C/2024/910

31.1.2024.

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. prosinca 2023. do 31. prosinca 2023.

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

(C/2024/910)

[1] SL L 136, 30.4.2004., str. 1.
[2] SL L 4, 7.1.2019., str. 43.

— **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
1.12.2023.	Zilbrysq	zilukoplan	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/23/1764	Otopina za injekciju	L04A	4.12.2023.
7.12.2023.	ELREXFIO	elranatamab	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/23/1770	Otopina za injekciju	Pending	8.12.2023.
7.12.2023.	Elucirem	gadopiklenol	Guerbet 15 rue des Vanesses, 93420, Villepinte, France	EU/1/23/1772	Otopina za injekciju	V08CA	8.12.2023.
7.12.2023.	JEMPERLI	dostarlimab	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1538	Koncentrat za otopinu za infuziju	L01FF07	11.12.2023.
7.12.2023.	Veoza	fezolinetant	Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, Nederland	EU/1/23/1771	Filmom obložena tableta	G02CX06	12.12.2023.
7.12.2023.	Vueway	gadopiklenol	Bracco Imaging SPA Via Egidio Folli, 50 20134 Milano, Italia	EU/1/23/1773	Otopina za injekciju	V08CA12	8.12.2023.
13.12.2023.	Dimethyl Fumarate Accord	dimetilfumarat	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1711	Želučanootporna tvrda kapsula	L04AX07	13.12.2023.
13.12.2023.	Dimethyl fumarate Mylan	dimetilfumarat	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/22/1634	Želučanootporna tvrda kapsula	L04AX07	13.12.2023.
13.12.2023.	Dimethyl fumarate Neuraxpharm	dimetilfumarat	Laboratorios Lesvi, S.L. Avda. Barcelona 69, 08970 Sant Joan Despí – Barcelona, España	EU/1/22/1637	Želučanootporna tvrda kapsula	L04AX07	16.12.2023.
13.12.2023.	Dimethyl fumarate Polpharma	dimetilfumarat	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19, 83-200 Starogard Gdański, Polska	EU/1/22/1635	Želučanootporna tvrda kapsula	L04AX07	13.12.2023.

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
13.12.2023.	Dimethyl Fumarate Teva	dimetilfumarat	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/22/1702	Želučanootporna tvrda kapsula	L04AX07	15.12.2023.
14.12.2023.	AGAMREE	vamorolon	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Straße 8, 79539 Lörrach, Deutschland	EU/1/23/1776	Peroralna suspenzija		15.12.2023.
15.12.2023.	Loargys	pegzilarginaza	Immedica Pharma AB SE-113 63, Stockholm, Sverige	EU/1/23/1774	otopina za injekciju ili infuziju	A16AB24	18.12.2023.
22.12.2023.	Rezzayo	Rezafungin	Mundipharma GmbH De-Saint-Exupery-Strasse 10, 60549 Frankfurt Am Main, Deutschland	EU/1/23/1775	Prašak za koncentrat za otopinu za infuziju	J02AX08	22.12.2023.

— **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
1.12.2023.	Bemfola	Gedeon Richter Plc. Gyömrői út 19-21, 1103 Budapest, Magyarország	EU/1/13/909	5.12.2023.
1.12.2023.	Beyfortus	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1689	4.12.2023.
1.12.2023.	Clopidogrel Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	5.12.2023.
1.12.2023.	Dificlir	Tillotts Pharma GmbH Warmbacher Strasse 80, 79618 Rheinfelden, Deutschland	EU/1/11/733	4.12.2023.
1.12.2023.	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	4.12.2023.
1.12.2023.	Vizamyl	GE Healthcare AS Nycoveien 1, 0485, Oslo, Norge	EU/1/14/941	6.12.2023.
1.12.2023.	VPRIV	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/10/646	6.12.2023.
7.12.2023.	Ammonaps	Immedica Pharma AB Solnavagen 3 H, Stockholm, 113 63, Sverige	EU/1/99/120	8.12.2023.
7.12.2023.	Atazanavir Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/19/1353	14.12.2023.
7.12.2023.	Benepali	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/15/1074	12.12.2023.
7.12.2023.	Besremi	AOP Orphan Pharmaceuticals GmbH Leopold-Ungar-Platz 2, 1190 Wien, Österreich	EU/1/18/1352	11.12.2023.
7.12.2023.	Byooviz	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/21/1572	12.12.2023.
7.12.2023.	CARVYKTI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1648	11.12.2023.
7.12.2023.	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	11.12.2023.
7.12.2023.	Fasturtec	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/00/170	8.12.2023.
7.12.2023.	Febuxostat Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1347	14.12.2023.
7.12.2023.	Fluad Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/20/1433	13.12.2023.
7.12.2023.	Flucelvax Tetra	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Nederland	EU/1/18/1326	14.12.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
7.12.2023.	Hemgenix	CSL Behring GmbH D-35041 Marburg, Deutschland	EU/1/22/1715	15.12.2023.
7.12.2023.	Imatinib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/13/845	11.12.2023.
7.12.2023.	Intrarosa	Endoceutics S.A. Rue Belliard 40, 1040 Bruxelles, Belgique/ Belliardstraat 40, 1040 Brussel, België	EU/1/17/1255	8.12.2023.
7.12.2023.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	11.12.2023.
7.12.2023.	Lyrica	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/04/279	12.12.2023.
7.12.2023.	Neupro	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/331	8.12.2023.
7.12.2023.	Omnitrope	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/06/332	11.12.2023.
7.12.2023.	Posaconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/19/1379	11.12.2023.
7.12.2023.	Pregabalin Pfizer	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/14/916	12.12.2023.
7.12.2023.	Steglatro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1267	8.12.2023.
7.12.2023.	Striascan	CIS bio international RN 306 – Saclay, B.P. 32, F-91192 Gif-sur-Yvette Cedex, France	EU/1/19/1372	8.12.2023.
7.12.2023.	Sycrest	Organon N.V. Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/10/640	10.12.2023.
7.12.2023.	Symkevi	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/18/1306	8.12.2023.
7.12.2023.	Tecartus	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	12.12.2023.
7.12.2023.	Tecovirimat SIGA	SIGA Technologies Netherlands B.V. Prinsenhil 29, Breda 4825 AX, Nederland	EU/1/21/1600	8.12.2023.
7.12.2023.	TECVAYLI	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/22/1675	11.12.2023.
7.12.2023.	TOOKAD	Steba Biotech B.A. 14a Rue des Bains, L-1212, Luxembourg, Luxembourg	EU/1/17/1228	11.12.2023.
7.12.2023.	Vizimpro	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1354	8.12.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
7.12.2023.	Vyepti	H. Lundbeck A/S Ottiliavej 9, 2500 Valby, Danmark	EU/1/21/1599	11.12.2023.
7.12.2023.	Xevudy	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	EU/1/21/1562	11.12.2023.
11.12.2023.	AYVAKYT	Blueprint Medicines (Netherlands) B.V. Gustav Mahlerplein 2, 1082 MA Amsterdam, Nederland	EU/1/20/1473	12.12.2023.
11.12.2023.	Brineura	BioMarin International Limited Shanbally, Ringaskiddy, County Cork, Ireland	EU/1/17/1192	12.12.2023.
11.12.2023.	Erelzi	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1195	15.12.2023.
11.12.2023.	Evkeeza	Ultragenyx Germany GmbH Rahel-Hirsch-Str. 10, 10557 Berlin, Deutschland	EU/1/21/1551	12.12.2023.
11.12.2023.	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	12.12.2023.
11.12.2023.	Mounjaro	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/22/1685	13.12.2023.
11.12.2023.	Moventig	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/14/962	12.12.2023.
11.12.2023.	Nepexto	Biosimilar Collaborations Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, D13 R20R, DUBLIN, Ireland	EU/1/20/1436	13.12.2023.
11.12.2023.	Pedea	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/04/284	12.12.2023.
11.12.2023.	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	12.12.2023.
11.12.2023.	Ventavis	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/03/255	12.12.2023.
14.12.2023.	AMGEVITA	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/16/1164	18.12.2023.
14.12.2023.	Enbrel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/126	19.12.2023.
14.12.2023.	NexoBrid	MediWound Germany GmbH Hans-Sachs-Strasse 100, 65428 Rüsselsheim, Deutschland	EU/1/12/803	21.12.2023.
14.12.2023.	Pepaxti	Oncopeptides AB (publ) Västra Trädgårdsgatan 15, 111 53 Stockholm, Sverige	EU/1/22/1669	15.12.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
18.12.2023.	Clopidogrel Taw Pharma	Taw Pharma (Ireland) Limited 104 Lower Baggot Street, Dublin 2, Ireland	EU/1/09/559	19.12.2023.
18.12.2023.	Clopidogrel Viatris	Viatris Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	21.12.2023.
19.12.2023.	Amvuttra	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/22/1681	20.12.2023.
19.12.2023.	Ibandronic Acid Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/10/642	21.12.2023.
19.12.2023.	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	20.12.2023.
19.12.2023.	Rinvoq	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/19/1404	20.12.2023.
19.12.2023.	Tacforius	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/17/1244	8.1.2024.
19.12.2023.	Tevimbra	BeiGene Ireland Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Co. Dublin, Ireland	EU/1/23/1758	22.12.2023.

— **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
11.12.2023.	Onbevzi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1499	13.12.2023.

— **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
11.12.2023.	Advocate	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/03/039	12.12.2023.
18.12.2023.	Baycox Iron	Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Deutschland	EU/2/19/239	20.12.2023.
19.12.2023.	Credelio Plus	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/21/271	21.12.2023.
19.12.2023.	ERAVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/199	20.12.2023.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.12.2023.	ERYSENG	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/14/166	21.12.2023.
19.12.2023.	Evalon	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/16/194	20.12.2023.
19.12.2023.	EVANT	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/18/233	21.12.2023.
19.12.2023.	Hiprabovis IBR Marker Live	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/10/114	21.12.2023.
19.12.2023.	Leucogen	Virbac 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/09/096	20.12.2023.
19.12.2023.	Meloxoral	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/10/111	20.12.2023.
19.12.2023.	MHYOSPHERE PCV ID	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/20/259	20.12.2023.
19.12.2023.	Nobivac LeuFel	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/17/217	20.12.2023.
19.12.2023.	Nobivac Myxo-RHD PLUS	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/19/244	21.12.2023.
19.12.2023.	RHINISENG	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/10/109	22.12.2023.
19.12.2023.	STARTVAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/08/092	22.12.2023.
19.12.2023.	Suvaxyn Circo	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/223	21.12.2023.
19.12.2023.	Suvaxyn Circo + MH RTU	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/15/190	21.12.2023.
19.12.2023.	UBAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/18/227	21.12.2023.

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