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*(Notices)*NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

EUROPEAN COMMISSION

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 to 31 October 2014***(published pursuant to Article 13 or 38 of Regulation (EC) No 726/2004 of the European Parliament and of the
Council ⁽¹⁾)**(2014/C 428/01)*

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

— Issuing of a marketing authorisation (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorisation	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
21.10.2014	IMBRUVICA	Ibrutinib	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	Capsule, hard	L01XE27	23.10.2014

— **Modification of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
1.10.2014	Apidra	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/04/285	6.10.2014
1.10.2014	Bexsero	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1, 53100 Siena, Italia	EU/1/12/812	3.10.2014
1.10.2014	BYDUREON	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/696	3.10.2014
1.10.2014	ellaOne	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/09/522	3.10.2014
1.10.2014	Iscover	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/070	3.10.2014
1.10.2014	Liprolog	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/01/195	3.10.2014
1.10.2014	Plavix	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/069	3.10.2014
1.10.2014	Voriconazole Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/13/835	3.10.2014
1.10.2014	Zoledronic acid Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/12/771	3.10.2014
3.10.2014	Forxiga	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/795	7.10.2014
3.10.2014	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/97/030	7.10.2014
3.10.2014	Jakavi	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/12/773	7.10.2014
3.10.2014	Xigduo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/13/900	7.10.2014
8.10.2014	Krystexxa	Crealta Pharmaceuticals Ireland Limited Commercial House, Millbank Business Park, Lower Lucan Road, Lucan, Co.Dublin, Ireland	EU/1/12/810	13.10.2014
8.10.2014	Tarceva	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311	10.10.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
8.10.2014	Yentreve	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/280	10.10.2014
10.10.2014	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/283	14.10.2014
10.10.2014	Evoltra	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/06/334	14.10.2014
10.10.2014	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	14.10.2014
10.10.2014	Translarna	PTC Therapeutics International Limited 77 Sir John Rogerson's Quay, Dublin 2, Ireland	EU/1/13/902	14.10.2014
15.10.2014	Atosiban SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	EU/1/13/852	17.10.2014
15.10.2014	Komboglyze	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/11/731	20.10.2014
15.10.2014	Onglyza	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/09/545	17.10.2014
15.10.2014	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/297	17.10.2014
20.10.2014	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/296	23.10.2014
21.10.2014	Clopidogrel Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/561	23.10.2014
22.10.2014	Lyxumia	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/12/811	24.10.2014
22.10.2014	Nevirapine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/598	24.10.2014
22.10.2014	Privigen	CSL Behring GmbH Emil-von-Behring-Straße 76, D-35041 Marburg, Deutschland	EU/1/08/446	24.10.2014
27.10.2014	Abraxane	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	EU/1/07/428	29.10.2014

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
27.10.2014	BindRen	Mitsubishi Tanabe Pharma Europe Ltd Dashwood House, 69 Old Broad Street, London EC2M 1QS United Kingdom	EU/1/12/804	29.10.2014
27.10.2014	Entacapone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/665	29.10.2014
27.10.2014	Fasturtec	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/00/170	29.10.2014
27.10.2014	Hexyon	Sanofi Pasteur MSD, SNC 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/13/829	29.10.2014
27.10.2014	Invanz	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/02/216	29.10.2014
27.10.2014	Myclausen	Herbert J. Passauer GmbH & Co. KG Stubenrauchstrasse 33, D-14167 Berlin, Deutschland	EU/1/10/647	29.10.2014
27.10.2014	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508	29.10.2014
27.10.2014	Vidaza	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	EU/1/08/488	29.10.2014
27.10.2014	Zavesca	Actelion Registration Ltd Cheswick Tower, 13th floor, 389 Cheswick High Road, London W4 4AL, United Kingdom	EU/1/02/238	29.10.2014
30.10.2014	Elonva	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/609	3.11.2014
30.10.2014	Hexacima	Sanofi Pasteur SA 2 avenue Pont Pasteur, F-69007 Lyon, France	EU/1/13/828	3.11.2014
30.10.2014	Mycophenolate mofetil Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/07/439	4.11.2014
30.10.2014	Myfenax	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/07/438	4.11.2014
30.10.2014	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/06/380	3.11.2014
30.10.2014	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	3.11.2014

— **Withdrawal of a marketing authorisation** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
1.10.2014	FLUENZ	MedImmune, LLC Lagelandseweg 78, NL-6545 CG Nijmegen, Nederland	EU/1/10/661	3.10.2014
1.10.2014	Topotecan Eagle	Eagle Laboratories Limited The Clock House, Station Approach, Marlow, Bucks SL7 1NT, United Kingdom	EU/1/11/744	3.10.2014
21.10.2014	Clopidogrel Teva Pharma B.V.	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/10/649	23.10.2014
27.10.2014	Ipreziv	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/11/735	29.10.2014

— **Modification of a marketing authorisation** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
21.10.2014	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kingdom	EU/2/08/090	23.10.2014
27.10.2014	Apoquel	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	29.10.2014

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

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