degarelix (as acetate)	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11 Copenhagen S 2300 DANMARK	EU/1/08/504/001-002	Powder and solvent for solution for injection	L02BX02	19.2.2009
19.2.2009	Thymanax	Agomelatine	Servier (Ireland) Industries Limited Gorey Road Arklow Co. Wicklow IRELAND	EU/1/08/498/001-008	Film-coated tablet	NO6AX22	23.2.2009
19.2.2009	Opgenra	Eptotermin alfa	Howmedica International S. de R. L. Raheen Business Park Limerick IRELAND	EU/1/08/489/001	Powders for suspension for implantation	M05BC02	23.2.2009

[1] OJ L 136, 30.4.2004, p. 1.

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
19.2.2009	Valdoxan	Agomelatine	Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	EU/1/08/499/001-008	Film-coated tablet	NO6AX22	23.2.2009
24.2.2009	FABLYN	Lasofoxifene	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	EU/1/08/500/001-004	Film-coated tablet	Non applicable	26.2.2009
24.2.2009	INTANZA	Influenza Vaccine (split virion, inactivated)	Sanofi Pasteur MSD SNC 8 rue Jonas Salk 69007 Lyon FRANCE	EU/1/08/505/001-006	Suspension for injection	J07BB02	26.2.2009
24.2.2009	IDflu	Influenza Vaccine (split virion, inactivated)	Sanofi Pasteur MSD SNC 8 rue Jonas Salk 69007 Lyon FRANCE	EU/1/08/507/001-006	Suspension for injection	J07BB02	26.2.2009
25.2.2009	Efient	Prasugrel	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/08/503/001-014	Film-coated tablet	Non applicable	27.2.2009

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
2.2.2009	Vfend	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ UNITED KINGDOM	EU/1/02/212/001-026	5.2.2009
2.2.2009	Gardasil	Sanofi Pasteur MSD SNC 8 rue Jonas Salk 69007 Lyon FRANCE	EU/1/06/357/001-021	4.2.2009
2.2.2009	Silgard	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/06/358/001-021	4.2.2009
2.2.2009	Vimpat	UCB Pharma S.A. Allée de la Recherche 60 1070 Bruxelles BELGIQUE	EU/1/08/470/001-016	4.2.2009
2.2.2009	DuoTrav	Alcon Laboratories (UK) Ltd Pentagon Park Boundary Way Hemel Hempstead Herts HP2 7UD UNITED KINGDOM	EU/1/06/338/001-003	4.2.2009
4.2.2009	Elaprase	Shire Human Genetic Therapies AB Svardvagen 11D 182 33 Danderyd SVERIGE	EU/1/06/365/001-003	6.2.2009
6.2.2009	REYATAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/03/267/001-010	10.2.2009
6.2.2009	Extavia	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/08/454/001-004	10.2.2009
10.2.2009	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/08/442/001-008	12.2.2009
10.2.2009	SUTENT	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ UNITED KINGDOM	EU/1/06/347/001-006	12.2.2009
10.2.2009	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/343/001-007	12.2.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
10.2.2009	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/363/001-011	12.2.2009
10.2.2009	Xolair	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/05/319/005- 010	12.2.2009
10.2.2009	TachoSil	Nycomed Austria GmbH St.-Peter-Straße 25 4020 Linz ÖSTERREICH	EU/1/04/277/001-004	12.2.2009
10.2.2009	Abraxane	Abraxis BioSciences Limited 2nd floor Titan Court 3 Bishops Sq Hatfield AL 10 9NA UNITED KINGDOM	EU/1/07/428/001	13.2.2009
10.2.2009	Arava	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/99/118/001-010	12.2.2009
10.2.2009	IVEMEND	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU UNITED KINGDOM	EU/1/07/437/001-002	12.2.2009
11.2.2009	Zonegran	Eisai Limited 3 Shortlands London W6 8EE UNITED KINGDOM	EU/1/04/307/001-013	13.2.2009
13.2.2009	Clopidogrel Winthrop	Sanofi Pharma Bristol-Myers Squibb SNC 174 Avenue de France 75013 Paris FRANCE	EU/1/08/465/001 EU/1/08/465/003 EU/1/08/465/005 EU/1/08/465/007 EU/1/08/465/009 EU/1/08/465/011 EU/1/08/465/013 EU/1/08/465/018-019	17.2.2009
13.2.2009	Clopidogrel BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/08/464/001 EU/1/08/464/003 EU/1/08/464/005 EU/1/08/464/007 EU/1/08/464/009 EU/1/08/464/011 EU/1/08/464/013 EU/1/08/464/018-019	17.2.2009
13.2.2009	Dafiro	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/371/001-036	17.2.2009
13.2.2009	Lyrica	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ UNITED KINGDOM	EU/1/04/279/001-043	17.2.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
13.2.2009	Copalia	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/372/001-036	17.2.2009
13.2.2009	Exforge	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/370/001-036	17.2.2009
13.2.2009	Tasmar	Meda Actiebolag Pipers väg 2A Box 906 170 09 Solna SVERIGE Valeant Pharmaceuticals Limited Cedarwood Chineham Business Park Crockford Lane Basingstoke RG24 8WD UNITED KINGDOM	EU/1/97/044/001-008	18.2.2009
13.2.2009	Imprida	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/06/373/001-036	17.2.2009
17.2.2009	Temodal	Schering Plough Europe Rue de Stalle, 73/Stallestraat, 73 1180 Bruxelles/1180 Brussel BELGIQUE/BELGIË	EU/1/98/096/001-022	19.2.2009
19.2.2009	Zerene	Meda AB Pipers väg 2A 170 09 Solna SVERIGE	EU/1/99/099/001-006	23.2.2009
19.2.2009	Insuman	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/97/030/170-189	23.2.2009
19.2.2009	Sonata	Meda AB Pipers väg 2A 170 09 Solna SVERIGE	EU/1/99/102/001-006	23.2.2009
19.2.2009	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH 65926 Frankfurt am Main DEUTSCHLAND	EU/1/06/368/143-162	23.2.2009
20.2.2009	Myozyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/06/333/001-003	24.2.2009
20.2.2009	Evoltra	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/06/334/001-004	24.2.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
20.2.2009	Luminity	Bristol-Myers Squibb Pharma Belgium Sprl Chaussée de la Hulpe, 185/Terhulpsesteenweg 185 1170 Bruxelles/1180 Brussel BELGIQUE/BELGIË	EU/1/06/361/001-002	24.2.2009
20.2.2009	Bondenza	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/03/266/003-006	24.2.2009
23.2.2009	Myozyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden NEDERLAND	EU/1/06/333/001-003	25.2.2009
23.2.2009	BeneFIX	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/97/047/001-007	25.2.2009
23.2.2009	Bonviva	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/03/265/003-006	25.2.2009
23.2.2009	Mabthera	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/98/067/001-002	25.2.2009
24.2.2009	Thalidomide Celgene	Celgene Europe Limited Riverside House Riverside Walk Windsor SL4 1NA UNITED KINGDOM	EU/1/08/443/001	26.2.2009
24.2.2009	Irbesartan HCT BMS	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/369/001-028	26.2.2009
24.2.2009	Viracept	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW UNITED KINGDOM	EU/1/97/054/004-005	26.2.2009
24.2.2009	Revlimid	Celgene Europe Limited Riverside House Riverside Walk Windsor Berkshire SL4 1NA UNITED KINGDOM	EU/1/07/391/001-004	26.2.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
24.2.2009	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	26.2.2009
25.2.2009	ORENCIA	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/07/389/001-003	27.2.2009
25.2.2009	Dynastat	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ UNITED KINGDOM	EU/1/02/209/001-008	27.2.2009
25.2.2009	Levitra	Bayer AG 51368 Leverkusen DEUTSCHLAND	EU/1/03/248/001-012	27.2.2009
25.2.2009	Forsteo	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/03/247/001-002	27.2.2009
25.2.2009	Zerit	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/96/009/001-009	27.2.2009
25.2.2009	Irbesartan Winthrop	SANOFI PHARMA BRISTOL MYERS SQUIBB SNC 174 avenue de France 75013 Paris FRANCE	EU/1/06/376/001-033	27.2.2009
25.2.2009	HUMIRA	Abbott Laboratories Ltd Queenborough Kent ME11 5EL UNITED KINGDOM	EU/1/03/256/001-010	27.2.2009
25.2.2009	Vivanza	Bayer AG 51368 Leverkusen DEUTSCHLAND	EU/1/03/249/001-012	27.2.2009
25.2.2009	Advagraf	Astellas Pharma Europe B.V. Elisabethhof 19 2353 EW Leiderdorp NEDERLAND	EU/1/07/387/001-010	27.2.2009
25.2.2009	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg Luxembourg CV Therapeutics Europe Limited 15 Meadway Court Rutherford Close Stevenage Hertfordshire SG1 2EF UNITED KINGDOM	EU/1/08/462/001-012	27.2.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
26.2.2009	Advate	Baxter AG Industriesstraße 67 1220 Vienna ÖSTERREICH	EU/1/03/271/001-006	2.3.2009
26.2.2009	ReFacto AF	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	EU/1/99/103/001-004	2.3.2009
26.2.2009	Myfenax	Teva Pharma B.V. Computerweg 10 DR Utrecht 3542 NEDERLAND	EU/1/07/438/001-004	2.3.2009
26.2.2009	Fasturtec	Sanofi-Aventis 174 avenue de France 75013 Paris FRANCE	EU/1/00/170/001-002	2.3.2009
26.2.2009	Mycophenolate mofetil Teva	Teva Pharma B.V. Computerweg 10 DR Utrecht 3542 NEDERLAND	EU/1/07/439/001-004	2.3.2009
26.2.2009	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/08/442/001-008	2.3.2009
26.2.2009	Protopic	Astellas Pharma GmbH Neumarkter Str. 61 81673 München DEUTSCHLAND	EU/1/02/201/001-006	4.3.2009
26.2.2009	Volibris	Glaxo Group Ltd Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/08/451/001-004	2.3.2009
26.2.2009	Telzir	Glaxo Group Ltd Greenford Road Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/04/282/001-002	2.3.2009
26.2.2009	Xeristar	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim am Rhein DEUTSCHLAND	EU/1/04/297/001-008	2.3.2009
26.2.2009	Karvezide	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/98/085/001-034	2.3.2009
26.2.2009	Karvea	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/97/049/001-039	2.3.2009

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
26.2.2009	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France 75013 Paris FRANCE	EU/1/98/086/001-034	2.3.2009
26.2.2009	Oprymea	KRKA, d. d. Novo mesto Šmarješka cesta 6 SI-8501 Novo mesto SLOVENIJA	EU/1/08/469/001-025	2.3.2009
26.2.2009	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France 75013 Paris FRANCE	EU/1/97/046/001-039	2.3.2009
26.2.2009	Tasigna	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM	EU/1/07/422/001-004	3.3.2009
26.2.2009	Baraclude	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/343/001-007	3.3.2009
26.2.2009	REYATAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/03/267/001-010	3.3.2009
26.2.2009	Sprycel	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UB8 1DH UNITED KINGDOM	EU/1/06/363/001-011	3.3.2009
26.2.2009	Tyverb	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0NN UNITED KINGDOM	EU/1/07/440/001-002	3.3.2009
26.2.2009	Xagrid	Shire Pharmaceutical Contracts Ltd Hampshire International Business Park Chineham Basingstoke Hampshire RG24 8EP UNITED KINGDOM	EU/1/04/295/001	3.3.2009
27.2.2009	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	EU/1/04/283/001-012	3.3.2009

— **Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
10.2.2009	Loxicom	Meloxicam	Norbrook Laboratories Limited Station Works Newry Co. Down BT35 6JP UNITED KINDGOM	EU/2/08/090/001-005 EU/2/08/090/006-008	Oral Suspension Solution for Injection	QM01AC06	12.2.2009
11.2.2009	STARTVAC	Escherichia coli J5: > 50 RED60 Staph. Aureus (CP8): > 50 RED80	Laboratorios Hipra, S.A. Avda. La Selva, 135 17170 Amer (Girona) ESPAÑA	EU/2/08/092/001-007	Emulsion for injection	QI02 AB	13.3.2009

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
12.2.2009	Purevax RCCh	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/049/001-002	16.2.2009
13.2.2009	Purevax RCP FeLV	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/048/001-002	17.2.2009
13.2.2009	Purevax RCPCh FeLV	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/047/001-002	17.2.2009
17.2.2009	Purevax RCPCh	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/050/001-002	19.2.2009
17.2.2009	ProMeris Duo	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36 1381 CP Weesp NEDERLAND	EU/2/06/065/001-010	19.2.2009
17.2.2009	Purevax RC	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/051/001-002	20.2.2009
17.2.2009	Purevax RCP	Merial 29 Avenue Tony Garnier 69007 Lyon FRANCE	EU/2/04/052/001-002	19.2.2009

— **Suspension of a marketing authorization (Article 45 of Regulation (EC) No 726/2004)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
20.2.2009	Porcilis Pesti	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer NEDERLAND	EU/2/99/016/001-006	24.2.2009

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

The European Medicines Agency
7, Westferry Circus
Canary Wharf
London E14 4HB
UNITED KINGDOM

Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 February 2009 to 28 February 2009

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

(2009/C 73/04)

— Issuing, maintenance or modification 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
4.2.2009	Nplate	Amgen Europe B.V. Minervum 7061 4817 ZK Breda NEDERLAND	This Decision is addressed to the Member States	6.2.2009
6.2.2009	Implanon	See Annex I	See Annex I	9.2.2009
16.2.2009	Diovan	See Annex II	See Annex II	17.2.2009
17.2.2009	FIRMAGON	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11 Copenhagen S 2300 DANMARK	This Decision is addressed to the Member States	18.2.2009
19.2.2009	Valdoxan	Laboratoires Servier 22 rue Garnier 92200 Neuilly-sur-Seine FRANCE	This Decision is addressed to the Member States	23.2.2009
19.2.2009	Opgenra	Howmedica International S. de R. L. Raheen Business Park Limerick IRELAND	This Decision is addressed to the Member States	23.2.2009
19.2.2009	Thymanax	Servier (Ireland) Industries Limited Gorey Road Arklow Co. Wicklow IRELAND	This Decision is addressed to the Member States	23.2.2009
24.2.2009	FABLYN	Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ UNITED KINGDOM	This Decision is addressed to the Member States	25.2.2009
25.2.2009	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare L-1611 Luxembourg LUXEMBOURG CV Therapeutics Europe Limited 15 Meadway Court Rutherford Close Stevenage Hertfordshire SG1 2EF UNITED KINGDOM	This Decision is addressed to the Member States	26.2.2009

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

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
25.2.2009	Efient	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten NEDERLAND	This Decision is addressed to the Member States	27.2.2009
26.2.2009	ReFacto AF	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH UNITED KINGDOM	This Decision is addressed to the Member States	27.2.2009

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION AND MARKETING AUTHORIZATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorization Holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	N.V. Organon Kloosterstraat 6 PO Box 20 5349 AB, Oss NEDERLAND		Implanon — Implantat	68 mg	Implant	Subcutaneous use
Belgium	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Czech Republic	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Denmark	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Finland	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
France	Organon SA Immeuble Optima 10 rue Godefroy 92821 Puteaux Cedex FRANCE		Implanon	68 mg	Implant	Subcutaneous use
Germany	Essex Pharma GmbH Thomas-Dehler-Straße, 27 81737 München DEUTSCHLAND		Implanon	68 mg	Implant	Subcutaneous use

Member State EU/EEA	Marketing Authorization Holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Hungary	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Iceland	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Ireland	Organon Ireland Ltd Drynam Road Swords Co. Dublin IRELAND		Implanon 68 mg implant	68 mg	Implant	Subcutaneous use
Italy	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Luxembourg	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Malta	Organon Laboratories Ltd Cambridge Science Park Milton Road Cambridge CB4 0FL UNITED KINGDOM		Implanon	68 mg	Implant	Subcutaneous use
Netherlands	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon 68 mg	68 mg	Implant	Subcutaneous use

Member State EU/EEA	Marketing Authorization Holder	Applicant	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Norway	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Portugal	Organon Portuguesa Produtos Químicos e Farmacêuticos, Lda Av. José Malhoa, 16B — 2° 1070-159 Lisboa PORTUGAL		Implanon	68 mg	Implant	Subcutaneous use
Slovak Republic	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
Spain	Organon Española, S.A. Ctra. de Hospitalet, 147-149 Cityparc Ronda de Dalt Edificio Amsterdam 08940 Cornellá de Llobregat, Barcelona ESPAÑA		Implanon	68 mg	Implant	Subcutaneous use
Sweden	N.V. Organon Kloosterstraat 6 PO Box 20 5340 BH, Oss NEDERLAND		Implanon	68 mg	Implant	Subcutaneous use
United Kingdom	Organon Laboratories Ltd Cambridge Science Park Milton Road Cambridge CB4 0FL UNITED KINGDOM		Implanon	68 mg	Implant	Subcutaneous use

ANNEX II

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

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Diovan 40 mg Filmtabletten	40 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Angiosan 40 mg Filmtabletten	40 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Diovan 80 mg Filmtabletten	80 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Angiosan 80 mg Filmtabletten	80 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Diovan 160 mg Filmtabletten	160 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Angiosan 160 mg Filmtabletten	160 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Diovan 320 mg Filmtabletten	320 mg	Film-coated tablets	Oral
Austria	Novartis Pharma GmbH Brunner Strasse 59 1235 Wien ÖSTERREICH	Angiosan 320 mg Filmtabletten	320 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Diovane 40 mg	40 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Novacard 40 mg	40 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Diovane 80 mg	80 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Novacard 80 mg	80 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Diovane 160 mg	160 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Novacard 160 mg	160 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Diovane 320 mg	320 mg	Film-coated tablets	Oral
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 1800 Vilvoorde BELGIQUE	Novacard 320 mg	320 mg	Film-coated tablets	Oral
Bulgaria	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg DEUTSCHLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg DEUTSCHLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Cyprus	Demetriades & Papaellinas ltd 21 Kasou P.O. Box 23490 Nicosia CYPRUS	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Cyprus	Demetriades & Papaellinas ltd 21 Kasou P.O. Box 23490 Nicosia CYPRUS	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Cyprus	Demetriades & Papaellinas ltd 21 Kasou P.O. Box 23490 Nicosia CYPRUS	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Cyprus	Demetriades & Papaellinas ltd 21 Kasou P.O. Box 23490 Nicosia CYPRUS	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 ČESKÁ REPUBLIKA	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 ČESKÁ REPUBLIKA	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Denmark	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANEMARK	Diovan 40 mg	40 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Denmark	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANEMARK	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Denmark	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANEMARK	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Denmark	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANEMARK	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Estonia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Estonia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Estonia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Estonia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON FRANCE	Tareg 40 mg	40 mg	Film-coated tablets	Oral
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON FRANCE	Tareg 80 mg	80 mg	Film-coated tablets	Oral
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON FRANCE	Tareg 160 mg	160 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Cordinate 40 mg	40 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Provas 40 mg	40 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Cordinate 80 mg	80 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Provas 80 mg	80 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Cordinate 160 mg	160 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Provas 160 mg	160 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Cordinate 320 mg	320 mg	Film-coated tablets	Oral
Germany	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Provas 320 mg	320 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 40 mg	40 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 40 mg	40 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 80 mg	80 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 160 mg	160 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 320 mg	320 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 80 mg	80 mg	Hard gelatine capsules	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 80 mg	80 mg	Hard gelatine capsules	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Diovan 160 mg	160 mg	Hard gelatine capsules	Oral
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis 144 51 Athens ΕΛΛΑΔΑ/GREECE	Dalzad 160 mg	160 mg	Hard gelatine capsules	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Varexan 40 mg	40 mg	Film-coated tablets	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Diovan 80 mg	80 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Varexan 80 mg	80 mg	Film-coated tablets	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Varexan 160 mg	160 mg	Film-coated tablets	Oral
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 1114 Budapest MAGYARORSZÁG/HUNGARY	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Iceland	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANMARK	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Iceland	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANMARK	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Iceland	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANMARK	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Iceland	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø DANMARK	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Ireland	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 40 mg	40 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Ireland	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Ireland	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Ireland	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Tareg 40 mg	40 mg	Film-coated tablets	Oral
Italy	LPB Instituto Farmaceutico S.r.l. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Rixil	40 mg	Film-coated tablets	Oral
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Tareg	80 mg	Film-coated tablets	Oral
Italy	LPB Instituto Farmaceutico S.r.l. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Rixil	80 mg	Film-coated tablets	Oral
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Tareg	160 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Italy	LPB Instituto Farmaceutico S.r.l. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Rixil	160 mg	Film-coated tablets	Oral
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Tareg	80 mg	Hard capsules	Oral
Italy	LPB Instituto Farmaceutico S.r.l. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Rixil	80 mg	Hard capsules	Oral
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Tareg	160 mg	Hard capsules	Oral
Italy	LPB Instituto Farmaceutico S.r.l. Largo Umberto Boccioni 1 21040 Origgio ITALIA	Rixil	160 mg	Hard capsules	Oral
Latvia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Latvia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Latvia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Latvia	Novartis Finland OY Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FI-02130 Espoo SUOMI/FINLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Luxembourg	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Luxembourg	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Luxembourg	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Luxembourg	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 320 mg	320 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Malta	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Malta	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Malta	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Malta	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Netherlands	Novartis Pharma B.V. Postbus 241 6824 DP Arnhem NEDERLAND	Diovan 40	40 mg	Film-coated tablets	Oral
Netherlands	Novartis Pharma B.V. Postbus 241 6824 DP Arnhem NEDERLAND	Diovan 80	80 mg	Film-coated tablets	Oral
Netherlands	Novartis Pharma B.V. Postbus 241 6824 DP Arnhem NEDERLAND	Diovan 160	160 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Netherlands	Novartis Pharma B.V. Postbus 241 6824 DP Arnhem NEDERLAND	Diovan 320	320 mg	Film-coated tablets	Oral
Norway	Novartis Norge AS Postboks 237 Økern NO-0510 Oslo	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Norway	Novartis Norge AS Postboks 237 Økern NO-0510 Oslo	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Norway	Novartis Norge AS Postboks 237 Økern NO-0510 Oslo	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Norway	Novartis Norge AS Postboks 237 Økern NO-0510 Oslo	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Poland	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg DEUTSCHLAND	Diovan	40 mg	Film-coated tablets	Oral
Poland	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan	80 mg	Film-coated tablets	Oral
Poland	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan	160 mg	Film-coated tablets	Oral
Poland	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan	320 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	Novartis Farma — Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P-2710-444 Sintra PORTUGAL	Diovan	40 mg	Film-coated tablets	Oral
Portugal	Novartis Farma — Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P-2710-444 Sintra PORTUGAL	Diovan	80 mg	Film-coated tablets	Oral
Portugal	Novartis Farma — Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P-2710-444 Sintra PORTUGAL	Diovan g	160 mg	Film-coated tablets	Oral
Portugal	Novartis Farma — Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P-2710-444 Sintra PORTUGAL	Diovan	320 mg	Film-coated tablets	Oral
Romania	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Romania	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Romania	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 160 mg	160 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 40 mg	40 mg	Film-coated tablets	Oral
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 80 mg	80 mg	Hard gelatine capsules	Oral
Slovak Republic	Novartis s.r.o. Praha ČESKÁ REPUBLIKA	Diovan 160 mg	160 mg	Hard gelatine capsules	Oral
Slovenia	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 40 mg filmsko obložene tablete	40 mg	Film-coated tablets	Oral
Slovenia	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 80 mg filmsko obložene tablete	80 mg	Film-coated tablets	Oral
Slovenia	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 160 mg filmsko obložene tablete	160 mg	Film-coated tablets	Oral
Slovenia	Novartis Pharma GmbH Roonstraße 25 90429 Nürnberg DEUTSCHLAND	Diovan 320 mg filmsko obložene tablete	320 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Diovan Cardio 40 mg	40 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Kalpress Cardio 40 mg	40 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Miten Cardio 40 mg	40 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Diovan 80 mg	80 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Kalpress 80 mg	80 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Miten 80 mg	80 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Diovan 160 mg	160 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Kalpress 160 mg	160 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Miten 160 mg	160 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Diovan 320 mg	320 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Kalpress 320 mg	320 mg	Film-coated tablets	Oral
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona ESPAÑA	Miten 320 mg	320 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	40 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Angiosan	40 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Valsartan Novartis	40 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	80 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Angiosan	80 mg	Film-coated tablets	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Valsartan Novartis	80 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	160 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Angiosan	160 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Valsartan Novartis	160 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	320 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Angiosan	320 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Valsartan Novartis	320 mg	Film-coated tablets	Oral
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	80 mg	Hard gelatine capsules	Oral

Member State EU/EEA	Marketing Authorization Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby SVERIGE	Diovan	160 mg	Hard gelatine capsules	Oral
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 40 mg	40 mg	Film-coated tablets	Oral
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 320 mg	320 mg	Film-coated tablets	Oral
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 40 mg	40 mg	Hard gelatine capsules	Oral
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 80 mg	80 mg	Hard gelatine capsules	Oral
United Kingdom	Novartis Pharmaceuticals UK Ltd Frimley Business Park Frimley Camberley Surrey GU16 7SR UNITED-KINGDOM	Diovan 160 mg	160 mg	Hard gelatine capsules	Oral

V

(Announcements)

ADMINISTRATIVE PROCEDURES

COMMISSION

MEDIA 2007 — DEVELOPMENT, DISTRIBUTION, PROMOTION AND TRAINING

Call for proposals — EACEA/03/09

Support for the transnational distribution of European films — The 'Automatic' Scheme 2009

(2009/C 73/05)

1. Objectives and description

This notice of a call for proposals is based on Decision No 1718/2006/EC of the European Parliament and of the Council of 15 November 2006 concerning the implementation of a programme of support for the European audiovisual sector (MEDIA 2007).

One of the objectives of the programme is to encourage and support the wider transnational distribution of recent European films by providing funds to distributors, based upon their performance on the market, for further reinvestment in new non-national European films.

The scheme also aims to encourage the development of links between the production and distribution sectors thus improving the market share of European films and the competitiveness of European companies.

2. Eligible applicants

This notice is aimed at European companies specialised in the theatrical distribution of European works and whose activities contribute to the attainment of the above objectives of the MEDIA programme as described in the Council Decision.

Applicants must be established in one of the following countries:

— the 27 countries of the European Union,

— the EFTA countries,

— Switzerland,

— Croatia.

3. Eligible actions

The 'automatic' support scheme works in two phases:

— generation of a potential Fund, proportional to the number of paying admission tickets sold for non-domestic European films in States participating in the Programme, up to a fixed ceiling per film and adjusted for each country,

— reinvestment of the potential Fund: thus generated by each company, the Fund must be reinvested in 3 modules (3 types of action) by 1 October 2010:

1. the co-production of non-domestic European films;
2. the acquisition of distribution rights, for example by means of minimum guarantees, of non-domestic European films; and/or in
3. editing costs (prints, dubbing and subtitling), promotion costs and publicity costs for non-domestic European films.

Action type 1 & 2:

The maximum duration of the actions is 30 months.

The actions have to start on 1 August 2009 and finish on 1 February 2012.

Action type 3:

The maximum duration of the actions is 42 months.

The actions have to start on 1 February 2009 and finish on 1 August 2012.

4. **Award criteria**

A potential Fund will be attributed to eligible European distribution companies on the basis of the admissions achieved by the European non-national films distributed by the applicant in the reference year (2008). Within the limit of the budgetary resources available, the potential Fund will be calculated based upon a fixed amount per eligible entry.

The support will take the form of a potential Fund (the 'Fund') available to distributors for further investments in recent non-national European films.

The Fund can be reinvested:

1. in the production of new non-national European films (i.e. films not yet completed at the date of application for reinvestment);
2. in the meeting of Minimum Distribution Guarantees for recent non-national European films;
3. in the meeting of distribution costs i.e. P&A (promotion and advertising) for recent non-national European films.

5. **Budget**

The total budget available is EUR 17 000 000.

There is no maximum amount.

The financial contribution awarded is a subsidy. The financial support from the Commission cannot exceed 40 %, 50 % or 60 % of the total eligible costs.

The Agency reserves the right not to allocate all the funds available.

6. **Deadline for submission of applications**

Proposals for the 'generation' of a potential Fund must be sent (postmark date) on **29 May 2009** at the latest and at the following address:

Education, Audiovisual and Culture Executive Agency (EACEA)
Constantin Daskalakis — BOUR 3/66
Avenue du Bourget, 1
1140 Brussels
BELGIUM

Only applications submitted on the official application form, duly signed by the person entitled to enter into legally binding commitments on behalf of the applicant organisation will be accepted. Envelopes must clearly mention:

MEDIA 2007 — DISTRIBUTION EACEA/03/09 — AUTOMATIC CINEMA

Applications sent by fax or e-mail will be rejected.

7. **Full details**

The full detailed guidelines together with the application forms can be found at the following Internet address:

http://ec.europa.eu/information_society/media/distrib/schemes/auto/index_en.htm

Applications must comply with all terms of the guidelines, be submitted on the forms provided and containing all the information and annexes specified in the full text of the call.

PROCEDURES RELATING TO THE IMPLEMENTATION OF THE COMPETITION POLICY

COMMISSION

Notice by the Ministry of the Economy of the Republic of Latvia of a call for tenders for hydrocarbon exploration and production within the exclusive economic zone of the Republic of Latvia

(2009/C 73/06)

Pursuant to the Law on Substrata, Cabinet Regulation No 597 of 4 September 2007 on hydrocarbon prospection, exploration and production and the amounts of and procedures for paying Government duties, and Cabinet Order No 594 of 21 September 2007 on establishing licensed hydrocarbon prospection sites within the exclusive economic zone of the Republic of Latvia, the Ministry of the Economy of the Republic of Latvia hereby gives notice of a call for tenders for hydrocarbon exploration and production in the exclusive economic zone of the Republic of Latvia within the following ellipsoidal (geographical) coordinates under the WGS 84 system:

Corner points	Latitude N	Longitude E
1	56°10′00″	19°10′14,5″
2	56°14′59,1″	19°13′22,8″
3	56°26′59,2″	19°20′52,7″
4	56°30′00″	19°22′23″
5	56°30′00″	19°40′00″
6	56°10′00″	19°40′00″

Pursuant to Article 3(2) of Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorizations for the prospection, exploration and production of hydrocarbons and paragraph 46 of the aforementioned Cabinet Regulation, the Ministry of the Economy invites all interested entities to obtain a copy of the regulations relating to the call for tenders for hydrocarbon prospection and production within the exclusive economic zone of the Republic of Latvia.

Type of licence: The successful tenderer will be issued with a hydrocarbon prospection and production licence.

Address and office hours for obtaining tender regulations: Ministry of the Economy of the Republic of Latvia, Brīvības iela 55, Riga, LV-1519, every weekday from 9 a.m. to 5 p.m. (GMT +2). The tender regulations may be obtained within 30 days of the date of publication of this notice.

Cost of obtaining the tender regulations: LVL 350. Payment must be made in LVL by transfer of funds to the Ministry of the Economy of the Republic of Latvia, registration no 90000086008, Treasury, code TRELLV22, account no LV10TREL212001C310000, indicating that it is 'Payment for tender regulations in relation to the call for tenders for hydrocarbon prospection and production within the exclusive economic zone of the Republic of Latvia'. To obtain the regulations, proof of payment must be presented.

Deadline for applications: A tender may be submitted in person at the Customer Service Centre of the Ministry of the Economy of the Republic of Latvia, or may be sent by mail to the Ministry of the Economy of the Republic of Latvia, Brīvības iela 55, Riga, LV-1519 within 90 days of the date of publication of this notice. The deadline for submission of applications is 5 p.m. (GMT +2) on the ninetieth day following the date of publication of this notice.

Contact person: Ilze Ruško, Head of the Licence, Permit and Coordination Division, Department of Energy, Ministry of the Economy of the Republic of Latvia, tel. +371 67013173, e-mail: ilze.rusko@em.gov.lv. Please apply for the tender regulations prior to submitting your application.

OTHER ACTS

COMMISSION

Publication of an application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

(2009/C 73/07)

This publication confers the right to object to the application pursuant to Article 7 of Council Regulation (EC) No 510/2006 ([1]). Statements of objection must reach the Commission within six months from the date of this publication.

SUMMARY

COUNCIL REGULATION (EC) No 510/2006

'ČERNÁ HORA'

EC No: CZ-PGI-0005-0409-19.10.2004

PDO ( ) PGI (X)

This summary sets out the main elements of the product specification for information purposes.

1. **Responsible department in the Member State:**

Name:	Úřad průmyslového vlastnictví
Address:	Antonína Čermáka 2a 160 68 Praha 6-Bubeneč ČESKÁ REPUBLIKA
Tel.	+420 220383111
Fax	+420 224324718
E-mail:	posta@upv.cz

2. **Group:**

Name:	Pivovar Černá Hora, a. s.
Address:	Černá Hora 3/5 679 21 Černá Hora ČESKÁ REPUBLIKA
Tel.	+420 516482411
Fax	+420 516437201
E-mail:	ekonom@pivovarch.cz
Composition:	Producers/processors (X) Other ( )

([1]) OJ L 93, 31.3.2006, p. 12.

This application derogates from Article 5(1) of Regulation (EC) No 510/2006 on account of the fact that there is only one producer in the area. The requirements laid down in Article 2 of Commission Regulation (EC) No 1898/2006 are fulfilled.

3. **Type of product:**

Class 2.1: Beer

4. **Specification:**

(Summary of requirements under Article 4(2) of Regulation (EC) No 510/2006)

4.1. *Name:*

'Černá Hora'

4.2. *Description:*

The light beer is medium to highly attenuated, golden yellow to golden brown in colour, good head with strong bite, medium to full-favoured, with a clean flavour of malt and hops, and hoppy aroma. The fullness of flavour is mainly due to the presence of unfermented residual extract, characterised by a difference between apparent and real attenuation. A very faint yeasty or fruity (ester) taste and aroma is permitted. The low intensity of the whole aroma is indicative of the relatively low content of unwanted fermentation by-products. The beer is medium to high in bitterness, and has a slight to mild harshness, with longer finish.

The dark beer is medium to highly attenuated, reddish to red-brown in colour with good head, pleasantly hoppy taste and aroma. It has a medium bite and a typically full flavour, owing to the difference between apparent and real attenuation and to the unfermentable compounds in the raw materials. Caramel and treacle are admissible by-flavours.

Varieties of beer and the sensory characteristics thereof:

The *Světlý ležák* (light lager) is medium to highly attenuated, golden yellow to golden brown in colour, good head with strong bite, medium-favoured, with clean flavour of malt and hops and a hoppy aroma. A very faint yeasty or fruity (ester) taste and aroma is permitted. The beer is of medium bitterness, and has a slight harshness, with longer finish.

The *Světlé výčepní pivo* (light draught beer) is medium to highly attenuated, golden yellow to golden brown in colour, good head with strong bite, full-favoured, with a clean flavour of malt and a hoppy aroma. A very faint yeasty or fruity (ester) taste and aroma is permitted. The beer is high in bitterness, moderately harsh, with a longer finish.

The *Nefiltrované výčepní pivo* (unfiltered draught beer) is characterised by a good head, golden yellow to golden brown colour, good bite and fullness of flavour, and by a yeasty flavour and aroma. The beer has a significant, moderately harsh, hoppy bitterness, leaving behind a feeling of pleasant, gradually diminishing bitterness, without any hint of harshness or astringency.

The *Tmavý ležák* (dark lager) is a beer with the addition of caramel and coloured malt, medium attenuated, garnet to red-brown in colour, caramel to sweetish taste with delicate bitterness.

The *Polotmavé výčepní pivo* (semi-dark draught beer) is medium to highly attenuated, reddish to garnet colour, strong bite, pleasantly hoppy and with a moderately caramel aroma and flavour with good head.

All types of 'Černá Hora' beer are low-fermentation beers characterised by particular sensory qualities, especially unique aroma and flavour with strong bite.

Light beer — quality benchmarks:

		Pale lager	Pale draught	Unfiltered pale draught
Original gravity	(% by weight)	11,00-12,99	8,00-10,99	8,00-10,99
Alcohol	(% by volume)	3,8-6,0	3,5-4,5	3,5-4,5
Colour	EBC units	8,0-16,0	7,0-16,0	7,8-16,0
Bitter substances	EBC units	20,0-45,0	16,0-28,0	16,0-28,0
pH		4,2-4,9	4,3-4,7	4,3-4,7
Difference between apparent and real attenuation	(% rel.)	1,0-10,0	1,0-10,0	1,0-10,0
Polyphenols	(mg/l)	130,0-230,0	130,0-230,0	130,0-230,0

Dark beer, semi-dark beer — quality benchmarks:

		Dark lager	Semi-dark draught
Original gravity	(% by weight)	11,00-12,99	8,00-10,99
Alcohol	(% by volume)	3,6-5,7	3,5-4,5
Colour	EBC units	50,0-120,0	16,0-40,0
Bitter substances	EBC units	20,0-45,0	16,0-28,0
pH		4,1-4,8	4,3-4,7
Difference between apparent and real attenuation	(% rel.)	1,0-10,0	1,0-10,0
Polyphenols	(mg/l)	130,0-230,0	130,0-230,0

Raw materials:

Barley malt

This is a light malt, known as 'Czech malt', which is produced from two-row spring barley. This barley malt is characterised by low solubility and fermentation.

The following table shows Congress Wort values produced from barley malt:

Extract in dry malt	(% by weight)	min.	80 %
Kolbach index	(%)		37-41 %
Diastatic power	(WK units)	min.	220
Actual attenuation	(%)	max.	82 %
Friability	(%)	min.	75 %

Hops

This is the *Žatecký poloraný červeňák* variety. These hops are highly specific: they differ primarily from other hop varieties in their ratio of alpha to beta-bitter acids and in their beta-farnesene content. Either dried hops or hop extract is used. (Keep the original wording, where the *Žatecký poloraný červeňák* variety rather than SKVN *Žatecký chmel* is used for the preparation of beer).

Water

Water from a variety of sources is used in the production of 'Černá Hora' beer. In terms of hardness, this water is considered soft to medium-hard.

Brewer's yeast

Bottom-fermenting yeast strains (*Saccharomyces cerevisiae* subs. *uvarum*) are used for producing 'Černá Hora' beer as they offer the requisite difference between apparent and real attenuation under this specification.

4.3. *Geographical area:*

The municipality of 'Černá Hora' in Southern Moravia, Czech Republic.

4.4. *Proof of origin:*

The applicant for registration of the geographical designation 'Černá Hora' keeps a register of suppliers of raw materials and a register of buyers of the finished product. For each product, compulsory data on products, including addresses, are provided, thereby enabling product traceability.

The entire beer production technology is continuously monitored. The implementation and results of checks are continuously recorded. All raw materials brought in for producing beer are also subject to quality control. Water quality is checked for microbiological suitability and is regularly controlled. A written record of all checks is kept. A record is also kept of the individual batches of raw materials used in the production of individual batches of beer.

Compliance with the specifications is monitored by the Czech Agriculture and Food Inspection Authority.

4.5. *Method of production:*

'Černá Hora' beer is produced solely by means of the double mash decoction process. Bitter wort is cooked depending on the beer's original gravity. The process of primary fermentation takes place separately from that of the maturing of the beer. This is classic production without intensification processes.

Beer production begins in the brewing house. After mixing the ground malt with the water, just a third of the volume is gradually warmed. This enables the starch and other substances of the malt extract to be transferred into the solution and the starch to be split. The mashing process is repeated twice, and each mash is warmed separately. After the mashing out process, the residue of the malt culms is separated out, giving rise to the first portion of wort. The culm is then drained off with hot water and the digest is mixed with the first portion of wort. The resulting wort is heated for 80 to 120 minutes with separately batched hops or hop products to obtain a hopped wort. Each brew is heated at the original concentration of the wort corresponding to the required gravity of the beer. In other words, during further production, the gravity of the beer is not altered.

The heated wort is then cooled to fermentation temperature, brewer's yeast is added, in particular bottom-fermenting yeast strains, and the first, and indeed main, stage of beer fermentation takes place. This main fermentation stage takes place in classic, open fermenting rooms. The main fermentation temperature must not exceed 9,5 °C. The main fermentation takes 6 to 12 days, depending on the gravity of the original wort.

After the completion of main fermentation comes the lagering stage. This takes place at lower temperatures than the main fermentation stage, as low as around 0 °C and under moderate excess pressure in closed tanks. The lagering process takes 21 to 60 days, depending on the gravity of the beer. During this stage, the beer becomes clear, is saturated with carbon dioxide, and its flavour is rounded off. This gives the beer bite, with a dense, firm head. During the lagering stage, the striking flavour and yeasty smell disappears, the bitterness softens and the aroma typical of certain types of beer emerges. After the completion of the lagering process, the beer is filtered immediately without first altering the original gravity and transferred into barrels, bottles and, where applicable, cans or tanks. Unfiltered beer is also permitted. The end product must satisfy the quality benchmarks set out in the tables in Section 4.2 of this summary.

4.6. *Link:*

The beer for which registration of designation of origin of the term 'Černá Hora' has been requested has been produced continuously in the municipality of 'Černá Hora' since the 13th century. The first written record of the brewery in 'Černá Hora' dates back to 1530.

Since then, there has been a rich history of breweries and beer making in 'Černá Hora'. Many owners have come and gone, but the production and quality of 'Černá Hora' beer has steadily increased. In 1949, the brewery was nationalised and gradually incorporated into various national firms. The production of 'Černá Hora' nevertheless went on uninterrupted, following traditional production methods and processes. In 1996 the brewery became independent as part of a privatisation drive.

Records of the brewery's rich history and beer production in 'Černá Hora' are contained in many documents stored in the Moravian national archive in Brno (for example, the Dominican era in 'Černá Hora', the Josefinsky estate for the municipalities of 'Černá Hora' and Bořitov and land transfer registry for the municipalities of 'Černá Hora' and Bořitov etc) and also in the archives of the *Pivovar Černá Hora, a.s.* (Černá Hora brewery).

With the development of the brewery, beer production increased and the buildings and production equipment were expanded and modernised accordingly. These changes had only a minor effect on the uniqueness of 'Černá Hora' beer, which can ultimately be considered a beverage derived from a centuries-old tradition. All 'Černá Hora' brewers have endeavoured to protect the historic uniqueness of 'Černá Hora' beer, which has been only minimally affected over time.

Testament to the quality of 'Černá Hora' beer and its popularity is the many prizes it has won in domestic and international competitions and fairs (for example, the *Táborský palcát* (Tabor mace), *Cena českých sládků* (Czech brewers' prize), *Pivo spanilých jízd* (Beer of the Hussite campaigns), *Zlatý pohár Pivex* (Pivex golden cup) and *Česká pivní pečeť* (Czech beer seal)).

The fame and popularity of 'Černá Hora' beer is also evidenced by the fact that in the municipality of 'Černá Hora' a wide-ranging cultural and social event to present the beer produced there has been held every spring and autumn for the last ten years. In April, it is the *Vítání jara (APRÝLES)* (Spring Welcome) and in September the *Pivní pouť* (Beer fair). These events regularly attract several thousand visitors, who come not just from around Černá Hora but from all over the Czech Republic, and indeed abroad.

Beer from Černá Hora is also mentioned in various encyclopaedias, for example Verhoef, Berry: Large Encyclopaedia of Beer, Čestlice, Rebo Productions, 2002; Jackson, Michael: Great Beer Guide, Prague, Fortuna Print, 2001. Many articles have also been written and published about it in national and local newspapers and magazines. In Černá Hora itself, the periodical 'Černohorský máz' is published, which among other things provides information on the successes of 'Černá Hora' beer in various competitions and fairs.

In 1995 the Brno historian Leoš Vašek wrote about 'Černá Hora' beer in his 1995 book '*V ČERNÉ HOŘE PIVA MOŘE — z historie černohorského pivovarnictví*' (IN ČERNA HORA A SEA OF BEER — on the history of the Černá Hora brewery).

4.7. *Inspection body:*

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4.8. *Description:*

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CORRIGENDA

Corrigendum to authorisation for State aid pursuant to Articles 87 and 88 of the EC Treaty — Cases where the Commission raises no objections

(Official Journal of the European Union C 62 of 17 March 2009)

(2009/C 73/08)

On page 11, against 'Reference number of the aid':

for: 'N 23/08',

read: 'N 23/09'.