Обобщение на решенията на Европейския съюз за разрешения за търговия по отношение на лекарствени продукти от 1 юни 2024 до 30 юни 2024

(Публикувано съгласно член 13 или член 38 от Регламент (ЕО) № 726/2004 на Европейския парламент и на Съвета [1] или Член 5 от Регламент (ЕС) 2019/6 на Европейския парламент и на Съвета [2])

(C/2024/4646)

— **Издаване на разрешение за търговия** (Член 13 от Регламент (ЕО) № 726/2004 на Европейския парламент и на Съвета): **Приети**

Дата на решението	Наименование на лекарствения продукт	INN (международно непатентно наименование)	Титуляр на разрешението за търговия	Регистрационен номер в регистъра на Общността	Фармацевтична форма	АТС код (код по анатомо-терапевтично-химичната класификация на СЗО)	Дата на нотифициране
3.6.2024	Fluenz	Ваксина срещу грип (жива атенюирана, назална)	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1816	Спрей за нос, суспензия	J07BB03	4.6.2024
17.6.2024	ALTUVOCT	ефанесоктоког алфа	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/24/1824	Прах и разтворител за инжекционен разтвор	B02BD02	18.6.2024
17.6.2024	Sirturo	бедахилин	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	таблетка	J04AK05	18.6.2024
17.6.2024	Truqap	капивасертиб	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/24/1820	Филмирана таблетка	L01EX27	18.6.2024
20.6.2024	FRUZAQLA	фруквинтиниб	Takeda Pharmaceuticals International AG Ireland Branch Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/24/1827	Капсула, твърда	L01EK	25.6.2024

[1] ОВ L 136, 30.4.2004 г., стр. 1, ELI: https://data.europa.eu/eli/reg/2004/726/oj.
[2] ОВ L 4, 7.1.2019 г., стр. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

20.6.2024	Tofidence	тоцилизумаб/tocilizumab	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/24/1825	Концентрат за инфузионен разтвор	L04AC07	21.6.2024
20.6.2024	Wezenla	устекинумаб	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/24/1823	Инжекционен разтвор Инжекционен разтвор в предварително напълнена спринцовка Концентрат за инфузионен разтвор	L04AC05	22.6.2024
27.6.2024	Eribulin Baxter	ерибулин	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/24/1819	Инжекционен разтвор	L01XX41	1.7.2024
27.6.2024	JERAYGO	апроцитентан (aprocitentan)	Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8, 79539 Loerrach, Deutschland	EU/1/24/1818	Филмирана таблетка	C02KN01	28.6.2024
27.6.2024	Obgemsa	Вибегрон	PIERRE FABRE MEDICAMENT Les Cauquillous, 81500 Lavaur, France	EU/1/24/1822	Филмирана таблетка	G04BD15	28.6.2024
27.6.2024	Rybrevant	амивантамаб	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/21/1594	Концентрат за инфузионен разтвор	L01FX18	28.6.2024
28.6.2024	IXCHIQ	Ваксина срещу чикунгуня (жива)	Valneva Austria GmbH Campus Vienna Biocenter 3, 1030 Wien, Österreich	EU/1/24/1828	Прах и разтворител за инжекционен разтвор	Pending	28.6.2024

ELI: http://data.europa.eu/eli/C/2024/4646/oj

ОВ C, 31.7.2024 г.

— **Изменение на разрешение за търговия** (Член 13 от Регламент (ЕО) № 726/2004 на Европейския парламент и на Съвета): **Приети**

Дата на решението	Наименование на лекарствения продукт	Титуляр на разрешението за търговия	Регистрационен номер в регистъра на Общността	Дата на нотифициране
6.6.2024	Alecensa	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/16/1169	7.6.2024
6.6.2024	Cinqaero	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/16/1125	11.6.2024
6.6.2024	Efavirenz/Emtricitabine/Tenofovir disoproxil Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/17/1263	17.6.2024
6.6.2024	Fasenra	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/17/1252	7.6.2024
6.6.2024	Lymphoseek	Navidea Biopharmaceuticals Europe Ltd. Kilminion South, Ballinroad, Dungarvan, Co. Waterford, X35 WP70, Ireland	EU/1/14/955	7.6.2024
6.6.2024	Pedmarqsi	Norgine B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/23/1734	7.6.2024
6.6.2024	Ritonavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	7.6.2024
6.6.2024	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	7.6.2024
6.6.2024	Sunlenca	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/22/1671	7.6.2024
6.6.2024	Synflorix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/09/508	10.6.2024
6.6.2024	Tepmetko	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/21/1596	10.6.2024
6.6.2024	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648	17.6.2024

6.6.2024	Veltassa	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	7.6.2024
10.6.2024	AMGLIDIA	AMMTeK 8 rue campagne première, 75014 Paris, France	EU/1/18/1279	12.6.2024
10.6.2024	Ozempic	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1251	11.6.2024
10.6.2024	Respreeza	CSL Behring GmbH Emil-von-Behring-Straße 76, 35041 Marburg, Deutschland	EU/1/15/1006	26.6.2024
10.6.2024	Wegovy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/21/1608	11.6.2024
13.6.2024	Atazanavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1091	14.6.2024
13.6.2024	Darunavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	14.6.2024
13.6.2024	Inbrija	Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/19/1390	14.6.2024
13.6.2024	Lopinavir/Ritonavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1067	14.6.2024
13.6.2024	Ritonavir Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1242	14.6.2024
13.6.2024	TALVEY	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/23/1748	14.6.2024
13.6.2024	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	14.6.2024
13.6.2024	Telmisartan Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/10/639	14.6.2024

17.6.2024	Eviplera	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/11/737	18.6.2024
17.6.2024	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	18.6.2024
17.6.2024	Galafold	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin D15 AKK1, Ireland	EU/1/15/1082	19.6.2024
17.6.2024	Giotrif	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/13/879	18.6.2024
17.6.2024	Givlaari	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/20/1428	18.6.2024
17.6.2024	Kinpeygo	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/22/1657	20.6.2024
17.6.2024	Mektovi	Pierre Fabre Médicament Les Cauquillous, 81500 Lavaur, France	EU/1/18/1315	18.6.2024
17.6.2024	Pioglitazone Actavis	Actavis Group PTC ehf. Dalshraun 1, 220 Hafnarfjörður, Íceland	EU/1/12/755	18.6.2024
17.6.2024	Rasagiline Viatris	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1090	18.6.2024
17.6.2024	Renagel	Sanofi B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/99/123	19.6.2024
17.6.2024	Verzenios	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1307	18.6.2024
17.6.2024	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	18.6.2024
17.6.2024	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	19.6.2024
17.6.2024	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/280	18.6.2024

17.6.2024	Zometa	Phoenix Labs Unlimited Company Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland	EU/1/01/176	18.6.2024
20.6.2024	Abecma	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/21/1539	26.6.2024
20.6.2024	Abiraterone Mylan	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/21/1571	21.6.2024
20.6.2024	Bridion	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/08/466	24.6.2024
20.6.2024	Cinacalcet Accordpharma	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1429	21.6.2024
20.6.2024	CONTROLOC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/515	25.6.2024
20.6.2024	Cymbalta	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/296	25.6.2024
20.6.2024	Duloxetine Lilly	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/14/972	24.6.2024
20.6.2024	Ifirmacombi	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/11/673	26.6.2024
20.6.2024	Kesimpta	Novartis Ireland Limited Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland	EU/1/21/1532	21.6.2024
20.6.2024	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	21.6.2024
20.6.2024	Ocrevus	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/17/1231	21.6.2024
20.6.2024	PANTOZOL Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/517	25.6.2024

20.6.2024	SOMAC Control	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/09/516	25.6.2024
20.6.2024	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	24.6.2024
20.6.2024	Tivicay	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/13/892	21.6.2024
20.6.2024	TOBI Podhaler	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/10/652	21.6.2024
20.6.2024	Vabysmo	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/22/1683	21.6.2024
20.6.2024	Voxzogo	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, P43 R298, Ireland	EU/1/21/1577	24.6.2024
20.6.2024	Xaluprine	Nova Laboratories Ireland Limited 3rd Floor, Ulysses House, Foley Street, Dublin 1, Ireland	EU/1/11/727	21.6.2024
20.6.2024	Xerava	PAION Deutschland GmbH Heussstraße 25, 52078 Aachen, Deutschland	EU/1/18/1312	24.6.2024
20.6.2024	Xtandi	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/13/846	21.6.2024
20.6.2024	Zabdeno	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1444	21.6.2024
20.6.2024	Zyclara	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/12/783	24.6.2024
20.6.2024	Zydelig	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/14/938	21.6.2024
20.6.2024	Вориконазол Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/835	21.6.2024

20.6.2024	Вориконазол Hikma	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó n.º 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal	EU/1/15/1004	28.6.2024
20.6.2024	Оланзапин Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/08/475	21.6.2024
27.6.2024	Byetta	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/06/362	28.6.2024
27.6.2024	Levetiracetam Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/11/712	28.6.2024
27.6.2024	Mepact	Takeda France SAS 112 avenue Kléber, 75116 Paris, France	EU/1/08/502	2.7.2024
27.6.2024	Nucala	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/15/1043	1.7.2024
27.6.2024	Rozlytrek	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1460	28.6.2024
27.6.2024	Stribild	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/830	28.6.2024
27.6.2024	Tavneos	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/21/1605	28.6.2024
27.6.2024	Vokanamet	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/14/918	28.6.2024
27.6.2024	Xospata	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/19/1399	28.6.2024
27.6.2024	Золедронова киселина medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/12/779	28.6.2024

28.6.2024	Cabazitaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/20/1448	1.7.2024
28.6.2024	CRYSVITA	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/17/1262	2.7.2024
28.6.2024	Dovprela	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1437	1.7.2024
28.6.2024	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	1.7.2024
28.6.2024	Edistride	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/15/1052	1.7.2024
28.6.2024	Emtricitabine/Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1133	1.7.2024
28.6.2024	Invokana	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/884	1.7.2024
28.6.2024	Isturisa	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/19/1407	1.7.2024
28.6.2024	Kineret	Swedish Orphan Biovitrum AB (publ) 112 76 Stockholm, Sverige	EU/1/02/203	9.7.2024
28.6.2024	Livmarli	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	1.7.2024
28.6.2024	Matever	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/11/711	3.7.2024
28.6.2024	Relvar Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/13/886	1.7.2024

28.6.2024	Revinty Ellipta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/14/929	1.7.2024
28.6.2024	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/05/330	2.7.2024
28.6.2024	Supemtek	Sanofi Pasteur 14 Espace Henry Vallée, 69007 Lyon, France	EU/1/20/1484	1.7.2024
28.6.2024	TAGRISSO	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/16/1086	1.7.2024
28.6.2024	Zonisamide Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1093	1.7.2024

— **Оттегляне на разрешение за търговия** (Член 13 от Регламент (ЕО) № 726/2004 на Европейския парламент и на Съвета)

Дата на решението	Наименование на лекарствения продукт	Титуляр на разрешението за търговия	Регистрационен номер в регистъра на Общността	Дата на нотифициране
6.6.2024	Nityr	Cycle Pharmaceuticals (Europe) Ltd 70 Sir John Rogerson's Quay, Dublin 2, D02 R296, Ireland	EU/1/18/1290	7.6.2024
10.6.2024	Lymphoseek	Navidea Biopharmaceuticals Europe Ltd. Kilminion South, Ballinroad, Dungarvan, Co. Waterford, X35 WP70, Ireland	EU/1/14/955	13.6.2024
28.6.2024	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	4.7.2024

— **Изменение на разрешение за търговия** (Член 38 от Регламент (ЕО) № 726/2004 на Европейския парламент и на Съвета; Член 5 от Регламент (ЕС) 2019/6 на Европейския парламент и на Съвета): **Приети**

Дата на решението	Наименование на лекарствения продукт	Титуляр на разрешението за търговия	Регистрационен номер в регистъра на Общността	Дата на нотифициране
6.6.2024	Arti-Cell Forte	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/18/228	7.6.2024
6.6.2024	Coxevac	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/10/110	7.6.2024

6.6.2024	Tessie	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/2/21/276	7.6.2024
13.6.2024	Eurican Herpes 205	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/01/029	17.6.2024
13.6.2024	Versican Plus Pi	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/168	18.6.2024

Моля всички желаещи да се запознаят с публичния доклад за оценката на въпросните лекарствени продукти и със свързаните с тях решения да се свържат с:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS