

## 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. listopada 2021. do 31. listopada 2021.**(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća<sup>(1)</sup>)

(2021/C 478/01)

— **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
1.10.2021.	COVID-19 Vaccine Janssen	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, Belgijë	EU/1/20/1525	1.10.2021.
4.10.2021.	Docetaxel Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España	EU/1/12/769	5.10.2021.
4.10.2021.	Docetaxel Kabi	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/12/770	6.10.2021.
4.10.2021.	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	5.10.2021.
4.10.2021.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	4.10.2021.
5.10.2021.	Comirnaty	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deuts- chland	EU/1/20/1528	5.10.2021.
5.10.2021.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	5.10.2021.

<sup>(1)</sup> SL L 136, 30.4.2004, str. 1.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
11.10.2021.	Copalia	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/372	12.10.2021.
11.10.2021.	COVID-19 Vaccine Janssen	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1525	11.10.2021.
11.10.2021.	Dafiro	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/371	12.10.2021.
11.10.2021.	Entecavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/17/1227	12.10.2021.
11.10.2021.	Equidacent	Centus Biotherapeutics Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, Ireland	EU/1/20/1472	8.11.2021.
11.10.2021.	Exforge	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/370	12.10.2021.
11.10.2021.	Onpattro	Alnylam Netherlands B.V. Antonio Vivaldistraat 150, 1083 HP Amsterdam, Nederland	EU/1/18/1320	13.10.2021.
11.10.2021.	Ovitrelle	Merck Europe B.V. Gustav Mahlerplein 102, 1082 MA Amsterdam, Nederland	EU/1/00/165	12.10.2021.
11.10.2021.	ReFacto AF	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/99/103	12.10.2021.
11.10.2021.	Sifrol	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/97/050	14.10.2021.
11.10.2021.	Vargatef	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/954	27.10.2021.
11.10.2021.	Vyndaquel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/11/717	12.10.2021.
15.10.2021.	Vaxzevria	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/21/1529	15.10.2021.
19.10.2021.	Ammonaps	Immedica Pharma AB SE-113 29 Stockholm, Sverige	EU/1/99/120	20.10.2021.
19.10.2021.	Busilvex	Pierre Fabre Médicament 45 place Abel Gance, 92654 Boulogne-Billancourt CEDEX, France	EU/1/03/254	20.10.2021.
19.10.2021.	Ceprotin	Takeda Manufacturing Austria AG Industriestraße 67, 1221 Wien, Österreich	EU/1/01/190	20.10.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.10.2021.	Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/19/1395	20.10.2021.
19.10.2021.	Duloxetine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1010	21.10.2021.
19.10.2021.	Ecalta	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/416	20.10.2021.
19.10.2021.	Erelzi	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/17/1195	20.10.2021.
19.10.2021.	Firmagon	Ferring Pharmaceuticals A/S Kay Fiskers Plads 11, 2300 Copenhagen S, Danmark	EU/1/08/504	25.10.2021.
19.10.2021.	Forsteo	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/03/247	25.10.2021.
19.10.2021.	Gazyvaro	Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland	EU/1/14/937	20.10.2021.
19.10.2021.	Gefitinib Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/18/1321	20.10.2021.
19.10.2021.	Hefiya	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1287	20.10.2021.
19.10.2021.	Imfinzi	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/18/1322	21.10.2021.
19.10.2021.	Inrebic	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/20/1514	21.10.2021.
19.10.2021.	Integrilin	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/99/109	20.10.2021.
19.10.2021.	KEYTRUDA	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/15/1024	21.10.2021.
19.10.2021.	Lopinavir/Ritonavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/15/1067	21.10.2021.
19.10.2021.	Memantine LEK	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/13/826	21.10.2021.
19.10.2021.	Memantine Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/13/827	20.10.2021.
19.10.2021.	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/97/051	21.10.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.10.2021.	Myozyme	Genzyme Europe B.V. Paasheuvelweg 25, 1105 BP Amsterdam, Nederland	EU/1/06/333	25.10.2021.
19.10.2021.	NovoEight	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/13/888	21.10.2021.
19.10.2021.	NovoMix	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd, Danmark	EU/1/00/142	21.10.2021.
19.10.2021.	Noxafil	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/05/320	21.10.2021.
19.10.2021.	OPDIVO	Bristol-Myers Squibb Pharma EEIG Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland	EU/1/15/1014	9.11.2021.
19.10.2021.	Prasugrel Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/18/1273	20.10.2021.
19.10.2021.	Rasagiline Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1090	20.10.2021.
19.10.2021.	REKAMBYS	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	EU/1/20/1482	20.10.2021.
19.10.2021.	Repaglinide Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/579	21.10.2021.
19.10.2021.	Semglee	Viatriis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/18/1270	20.10.2021.
19.10.2021.	Spedra	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/13/841	21.10.2021.
19.10.2021.	Sunosi	Jazz Pharmaceuticals Ireland Ltd 5th Floor, Waterloo Exchange, Waterloo Road, Dublin D04 E5W7, Ireland	EU/1/19/1408	21.10.2021.
19.10.2021.	Tasmar	Meda AB Pipers väg 2A, 170 09 Solna, Sverige	EU/1/97/044	21.10.2021.
19.10.2021.	Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1129	20.10.2021.
19.10.2021.	Torisel	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/424	20.10.2021.
19.10.2021.	Vaborem	Menarini International Operations Luxembourg S.A. 1 avenue de la Gare, 1611 Luxembourg, Luxembourg	EU/1/18/1334	20.10.2021.
19.10.2021.	Vfend	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/02/212	21.10.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
19.10.2021.	Vocabria	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	EU/1/20/1481	20.10.2021.
19.10.2021.	Xydalba	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland	EU/1/14/986	20.10.2021.
19.10.2021.	Zessly	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1280	20.10.2021.
22.10.2021.	Adempas	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/13/907	5.11.2021.
22.10.2021.	Alofisel	Takeda Pharma A/S Delta Park 45, 2665 Vallensbaek Strand, Danmark	EU/1/17/1261	28.10.2021.
22.10.2021.	Betaferon	Bayer AG D-51368 Leverkusen, Deutschland	EU/1/95/003	5.11.2021.
22.10.2021.	Biktarvy	Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	EU/1/18/1289	27.10.2021.
22.10.2021.	Clopidogrel ratio-pharm	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/14/975	26.10.2021.
22.10.2021.	Hyrimoz	Sandoz GmbH Biochemiestrasse 10, 6250 Kundl, Österreich	EU/1/18/1286	25.10.2021.
22.10.2021.	Idacio	Fresenius Kabi Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg vor der Höhe, Deutschland	EU/1/19/1356	25.10.2021.
22.10.2021.	Imcivree	Rhythm Pharmaceuticals Netherlands B.V. Herengracht 280, 1016 BX Amsterdam, Ne- derland	EU/1/21/1564	26.10.2021.
22.10.2021.	Inflectra	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/13/854	25.10.2021.
22.10.2021.	Jardiance	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/14/930	25.10.2021.
22.10.2021.	Retacrit	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België	EU/1/07/431	25.10.2021.
22.10.2021.	Steglatro	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1267	25.10.2021.
22.10.2021.	Veltassa	Vifor Fresenius Medical Care Renal Pharma France 100-101 terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France	EU/1/17/1179	9.11.2021.

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
22.10.2021.	Zepatier	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/16/1119	25.10.2021.
25.10.2021.	Clopidogrel Taw Pharma	Mylan S.A.S. 117 allée des Parcs, 69800 Saint Priest, France	EU/1/09/559	26.10.2021.
25.10.2021.	Clopidogrel Viatriis	Viatriis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/09/568	1.11.2021.
25.10.2021.	Firazyr	Takeda Pharmaceuticals International AG Ireland Branch Block 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland	EU/1/08/461	27.10.2021.
25.10.2021.	Forxiga	AstraZeneca AB 151 85 Södertälje, Sverige	EU/1/12/795	26.11.2021.
25.10.2021.	Latuda	Aziende Chimiche Riunite Angelini Francesco – A.C.R.A.F. S.p.A. Viale Amelia 70, 00181 Roma, Italia	EU/1/14/913	26.10.2021.
25.10.2021.	Nerlynx	Pierre Fabre Médicament 45, place Abel Gance, 92100 Boulogne-Billancourt, France	EU/1/18/1311	10.11.2021.
25.10.2021.	Segluromet	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, Nederland	EU/1/18/1265	28.10.2021.
25.10.2021.	Zyllt	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	27.10.2021.
28.10.2021.	Clopidogrel Krka	KRKA d d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	2.11.2021.
28.10.2021.	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Deutschland	EU/1/09/555	3.11.2021.
28.10.2021.	Darunavir Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/16/1140	5.11.2021.
28.10.2021.	Mysildecard	Viatriis Limited Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland	EU/1/16/1134	29.10.2021.
28.10.2021.	Ontozry	Angelini Pharma S.p.A Viale Amelia 70, 00181 Rome, Italia	EU/1/21/1530	29.10.2021.
28.10.2021.	Tyverb	Novartis Europharm Limited Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/07/440	29.10.2021.
28.10.2021.	Voriconazole Accord	Accord Healthcare S.L.U. World Trade Center, Moll de Barcelona s/n, Edifici Est, 6a planta, 08039 Barcelona, España	EU/1/13/835	29.10.2021.
29.10.2021.	Spikevax	MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30, 28010 Madrid, España	EU/1/20/1507	29.10.2021.

— **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
11.10.2021.	Docetaxel Teva	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/09/611	12.10.2021.
11.10.2021.	Equidacent	Centus Biotherapeutics Europe Limited 6th Floor, South Bank House, Barrow Street, Dublin 4, Ireland	EU/1/20/1472	8.11.2021.

— **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
18.10.2021.	Oxyglobin	OPK Biotech Netherlands BV Herikerbergweg 88, 1101CM Amsterdam, Nederland	EU/2/99/015	5.11.2021.
25.10.2021.	Activyl Tick Plus	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/11/137	26.10.2021.
25.10.2021.	Canigen L4	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/15/183	26.10.2021.
25.10.2021.	Nobilis IB Primo QX	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/14/174	27.10.2021.
25.10.2021.	Tulissin	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France	EU/2/20/252	28.10.2021.
25.10.2021.	Vectra 3D	Ceva Santé Animale 10 avenue de La Ballastière, 33500 Libourne, France	EU/2/13/156	26.10.2021.

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