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 2020. do 31. prosinca 2020.

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

(2021/C 33/01)

([1]) SL L 136, 30.4.2004., str. 1.

— **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
9.12.2020.	Leqvio	inklisiran	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1494	Otopina za injekciju	C10AX16	10.12.2020.
9.12.2020.	TRIXEO AEROSPHERE	Formoterol / glikopironij bromid / budezonid	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/20/1498	Stlačeni inhalat, suspenzija	R03AL11	10.12.2020.
14.12.2020.	Tecartus	autologne CD3+ stanice transducirane pomoću anti CD19	Kite Pharma EU B.V. Tufsteen 1, 2132 NT Hoofddorp, Nederland	EU/1/20/1492	Disperzija za infuziju	L01X	15.12.2020.
17.12.2020.	Libmeldy	obogaćena populacija autologni CD34+ stanica koja sadrži hematopoetske matične i progenitorne stanice transducirane ex vivo lentivirusnim vektorom koji kodira gen ljudske arilsulfataze A	Orchard Therapeutics (Netherlands) B.V. Prins Bernhardplein 200, 1097 JB, Noord-Holland, Amsterdam, Nederland	EU/1/20/1493	Disperzija za infuziju	Pending	18.12.2020.

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
17.12.2020.	REKAMBYS	rilpivirin	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1482	Suspenzija s produljenim oslobađanjem za injekciju	J05AG05	21.12.2020.
17.12.2020.	Vocabria	kabotegravir	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	Filmom obložena tableta Suspenzija s produljenim oslobađanjem za injekciju	J05AJ04	21.12.2020.
18.12.2020.	Fintepla	Fenfluramin	Zogenix ROI Limited Trinity House, Charleston Road, Ranelagh, Dublin 6, D06 C8X4, Ireland	EU/1/20/1491	Peroralna otopina	N03AX	21.12.2020.
18.12.2020.	Lenalidomide Mylan	lenalidomid	Mylan Ireland Limited Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland	EU/1/20/1490	Kapsula, tvrda	L04AX04	21.12.2020.
21.12.2020.	Phesgo	pertuzumab/trastuzumab	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/20/1497	Otopina za injekciju	L01XY02	22.12.2020.

— **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
1.12.2020.	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	2.12.2020.
1.12.2020.	Zonisamide Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/16/1093	4.12.2020.
9.12.2020.	Aldara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/98/080	11.12.2020.
9.12.2020.	Caspofungin Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/15/1081	11.12.2020.
9.12.2020.	Epidyolex	GW Pharma (International) B.V. Databankweg 26, 3821AL Amersfoort, Nederland	EU/1/19/1389	11.12.2020.
9.12.2020.	Inlyta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/12/777	11.12.2020.
9.12.2020.	Kadcyla	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/13/885	10.12.2020.
9.12.2020.	Lucentis	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/374	10.12.2020.
9.12.2020.	MAVENCLAD	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/17/1212	11.1.2021.
9.12.2020.	Miglustat Dipharma	Dipharma B.V. Prins Bernhardplein 200, 1097 JB Amsterdam, Nederland	EU/1/18/1346	10.12.2020.
9.12.2020.	Neofordex	Laboratoires CTRS 63 rue de l'Est, 92100 Boulogne-Billancourt, France	EU/1/15/1053	11.12.2020.
9.12.2020.	Olazax Disperzi	Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b, 14078 Praha 4, Česká republika	EU/1/09/592	11.12.2020.
9.12.2020.	Onbrez Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/593	10.12.2020.
9.12.2020.	Orbactiv	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/15/989	10.12.2020.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
9.12.2020.	Orencia	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/07/389	10.12.2020.
9.12.2020.	Polivy	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/19/1388	10.12.2020.
9.12.2020.	SCENESSE	Clinuvel Europe Limited 10 Earlsfort Terrace, Dublin 2, D02 T380, Ireland	EU/1/14/969	10.12.2020.
9.12.2020.	Seebri Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/788	10.12.2020.
9.12.2020.	Tovanor Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/790	6.1.2021.
14.12.2020.	ADCETRIS	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/12/794	15.12.2020.
14.12.2020.	Bosulif	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/818	15.12.2020.
14.12.2020.	Gilenya	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/11/677	15.12.2020.
14.12.2020.	Hirobriz Breezhaler	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/09/594	17.12.2020.
14.12.2020.	Jakavi	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/12/773	17.12.2020.
14.12.2020.	JEVTANA	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Paris, France	EU/1/11/676	17.12.2020.
14.12.2020.	Lonsurf	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes CEDEX, France	EU/1/16/1096	15.12.2020.
14.12.2020.	Plegridy	Biogen Netherlands B.V. Prins Mauritslaan 13, 1171 LP Badhoevedorp, Nederland	EU/1/14/934	15.12.2020.
14.12.2020.	Revatio	Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland	EU/1/05/318	21.12.2020.
14.12.2020.	Uptravi	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/15/1083	16.12.2020.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
14.12.2020.	Zyclara	Meda AB Pipers väg 2A, 170 73 Solna, Sverige	EU/1/12/783	17.12.2020.
17.12.2020.	Empliciti	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/16/1088	19.12.2020.
17.12.2020.	Halimatoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1288	7.1.2021.
17.12.2020.	Keppra	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/00/146	21.12.2020.
17.12.2020.	Kyprolis	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1060	18.12.2020.
17.12.2020.	Lorviqua	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/19/1355	18.12.2020.
17.12.2020.	Rubraca	Clovis Oncology Ireland Limited Regus Dublin Airport, Skybridge House – Dublin Airport, Swords, Co. Dublin, K67 P6K2, Ireland	EU/1/17/1250	21.12.2020.
17.12.2020.	Taltz	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/15/1085	22.12.2020.
17.12.2020.	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/16/1126	30.12.2020.
17.12.2020.	Verzenios	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/18/1307	22.12.2020.
17.12.2020.	Votrient	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/10/628	20.12.2020.
17.12.2020.	Wakix	Bioprojet Pharma 9 rue Rameau, 75002 Paris, France	EU/1/15/1068	6.1.2021.
17.12.2020.	Xyrem	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/05/312	18.12.2020.
17.12.2020.	Ziextenzo	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1327	7.1.2021.
18.12.2020.	Cerezyme	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/97/053	21.12.2020.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
18.12.2020.	Galvus	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/414	6.1.2021.
18.12.2020.	Jalra	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/485	6.1.2021.
18.12.2020.	Jivi	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/18/1324	22.12.2020.
18.12.2020.	Pixuvri	Les Laboratoires Servier 50 rue Carnot, 92284 Suresnes Cedex, France	EU/1/12/764	22.12.2020.
18.12.2020.	Rixubis	Baxalta Innovations GmbH Industriestraße 67, 1221 Wien, Österreich	EU/1/14/970	22.12.2020.
18.12.2020.	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	21.12.2020.
18.12.2020.	Xiliarx	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/08/486	6.1.2021.
21.12.2020.	Veklury	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/20/1459	22.12.2020.
22.12.2020.	BLINCYTO	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/15/1047	25.12.2020.
22.12.2020.	Zirabev	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/18/1344	23.12.2020.

— **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
17.12.2020.	Prepandrix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/08/453	4.1.2021.
18.12.2020.	Halimatoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1288	8.1.2021.
18.12.2020.	Truberzi	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/16/1126	5.1.2021.

— **Izdavanje odobrenja za stavljanje u promet** (članak 38 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
3.12.2020.	REXXOLIDE	tulatromicin	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, Nederland	EU/2/20/263	Otopina za injekciju	QJ01FA94	9.12.2020.
9.12.2020.	CircoMax Myco	Cjepivo protiv cirkovirusa svinja (inaktivirano, rekombinantno) i protiv Mycoplasma hyopneumoniae (inaktivirano)	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/20/264	Emulzija za injekciju	QI09AL08	11.12.2020.
9.12.2020.	Enteroporc Coli AC	Cjepivo za neonatalnu prasad protiv kolibaciloze (rekombinantno, inaktivirano) i Clostridium perfringens (inaktivirano)	IDT Biologika GmbH Am Pharmapark, 06861 Dessau-Rosslau, Deutschland	EU/2/20/262	Liofilizat i suspenzija za suspenziju za injekciju	Pending	10.12.2020.
9.12.2020.	Nobivac DP Plus	Vakcina psećeg štenećaka (živi atenuirani virus) i vakcina psećeg parvovirusa (živi, rekombinantni)	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/20/265	Liofilizat i otapalo, suspenzija za injekciju	QI07AD03	10.12.2020.

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
9.12.2020.	Vectormune FP ILT	Cjepivo virusa boginja peradi (živo, rekombinirano) i cjepivo zaraznog laringotraheitisa peradi (živo)	Ceva-Phylaxia Co. Ltd. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/20/266	Liofilizat i otapalo, suspenzija za injekciju	Pending	10.12.2020.

— **Izmjena odobrenja za stavljanje u promet** (članak 38 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
3.12.2020.	Bravecto Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/18/224	4.12.2020.
3.12.2020.	Exzolt	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/17/212	4.12.2020.
9.12.2020.	Bravecto	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/13/158	10.12.2020.
9.12.2020.	Circovac	Ceva-Phylaxia Zrt. Szállás u. 5, 1107 Budapest, Magyarország	EU/2/07/075	11.12.2020.
9.12.2020.	Zulvac SBV	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/14/178	11.12.2020.
11.12.2020.	Onsior	Elanco GmbH Heinz-Lohmann-Straße 4, 27472 Cuxhaven, Deutschland	EU/2/08/089	14.12.2020.
17.12.2020.	Nobilis IB 4-91	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/98/006	21.12.2020.

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