

**Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. svibnja 2020. do 31. svibnja 2020.**

*(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća<sup>(1)</sup>)*

(2020/C 213/02)

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<sup>(1)</sup> 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
18.5.2020.	Zolgensma	onasemnogen abeparvovek	AveXis EU Limited Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland	EU/1/20/1443	Otopina za infuziju	M09AX09	18.5.2020.
20.5.2020.	Fluad Tetra	Cjepivo protiv influence (površinski antigen) inaktivirano, adjuvantirano	Seqirus Netherlands B.V. Paasheuvelweg 28, 1105 BJ Amsterdam, Netherlands	EU/1/20/1433	Suspencija za injekciju u napunjenoj štrcaljki (injekcija).	J07BB02	26.5.2020.
20.5.2020.	Nepexto	etanercept	Mylan IRE Healthcare Limited Unit 35/36 Grange Parade, Baldoye Industrial Estate, Dublin 13 Ireland	EU/1/20/1436	Otopina za injekciju	L04AB01	29.5.2020.
30.5.2020.	Aectura Breezhaler	indakaterol/mometazonfuroat	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1439	Prašak inhalata, tvrda kapsula	R03AK14	2.6.2020.
30.5.2020.	Bemrist Breezhaler	indakaterol/mometazonfuroat	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/20/1441	Prašak inhalata, tvrda kapsula	R03AK	2.6.2020.
30.5.2020.	Sarclisa	isatuksimab	Sanofi-Aventis groupe 54 rue La Boétie, 75008 Pariz, France	EU/1/20/1435	Koncentrat za otopinu za infuziju	L01XC38	3.6.2020.

— **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
4.5.2020.	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstraße 100 D-60318 Frankfurt am Main, Deutschland	EU/1/02/218	8.5.2020.
4.5.2020.	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	12.5.2020.
4.5.2020.	Bronchitol	Pharmaxis Europe Limited 108 Q House, Furze Road, Sandymount Dublin 18, D18AY29, Ireland	EU/1/12/760	5.5.2020.
4.5.2020.	Clopidogrel Apotex	Apotex Europe B.V. Archimedesweg 2, 2333 CN Leiden, Nederland	EU/1/09/568	6.5.2020.
4.5.2020.	Clopidogrel Mylan	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/09/559	5.5.2020.
4.5.2020.	Clopidogrel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/540	7.5.2020.
4.5.2020.	Cystadrops	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/15/1049	6.5.2020.
4.5.2020.	Ferriprox	Chiesi Farmaceutici S.p.A. Via Palermo 26/A, 43122 Parma, Italia	EU/1/99/108	7.5.2020.
4.5.2020.	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	5.5.2020.
4.5.2020.	Ilumetri	Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/18/1323	5.5.2020.
4.5.2020.	Pemetrexed Krka	KRKA, d.d. Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/18/1283	12.5.2020.
4.5.2020.	Pemetrexed medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstraße 6, 22880 Wedel, Deutschland	EU/1/15/1038	12.5.2020.
4.5.2020.	Raxone	Santhera Pharmaceuticals (Deutschland) GmbH Marie-Curie Straße 8, 79539 Lörrach, Deutschland	EU/1/15/1020	14.5.2020.
4.5.2020.	Tafinlar	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/13/865	8.5.2020.
4.5.2020.	Wilzin	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/04/286	5.5.2020.
4.5.2020.	Xultophy	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/14/947	6.5.2020.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
5.5.2020.	Naglazyme	BioMarin International Limited Shanbally, Ringaskiddy, County Cork P43 R298, Ireland	EU/1/05/324	6.5.2020.
12.5.2020.	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	19.5.2020.
12.5.2020.	Clopidogrel Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	13.5.2020.
12.5.2020.	Movymia	STADA Arzneimittel AG Stadastraße 2-18, 61118 Bad Vilbel, Deutschland	EU/1/16/1161	13.5.2020.
12.5.2020.	Pemetrexed Hospira	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/Pleinlaan 17, 1050 Brussel, België	EU/1/15/1057	14.5.2020.
12.5.2020.	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	14.5.2020.
12.5.2020.	Steglatro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1267	14.5.2020.
12.5.2020.	Steglujan	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1266	14.5.2020.
12.5.2020.	Vedrop	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/09/533	13.5.2020.
14.5.2020.	Clopidogrel Krka d.d.	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/562	18.5.2020.
14.5.2020.	Firdapse	SERB S.A. Avenue Louise 480, 1050 Bruxelles, Belgique/Louizalaan 480, 1050 Brussel, België	EU/1/09/601	15.5.2020.
14.5.2020.	Yellox	Bausch Health Ireland Limited 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24PPT3, Ireland	EU/1/11/692	15.5.2020.
18.5.2020.	Signifor	Recordati Rare Diseases Immeuble Le Wilson, 70 avenue du Général de Gaulle, 92 800 Puteaux, France	EU/1/12/753	19.5.2020.
20.5.2020.	Daxas	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/10/636	28.5.2020.
20.5.2020.	Ivabradine Anpharm	ANPHARM Przedsiębiorstwo Farmaceutyczne S.A. ul. Annopol 6B, 03–236 Warszawa, Polska	EU/1/15/1041	25.5.2020.
20.5.2020.	Jorveza	Dr. Falk Pharma GmbH Leinenweberstraße 5, 79041 Freiburg im Breisgau, Deutschland	EU/1/17/1254	26.5.2020.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
20.5.2020.	Lenvima	Eisai GmbH Lyoner StraÙe 36, 60528 Frankfurt am Main, Deutschland	EU/1/15/1002	26.5.2020.
20.5.2020.	LIBTAYO	Regeneron Ireland Designated Activity Com- pany (DAC) Europa House, Harcourt Centre, Harcourt Street, Dublin 2, Ireland	EU/1/19/1376	26.5.2020.
20.5.2020.	Nplate	Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, Nederland	EU/1/08/497	25.5.2020.
20.5.2020.	Odomzo	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, 2132 JH Hoofddorp, Ne- derland	EU/1/15/1030	28.5.2020.
20.5.2020.	Onpattro	Alnylam Netherlands B.V. Strawinskylaan 3051, 1077 ZX, Amsterdam, Nederland	EU/1/18/1320	25.5.2020.
20.5.2020.	Pregabalin Zentiva	Zentiva, k.s. U Kabelovny 130, 102 37 Praha 10, Èeská republika	EU/1/15/1021	25.5.2020.
20.5.2020.	Revestive	Shire Pharmaceuticals Ireland Limited Block 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, D02 Y754 Dublin 2, Ireland	EU/1/12/787	11.6.2020.
20.5.2020.	Tybost	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/13/872	25.5.2020.

— **Izmjena odobrenja za stavljanje u promet** (èlanak 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
20.5.2020.	Emgality	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Neder- land	EU/1/18/1330	27.5.2020.

— **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
18.5.2020.	Lydaxx	tulatromicin	VETOQUINOL S.A. Magny-Vernois, 70200 Lure, France	EU/2/20/253	Otopina za injekciju	QJ01FA94	19.5.2020.

— **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
4.5.2020.	Apoquel	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/13/154	7.5.2020.
4.5.2020.	Loxicom	Norbroom Laboratories (Ireland) Limited Rossmore Industrial Estate, Monaghan, Ireland	EU/2/08/090	7.5.2020.
12.5.2020.	Equilis Prequenza Te	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/057	15.5.2020.
18.5.2020.	Equilis Prequenza	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/056	20.5.2020.
18.5.2020.	Equilis Te	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/05/055	20.5.2020.
27.5.2020.	CYTOPOINT	Zoetis Belgium S.A. rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique	EU/2/17/205	27.5.2020.
27.5.2020.	Porcilis PCV ID	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/15/187	2.6.2020.

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

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NETHERLANDS