**Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. prosinca 2024. do 31. prosinca 2024.**

*(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća ([1]) ili Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća ([2]))*

(C/2025/476)

— **Izdavanje odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

| Datum odluke | Naziv lijeka | INN (međunarodni nezaštićeni naziv lijeka) | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Farmaceutski oblik | Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova) | Datum obavijesti |
|---|---|---|---|---|---|---|---|
| 12.12.2024 | ABSIMKY | ustekinumab | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/24/1880 | Koncentrat za otopinu za infuziju<br>Otopina za injekciju u napunjenoj štrcaljki | L04AC05 | 13.12.2024 |
| 12.12.2024 | Eltrombopag Viatris | eltrombopag | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/24/1869 | Filmom obložena tableta | B02BX05 | 13.12.2024 |
| 12.12.2024 | IMULDOSA | ustekinumab | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/24/1872 | Koncentrat za otopinu za infuziju<br>Otopina za injekciju | L04AC05 | 16.12.2024 |
| 13.12.2024 | Alhemo | koncizumab | Novo Nordisk A/S<br>Novo Alle 1, 2880 Bagsvaerd, Danmark | EU/1/24/1881 | Otopina za injekciju | B02BX10 | 16.12.2024 |
| 19.12.2024 | Buprenorphine Neuraxpharm | buprenorphine | Neuraxpharm Pharmaceuticals, S.L.<br>Avda. Barcelona 69, 08970 Sant Joan Despí - Barcelona, España | EU/1/24/1809 | sublingvalni film | N07BC01 | 20.12.2024 |

([1]) SL L 136, 30.4.2004, str. 1, ELI: https://data.europa.eu/eli/reg/2004/726/oj.
([2]) SL L 4, 7.1.2019, str. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

— **Izdavanje odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Odbijeno**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 16.12.2024 | Syfovre | Apellis Europe B.V.<br>Piet Heinkade 55, Amsterdam, Noord-Holland 1019 GM, Nederland | - | 19.12.2024 |
| 19.12.2024 | Masitinib AB Science | AB Science<br>3 avenue George V, 75008 Paris, France | - | 10.1.2025 |

— **Izmjena odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): **Prihvaćeno**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 4.12.2024 | Defitelio | Gentium S.r.I.<br>Piazza XX Settembre, 2, 22079 Villa Guardia (CO), Italia | EU/1/13/878 | 5.12.2024 |
| 4.12.2024 | Hemgenix | CSL Behring GmbH<br>D-35041 Marburg, Deutschland | EU/1/22/1715 | 10.12.2024 |
| 4.12.2024 | Hexacima | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/13/828 | 5.12.2024 |
| 4.12.2024 | Hexyon | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/13/829 | 5.12.2024 |
| 4.12.2024 | Hyftor | Plusultra pharma GmbH<br>Fritz-Vomfelde-Str. 36, 40547 Düsseldorf, Deutschland | EU/1/23/1723 | 12.12.2024 |
| 4.12.2024 | Vevizye | Laboratoires Thea<br>12 Rue Louis Bleriot, 63100 Clermont-Ferrand, France | EU/1/24/1857 | 5.12.2024 |
| 4.12.2024 | Xeljanz | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/17/1178 | 6.12.2024 |
| 6.12.2024 | Cerdelga | Sanofi B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/14/974 | 10.12.2024 |
| 9.12.2024 | Apretude | ViiV Healthcare BV<br>Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland | EU/1/23/1760 | 10.12.2024 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 9.12.2024 | Feraccru | Norgine B.V.<br>Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland | EU/1/15/1075 | 13.12.2024 |
| 9.12.2024 | Olanzapine Viatris | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/08/475 | 11.12.2024 |
| 9.12.2024 | Tegsedi | Akcea Therapeutics Ireland Ltd<br>St. James House, 72 Adelaide Road, Dublin 2, D02 Y017, Ireland | EU/1/18/1296 | 10.12.2024 |
| 11.12.2024 | Rivastigmine Sandoz | Sandoz GmbH<br>Biochemiestrasse 10, 6250 Kundl, Österreich | EU/1/09/599 | 13.12.2024 |
| 12.12.2024 | Abiraterone Mylan | Mylan Pharmaceuticals Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/21/1571 | 16.12.2024 |
| 12.12.2024 | Alimta | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/04/290 | 17.12.2024 |
| 12.12.2024 | Armisarte | Actavis Group PTC ehf.<br>Dalshraun 1, 220 Hafnarfjörður, Íceland | EU/1/15/1063 | 16.12.2024 |
| 12.12.2024 | BIMERVAX | Hipra Human Health, S.L.U.<br>Avda. la Selva, 135, 17170 Amer (Girona), España | EU/1/22/1709 | 13.12.2024 |
| 12.12.2024 | Bridion | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem, Nederland | EU/1/08/466 | 13.12.2024 |
| 12.12.2024 | Cinacalcet Accordpharma | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/20/1429 | 13.12.2024 |
| 12.12.2024 | Dengvaxia | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/18/1338 | 16.12.2024 |
| 12.12.2024 | Hukyndra | STADA Arzneimittel AG<br>Stadastraße 2-18, 61118 Bad Vilbel, Deutschland | EU/1/21/1589 | 13.12.2024 |
| 12.12.2024 | Imlygic | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/15/1064 | 13.12.2024 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 12.12.2024 | Keppra | UCB Pharma S.A.<br>Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België | EU/1/00/146 | 16.12.2024 |
| 12.12.2024 | Kyprolis | Amgen Europe B.V.<br>Minervum 7061, 4817 ZK Breda, Nederland | EU/1/15/1060 | 13.12.2024 |
| 12.12.2024 | Nintedanib Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/24/1803 | 13.12.2024 |
| 12.12.2024 | Opdualag | Bristol Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland | EU/1/22/1679 | 16.12.2024 |
| 12.12.2024 | Pemetrexed Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/15/1071 | 16.12.2024 |
| 12.12.2024 | Prometax | Almirall, S.A.<br>Ronda General Mitre, 151, 08022 Barcelona, España | EU/1/98/092 | 18.12.2024 |
| 12.12.2024 | Refixia | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsvaerd, Danmark | EU/1/17/1193 | 16.12.2024 |
| 12.12.2024 | Rivastigmine HEXAL | Hexal AG<br>Industriestraße 25, 83607 Holzkirchen, Deutschland | EU/1/09/589 | 13.12.2024 |
| 12.12.2024 | Sevelamer carbonate Winthrop | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/14/952 | 16.12.2024 |
| 12.12.2024 | Skytrofa | Ascendis Pharma Endocrinology Division A/S<br>Tuborg Boulevard 12, 2900 Hellerup, Danmark | EU/1/21/1607 | 13.12.2024 |
| 12.12.2024 | Spravato | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/19/1410 | 16.12.2024 |
| 12.12.2024 | Tepkinly | AbbVie Deutschland GmbH & Co. KG<br>Knollstrasse, 67061 Ludwigshafen, Deutschland | EU/1/23/1759 | 16.12.2024 |
| 12.12.2024 | Tibsovo | Les Laboratoires Servier<br>50 rue Carnot, 92284 Suresnes CEDEX, France | EU/1/23/1728 | 13.12.2024 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 12.12.2024 | Toujeo | Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland | EU/1/00/133 | 16.12.2024 |
| 12.12.2024 | Valdoxan | Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France | EU/1/08/499 | 16.12.2024 |
| 12.12.2024 | Vocabria | ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland | EU/1/20/1481 | 16.12.2024 |
| 12.12.2024 | Vueway | Bracco Imaging SPA Via Egidio Folli, 50 20134 Milano, Italia | EU/1/23/1773 | 13.12.2024 |
| 12.12.2024 | Zykadia | Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/15/999 | 17.12.2024 |
| 13.12.2024 | CellCept | Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/96/005 | 16.12.2024 |
| 13.12.2024 | Evkeeza | Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland | EU/1/21/1551 | 16.12.2024 |
| 13.12.2024 | Teriflunomide Viatris | Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/22/1698 | 16.12.2024 |
| 13.12.2024 | Trepulmix | SciPharm Sàrl 7, Fausermillen, 6689 Mertert, Luxembourg | EU/1/19/1419 | 17.12.2024 |
| 16.12.2024 | Gilenya | Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/11/677 | 17.12.2024 |
| 19.12.2024 | Azacitidine Accord | Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España | EU/1/19/1413 | 20.12.2024 |
| 19.12.2024 | Cinacalcet Viatris | Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/15/1054 | 20.12.2024 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 19.12.2024 | Erbitux | Merck Europe B.V.<br>Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland | EU/1/04/281 | 20.12.2024 |
| 19.12.2024 | Erelzi | Sandoz GmbH<br>Biochemiestrasse 10, 6250 Kundl, Österreich | EU/1/17/1195 | 7.1.2025 |
| 19.12.2024 | Exelon | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/98/066 | 7.1.2025 |
| 19.12.2024 | Fluad Tetra | Seqirus Netherlands B.V.<br>Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland | EU/1/20/1433 | 20.12.2024 |
| 19.12.2024 | Libmyris | STADA Arzneimittel AG<br>Stadastraße 2-18, 61118 Bad Vilbel, Deutschland | EU/1/21/1590 | 20.12.2024 |
| 19.12.2024 | LIBTAYO | Regeneron Ireland Designated Activity Company (DAC)<br>One Warrington Place, Dublin 2, D02 HH27, Ireland | EU/1/19/1376 | 20.12.2024 |
| 19.12.2024 | Litak | Lipomed GmbH<br>Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland | EU/1/04/275 | 20.12.2024 |
| 19.12.2024 | Lyrica | Upjohn EESV<br>Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland | EU/1/04/279 | 7.1.2025 |
| 19.12.2024 | Omvoh | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/23/1736 | 20.12.2024 |
| 19.12.2024 | OPDIVO | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/15/1014 | 20.12.2024 |
| 19.12.2024 | Palforzia | STALLERGENES<br>6 rue Alexis de Tocqueville, 92160 Antony, France | EU/1/20/1495 | 20.12.2024 |
| 19.12.2024 | Pemetrexed Fresenius Kabi | Fresenius Kabi Deutschland GmbH<br>Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland | EU/1/16/1115 | 20.12.2024 |
| 19.12.2024 | Relistor | Bausch Health Ireland Limited<br>3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland | EU/1/08/463 | 7.1.2025 |

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 19.12.2024 | Renvela | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/09/521 | 20.12.2024 |
| 19.12.2024 | Rivaroxaban Viatris | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/21/1588 | 20.12.2024 |
| 19.12.2024 | Rivastigmine 1 A Pharma | 1 A Pharma GmbH<br>Industriestraße 18, 83607 Holzkirchen, Deutschland | EU/1/09/585 | 23.12.2024 |
| 19.12.2024 | Rybrevant | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/21/1594 | 20.12.2024 |
| 19.12.2024 | Sitagliptin/ Metformin hydrochloride Mylan | Mylan Pharmaceuticals Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland | EU/1/21/1619 | 20.12.2024 |
| 19.12.2024 | TAGRISSO | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/16/1086 | 20.12.2024 |
| 19.12.2024 | Trazimera | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/18/1295 | 20.12.2024 |
| 19.12.2024 | Vabysmo | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/22/1683 | 20.12.2024 |
| 19.12.2024 | Vidaza | Bristol Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland | EU/1/08/488 | 20.12.2024 |
| 19.12.2024 | YERVOY | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/11/698 | 20.12.2024 |

— **Povlačenje odobrenja za stavljanje u promet** (članak 13 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 13.12.2024 | Alofisel | Takeda Pharma A/S<br>Delta Park 45, 2665 Vallensbaek Strand, Danmark | EU/1/17/1261 | 13.12.2024 |

— **Izdavanje odobrenja za stavljanje u promet** (članak 38 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća; Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća): **Prihvaćeno**

| Datum odluke | Naziv lijeka | INN (međunarodni nezaštićeni naziv lijeka) | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Farmaceutski oblik | Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova) | Datum obavijesti |
|---|---|---|---|---|---|---|---|
| 19.12.2024 | Carprofen Orion | karprofen | Orion Corporation<br>Orionintie 1, 02200 Espoo, Suomi | EU/2/24/328 | Otopina za injekciju<br>Tablete za žvakanje | QM01AE91 | 20.12.2024 |

— **Izmjena odobrenja za stavljanje u promet** (članak 38 Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća; Članak 5. Uredbe (EU) 2019/6 Europskog parlamenta i Vijeća): **Prihvaćeno**

| Datum odluke | Naziv lijeka | Nositelj odobrenja za stavljanje u promet | Broj upisa u registar Zajednice | Datum obavijesti |
|---|---|---|---|---|
| 19.12.2024 | Daxocox | Ecuphar NV<br>Legeweg 157-i, 8020 Oostkamp, België | EU/2/21/270 | 28.12.2024 |
| 19.12.2024 | Equisolon | Le Vet B.V.<br>Wilgenweg 7, 3421 TV Oudewater, Nederland | EU/2/14/161 | 23.12.2024 |
| 19.12.2024 | Locatim | MELCHIOR SANTE ANIMALE<br>5 Rue Victor Hugo, 69002 Lyon, France | EU/2/99/011 | 20.12.2024 |
| 19.12.2024 | Simparica Trio | Zoetis Belgium<br>rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/19/243 | 20.12.2024 |

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NETHERLANDS