IV

(Informazzjoni)

INFORMAZZJONI MINN ISTITUZZJONIJIET, KORPI, UFFIĊĊJI U AĠENZIJI TAL-UNJONI EWROPEA

IL-KUMMISSJONI EWROPEA

Sommarju ta' deċiżjonijiet tal-Unjoni Ewropea dwar l-awtorizzazzjonijiet għat-tqegħid fis-suq tal-prodotti mediċinali mill-1 ta' Frar 2017 sat-28 ta' Frar 2017

(Ippubblikat skont l-Artikolu 13 jew l-Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill ([1]))

(2017/C 102/01)

([1]) ĠU L 136, 30.4.2004, p. 1.

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
13.2.2017	LIFMIOR	etanercept	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/16/1165	Trab u solvent għal soluzzjoni għall-injezzjoni	L04AB01	15.2.2017
13.2.2017	Olumiant	baricitinib	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/16/1170	Pillola miksija b'rita	L04AA37	15.2.2017
13.2.2017	Vihuma	simoctocog alfa	Octapharma AB Lars Forssells gata 23, 112 75 Stockholm, Sverige	EU/1/16/1168	Trab u solvent għal soluzzjoni għall-injezzjoni	B02BD02	15.2.2017
16.2.2017	Alecensa	alectinib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/16/1169	Kapsula, iebsa	L01XE36	20.2.2017
17.2.2017	Truxima	rituximab	Celltrion Healthcare Hungary Kft. 1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410, Magyarország	EU/1/16/1167	Konċentrat għal soluzzjoni għal infużjoni	L01XC02	22.2.2017
27.2.2017	Pregabalin Zentiva k.s	pregabalin	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/16/1166	Kapsula, iebsa	N03AX16	1.3.2017

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 13 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
6.2.2017	Alimta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/290	8.2.2017
6.2.2017	Amyvid	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/12/805	8.2.2017
6.2.2017	APTIVUS	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/05/315	8.2.2017
6.2.2017	Gardasil	MSD VACCINS 162 avenue Jean Jaurès, 69007 Lyon, France	EU/1/06/357	8.2.2017
6.2.2017	Imvanex	Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark	EU/1/13/855	8.2.2017
6.2.2017	Scintimun	CIS bio international Boîte postale 32, F-91192 Gif-sur-Yvette, France	EU/1/09/602	8.2.2017
6.2.2017	Silgard	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358	8.2.2017
6.2.2017	Stribild	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/830	8.2.2017
6.2.2017	Tolucombi	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/13/821	9.2.2017
6.2.2017	Victrelis	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/11/704	8.2.2017
8.2.2017	Optruma	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/98/074	10.2.2017
13.2.2017	Aripiprazole Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Česká republika	EU/1/15/1009	15.2.2017
13.2.2017	Senshio	Shionogi Limited 33 Kingsway, London WC2B 6UF, United Kingdom	EU/1/14/978	15.2.2017
13.2.2017	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110	15.2.2017
16.2.2017	Aripiprazole Sandoz	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/15/1029	20.2.2017

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
16.2.2017	Armisarte	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Íceland	EU/1/15/1063	20.2.2017
16.2.2017	Brimica Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/963	20.2.2017
16.2.2017	Docetaxel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/611	20.2.2017
16.2.2017	Duaklir Genuair	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/14/964	20.2.2017
16.2.2017	Enyglid	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/580	20.2.2017
16.2.2017	EVOTAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/15/1025	20.2.2017
16.2.2017	Farydak	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/15/1023	20.2.2017
16.2.2017	Forsteo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/03/247	20.2.2017
16.2.2017	Genvoya	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/15/1061	20.2.2017
16.2.2017	INOmax	Linde Healthcare AB SE-181 81 Lidingö, Sverige	EU/1/01/194	22.2.2017
16.2.2017	Irbesartan/Hydrochlorothiazide Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/583	20.2.2017
16.2.2017	Kadcyla	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/885	20.2.2017
16.2.2017	Kalydeco	Vertex Pharmaceuticals (Europe) Limited 2 Kingdom Street, London W2 6BD, United Kingdom	EU/1/12/782	20.2.2017
16.2.2017	Leganto	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/11/695	20.2.2017
16.2.2017	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/051	20.2.2017
16.2.2017	Neupro	UCB Manufacturing Ireland Ltd Shannon Industrial Estate, Co, Clare, Ireland	EU/1/05/331	20.2.2017

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
16.2.2017	Nimenrix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/12/767	20.2.2017
16.2.2017	Nonafact	Sanquin Plasma Products B.V. Plesmanlaan 125, NL-1066 CX Amsterdam, Nederland	EU/1/01/186	20.2.2017
16.2.2017	Nucala	GlaxoSmithKline Trading Services Limited Currabinny, Carrigaline, County Cork, Ireland	EU/1/15/1043	20.2.2017
16.2.2017	Optimark	Mallinckrodt Deutschland GmbH Josef-Dietzgen-Strasse 1, D-53773 Hennef, Deutschland	EU/1/07/398	20.2.2017
16.2.2017	Portrazza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1084	20.2.2017
16.2.2017	Quinsair	Horizon Pharma Europe B.V. Naritaweg 165, NL-1043 BW Amsterdam, Nederland	EU/1/14/973	20.2.2017
16.2.2017	Ravicti	Horizon Pharma Ireland Limited Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland	EU/1/15/1062	20.2.2017
16.2.2017	Repaglinide Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/579	20.2.2017
16.2.2017	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	20.2.2017
16.2.2017	Revolade	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/10/612	20.2.2017
16.2.2017	Rivastigmine Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Ísland	EU/1/11/693	20.2.2017
16.2.2017	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050	20.2.2017
16.2.2017	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111	20.2.2017
16.2.2017	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/10/648	20.2.2017
16.2.2017	Viread	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/01/200	20.2.2017

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
16.2.2017	Zyprexa Velotab	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/99/125	20.2.2017
17.2.2017	Caprelsa	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/11/749	21.2.2017
17.2.2017	Cyramza	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/957	21.2.2017
17.2.2017	Emend	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/03/262	21.2.2017
17.2.2017	IMBRUVICA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/945	21.2.2017
17.2.2017	Pioglitazone Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/757	21.2.2017
17.2.2017	Pioglitazone Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/12/758	21.2.2017
17.2.2017	Repatha	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1016	21.2.2017
23.2.2017	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	27.2.2017
23.2.2017	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/14/939	27.2.2017
23.2.2017	Docetaxel Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/769	27.2.2017
23.2.2017	Docetaxel Kabi	Fresenius Kabi Oncology Plc. Lion Court, Farnham Road, Bordon, Hampshire GU35 0NF, United Kingdom	EU/1/12/770	27.2.2017
23.2.2017	Exviera	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/14/983	27.2.2017
23.2.2017	Harvoni	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/14/958	27.2.2017
23.2.2017	Ilaris	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/09/564	27.2.2017

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
23.2.2017	Ketoconazole HRA	Laboratoire HRA Pharma 15 rue Béranger, F-75003 Paris, France	EU/1/14/965	27.2.2017
23.2.2017	Lamivudine Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/566	27.2.2017
23.2.2017	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/924	27.2.2017
23.2.2017	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	27.2.2017
23.2.2017	Sovaldi	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/13/894	27.2.2017
23.2.2017	Tivicay	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/13/892	27.2.2017
23.2.2017	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	27.2.2017
23.2.2017	Viekirax	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/14/982	27.2.2017
23.2.2017	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	27.2.2017
27.2.2017	Adcirca	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/08/476	1.3.2017
27.2.2017	Kisplyx	Eisai Europe Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/16/1128	1.3.2017
27.2.2017	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	1.3.2017

— **Ħruġ ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	INN (Denominazzjoni Internazzjonali Komuni)	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Forma farmaċewtika	Kodiċi ATC (Kodiċi Anatomiku Terapewtiku Kimiku)	Data ta' notifika
2.2.2017	VarroMed	diitrat tal-aċidu ossaliku/aċidu formiku	BeeVital GmbH Wiesenbergstrasse 19, 5164, Seeham, Österreich	EU/2/16/203	Dispersjoni tad-doqqajs	Pending	6.2.2017
9.2.2017	Stronghold Plus	Selamektin/sarolaner	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/16/204	Taħlita likwida għall-użu lokalizzat	QP54AA55	13.2.2017

— **Modifika ta' awtorizzazzjoni għat-tqegħid fis-suq** (Artikolu 38 tar-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill): **Aċċettat**

Data tad-deċiżjoni	Isem tal-prodott mediċinali	Detentur tal-awtorizzazzjoni għat-tqegħid fis-suq	Numru tal-entrata fir-Reġistru Komunitarju	Data ta' notifika
9.2.2017	EQUIOXX	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/08/083	13.2.2017
10.2.2017	Vectormune ND	CEVA-Phylaxia Co. Ltd. Budapest, Szállás u. 5, 1107 MAGYARORSZÁG	EU/2/15/188	14.2.2017
17.2.2017	ERYSENG PARVO	Laboratorios Hipra, S.A. Avda. La Selva, 135, E-17170- Amer (Girona), España	EU/2/14/167	21.2.2017
17.2.2017	Trifexis	Eli Lilly and Company Ltd, Elanco Animal Health Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom	EU/2/13/155	21.2.2017
17.2.2017	Vectra 3D	CEVA SANTE ANIMALE 10 avenue de la Ballastière, F-33500 Libourne, France	EU/2/13/156	21.2.2017
27.2.2017	Equip WNV	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/08/086	1.3.2017

Kull min jixtieq jikkonsulta r-rapport ta' evalwazzjoni pubblika dwar il-prodotti mediċinali kkonċernati u d-deċiżjonijiet marbuta magħhom għandu jikkuntattja lil:

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom