IV.

(Obavijesti)

OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

EUROPSKA KOMISIJA

Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. prosinca 2022. do 31. prosinca 2022.

(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])

(2023/C 37/01)

[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
2.12.2022.	Mycapssa	oktreotid	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/22/1690	Želučanootporna tvrda kapsula	H01CB02	5.12.2022.
5.12.2022.	Qdenga	četverovalentno cjepivo protiv denge (živo, atenuirano)	Takeda GmbH Byk-Gulden-Straße 2, 78467 Konstanz, Deutschland	EU/1/22/1699	Prašak i otapalo za otopinu za injekciju	J07BX04	6.12.2022.
9.12.2022.	Livmarli	maraliksibatklorid	Mirum Pharmaceuticals International B.V. Kingsfordweg 151, 1043 GR Amsterdam, Noord-Holland, Nederland	EU/1/22/1704	Peroralna otopina	A05AX04	12.12.2022.
9.12.2022.	Locametz	gozetotid	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1692	Prašak za otopinu za injekciju	V09IX14	12.12.2022.
9.12.2022.	Pemetreksed Baxter	pemetrekseda	Baxter Holding B.V. Kobaltweg 49, 3542 CE Utrecht, Nederland	EU/1/22/1705	Prašak za koncentrat za otopinu za infuziju	L01BA04	13.12.2022.
9.12.2022.	Pluvicto	lutecij[^{177}Lu]vipivotidtetraksetan	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/22/1703	otopina za injekciju ili infuziju	V10XX05	12.12.2022.
9.12.2022.	Spevigo	spezolimab	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/22/1688	Koncentrat za otopinu za infuziju	L04AC22	12.12.2022.
12.12.2022.	Dimethyl Fumarate Teva	dimetilfumarat	Teva GmbH Graf-Arco-Straße 3, 89079 Ulm, Deutschland	EU/1/22/1702	Želučanootporna tvrda kapsula	L04AX07	3.1.2023.

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
12.12.2022.	Eladynos	abaloparatid	Radius Health (Ireland) Ltd. 13 Classon House, Dundrum Business Park, Dundrum, Dublin D14 W9Y3, Ireland	EU/1/22/1706	Otopina za injekciju	H05AA04	13.12.2022.
16.12.2022.	Ebvallo	Tabelekleucel	Atara Biotherapeutics Ireland Limited Arthur Cox Building, 10 Earlsfort Terrace, Dublin 2 D02 T380, Ireland	EU/1/22/1700	Disperzija za injekciju	Pending	16.12.2022.
16.12.2022.	Plerixafor Accord	pleriksafor	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/22/1701	Otopina za injekciju	L03AX16	19.12.2022.
20.12.2022.	Zynlonta	lonkastuksimab tesirin	ADC Therapeutics (NL) B.V. Laarderhoogtweg 25, Amsterdam, Noord-Holland, 1101 EB, Nederland	EU/1/22/1695	Prašak za koncentrat za otopinu za infuziju	L01FX22	22.12.2022.

— **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
2.12.2022.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	2.12.2022.
2.12.2022.	DuoPlavin	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/10/619	5.12.2022.
2.12.2022.	Kaftrio	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/20/1468	5.12.2022.
2.12.2022.	Kalydeco	Vertex Pharmaceuticals (Ireland) Limited Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland	EU/1/12/782	5.12.2022.
2.12.2022.	QINLOCK	Deciphera Pharmaceuticals (Netherlands) B.V. Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland	EU/1/21/1569	8.12.2022.
2.12.2022.	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/97/050	7.12.2022.
2.12.2022.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	7.12.2022.
2.12.2022.	Trizivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/00/156	5.12.2022.
2.12.2022.	Trogarzo	Theratechnologies Europe Limited 4th Floor, 2 Hume Street, Dublin 2, D02 DV24, Ireland	EU/1/19/1359	14.12.2022.
2.12.2022.	Trydonis	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/18/1274	5.12.2022.
2.12.2022.	Zyclara	Viatris Healthcare Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/12/783	6.12.2022.
5.12.2022.	Shingrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/18/1272	6.12.2022.
5.12.2022.	Steglujan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1266	6.12.2022.
5.12.2022.	Xarelto	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/08/472	6.12.2022.
9.12.2022.	Abevmy	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1515	14.12.2022.
9.12.2022.	Atriance	Sandoz Pharmaceuticals d.d. Verovškova ulica 57, 1000 Ljubljana, Slovenija	EU/1/07/403	12.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.12.2022.	Aybintio	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1454	13.12.2022.
9.12.2022.	Bortezomib Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1019	15.12.2022.
9.12.2022.	Deferiprone Lipomed	Lipomed GmbH Hegenheimer Straße 2, 79576 Weil/Rhein, Deutschland	EU/1/18/1310	12.12.2022.
9.12.2022.	Duaklir Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/14/964	12.12.2022.
9.12.2022.	Eklira Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/12/778	14.12.2022.
9.12.2022.	Erleada	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/18/1342	12.12.2022.
9.12.2022.	Eylea	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/12/797	13.12.2022.
9.12.2022.	Herzuma	Celltrion Healthcare Hungary Kft. Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország	EU/1/17/1257	14.12.2022.
9.12.2022.	Insulin aspart Sanofi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1447	13.12.2022.
9.12.2022.	Insulin lispro Sanofi	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1203	13.12.2022.
9.12.2022.	Onbevzi	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	EU/1/20/1499	13.12.2022.
9.12.2022.	Oyavas	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/20/1510	12.12.2022.
9.12.2022.	Qarziba	EUSA Pharma (Netherlands) B.V. Beechavenue 54, 1119PW Schiphol-Rijk, Nederland	EU/1/17/1191	14.12.2022.
9.12.2022.	Retsevmo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/20/1527	12.12.2022.
9.12.2022.	Riarify	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/18/1275	12.12.2022.
9.12.2022.	Spravato	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/19/1410	12.12.2022.
9.12.2022.	Suliqua	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/16/1157	13.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.12.2022.	Vaxelis	MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, Nederland	EU/1/15/1079	13.12.2022.
9.12.2022.	Vydura	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1645	12.12.2022.
9.12.2022.	Xydalba	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland	EU/1/14/986	12.12.2022.
9.12.2022.	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	12.12.2022.
12.12.2022.	Alymsys	Mabxience Research SL C/ Manuel Pombo Angulo 28 – 3a y 4a Planta, 28050 Madrid, España	EU/1/20/1509	13.12.2022.
12.12.2022.	Cablivi	Ablynx N.V. Technologiepark 21, 9052 Zwijnaarde, België	EU/1/18/1305	21.12.2022.
12.12.2022.	Dificlir	Tillotts Pharma GmbH Warmbacher Strasse 80, 79618 Rheinfelden, Deutschland	EU/1/11/733	13.12.2022.
12.12.2022.	DuoPlavin	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/10/619	14.12.2022.
12.12.2022.	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	13.12.2022.
12.12.2022.	Enhertu	Daiichi Sankyo Europe GmbH Zielstattstraße 48, 81379 München, Deutschland	EU/1/20/1508	13.12.2022.
12.12.2022.	Karvezide	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/085	13.12.2022.
12.12.2022.	Kisqali	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/17/1221	13.12.2022.
12.12.2022.	Refixia	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/17/1193	13.12.2022.
16.12.2022.	Avastin	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/04/300	19.12.2022.
16.12.2022.	Bretaris Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/12/781	3.1.2023.
16.12.2022.	Brilique	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/655	19.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2022.	Brimica Genuair	Covis Pharma Europe B.V. Gustav Mahlerplein 2, 1082MA Amsterdam, Nederland	EU/1/14/963	19.12.2022.
16.12.2022.	Caprelsa	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/11/749	19.12.2022.
16.12.2022.	Ceprotin	Baxter AG Industriestraße 67, 1221 Wien, Österreich	EU/1/01/190	19.12.2022.
16.12.2022.	Combivir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/98/058	19.12.2022.
16.12.2022.	Corbilta	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/13/859	20.12.2022.
16.12.2022.	DUAVIVE	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/14/960	20.12.2022.
16.12.2022.	DuoPlavin	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/10/619	19.12.2022.
16.12.2022.	Dupixent	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/17/1229	19.12.2022.
16.12.2022.	Eptifibatid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/15/1065	19.12.2022.
16.12.2022.	Granpidam	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/16/1137	19.12.2022.
16.12.2022.	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	19.12.2022.
16.12.2022.	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	19.12.2022.
16.12.2022.	Inhixa	Techdow Pharma Netherlands B.V. Strawinskylaan 1143, Toren C-11, 1077 XX Amsterdam, Nederland	EU/1/16/1132	22.12.2022.
16.12.2022.	Intuniv	Takeda Pharmaceuticals International AG Ireland Branch Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/15/1040	20.12.2022.
16.12.2022.	Iscover	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/070	19.12.2022.
16.12.2022.	Iscover	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/070	19.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2022.	Iscover	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/070	19.12.2022.
16.12.2022.	Karvea	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/97/049	20.12.2022.
16.12.2022.	Levodopa/Carbidopa/Entacapone Orion	Orion Corporation Orionintie 1, 02200 Espoo, Suomi	EU/1/11/706	21.12.2022.
16.12.2022.	Lynparza	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/14/959	19.12.2022.
16.12.2022.	Moventig	Kyowa Kirin Holdings B.V. Bloemlaan 2, 2132 NP Hoofddorp, Nederland	EU/1/14/962	21.12.2022.
16.12.2022.	Mvabea	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1445	20.12.2022.
16.12.2022.	Myalepta	Amryt Pharmaceuticals DAC 45 Mespil Road, Dublin 4, Ireland	EU/1/18/1276	21.12.2022.
16.12.2022.	Neulasta	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/02/227	20.12.2022.
16.12.2022.	Ocaliva	ADVANZ PHARMA Limited Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland	EU/1/16/1139	19.12.2022.
16.12.2022.	Ozawade	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/21/1546	19.12.2022.
16.12.2022.	Plavix	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/069	19.12.2022.
16.12.2022.	Plavix	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/069	19.12.2022.
16.12.2022.	Plavix	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/98/069	19.12.2022.
16.12.2022.	Resolor	Takeda Pharmaceuticals International AG Ireland Branch Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland	EU/1/09/581	20.12.2022.
16.12.2022.	Rybelsus	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/20/1430	20.12.2022.
16.12.2022.	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	19.12.2022.
16.12.2022.	Saxenda	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/15/992	19.12.2022.
16.12.2022.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle del Principe de Vergara 132 Plt 12, 28002 Madrid, España	EU/1/20/1507	19.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
16.12.2022.	Trajenta	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/11/707	19.12.2022.
16.12.2022.	Tresiba	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/12/807	20.12.2022.
16.12.2022.	Truvelog Mix 30	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/22/1639	19.12.2022.
16.12.2022.	Twynsta	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/10/648	3.1.2023.
16.12.2022.	Zoledronic acid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/13/834	19.12.2022.
19.12.2022.	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	20.12.2022.
20.12.2022.	Ibandronic acid Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/798	22.12.2022.
20.12.2022.	Mvasi	Amgen Technology (Ireland) UC Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	EU/1/17/1246	4.1.2023.
20.12.2022.	Rivaroxaban Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/20/1488	22.12.2022.
20.12.2022.	Sarclisa	Sanofi Winthrop Industrie 82 avenue Raspail, 94250 Gentilly, France	EU/1/20/1435	21.12.2022.
20.12.2022.	Sirturo	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/13/901	21.12.2022.
20.12.2022.	Skytrofa	Ascendis Pharma Endocrinology Division A/S Tuborg Boulevard 12, 2900 Hellerup, Danmark	EU/1/21/1607	21.12.2022.
22.12.2022.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland	EU/1/20/1528	22.12.2022.
22.12.2022.	Paxlovid	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/22/1625	22.12.2022.

— **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
5.12.2022.	Trogarzo	Theratechnologies Europe Limited 4th Floor, 2 Hume Street, Dublin 2, D02 DV24, Ireland	EU/1/19/1359	5.1.2023.
9.12.2022.	NeuroBloc	Sloan Pharma S.a.r.l. 33 Rue de Puits Romain, 8070 Bertrange, Luxembourg	EU/1/00/166	12.12.2022.

— **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
20.12.2022.	NEOLEISH	Cjepivo protiv lišmanioze u pasa (plazmid rekombinantne DNK)	CZ Veterinaria, S.A. La Relva s/n – Torneiros, 36410 Porriño, España	EU/2/22/290	sprej za nos, otopina	Pending	21.12.2022.

— **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
2.12.2022.	CYTOPOINT	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/205	5.12.2022.
2.12.2022.	Fevaxyn Pentofel	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/96/002	6.12.2022.
2.12.2022.	Solensia	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/269	5.12.2022.
2.12.2022.	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	6.12.2022.
2.12.2022.	Zenalpha	Vetcare Oy P.O. Box 99, 24101 Salo, Suomi	EU/2/21/279	7.12.2022.
9.12.2022.	Convenia	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/06/059	14.12.2022.
9.12.2022.	Zeleris	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/210	14.12.2022.
13.12.2022.	Innovax-ND-ILT	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/20/256	14.12.2022.
13.12.2022.	Versican Plus DHPPi/L4R	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/163	14.12.2022.
15.12.2022.	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	20.12.2022.
15.12.2022.	Librela	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/261	21.12.2022.
15.12.2022.	NEXGARD SPECTRA	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/14/177	16.12.2022.
15.12.2022.	Porcilis PCV M Hyo	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/175	20.12.2022.
15.12.2022.	Simparica Trio	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/243	20.12.2022.
15.12.2022.	Simparica Trio	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/19/243	20.12.2022.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
15.12.2022.	UBAC	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/18/227	21.12.2022.
15.12.2022.	Versican Plus Pi/L4R	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/173	16.12.2022.
16.12.2022.	Equip WNV	Zoetis Belgium rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/08/086	20.12.2022.
20.12.2022.	Lydaxx	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/253	21.12.2022.
20.12.2022.	Novem	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/04/042	22.12.2022.
20.12.2022.	Onsior	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/08/089	21.12.2022.
20.12.2022.	ProteqFlu	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/03/037	22.12.2022.
20.12.2022.	ProteqFlu-Te	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/03/038	22.12.2022.
20.12.2022.	Rabitec	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/17/219	21.12.2022.
20.12.2022.	RHINISENG	Laboratorios Hipra, S.A. Avda. La Selva, 135, 17170 Amer (Girona), España	EU/2/10/109	22.12.2022.
20.12.2022.	Suprelorin	VIRBAC S.A. 1ère Avenue – 2065 m – L.I.D., 06516 Carros CEDEX, France	EU/2/07/072	23.12.2022.
20.12.2022.	Tulaven	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/20/251	21.12.2022.

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
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NIZOZEMSKA