

IV

(Informazioni)

INFORMAZIONI PROVENIENTI DALLE ISTITUZIONI, DAGLI ORGANI E DAGLI ORGANISMI DELL'UNIONE EUROPEA

COMMISSIONE EUROPEA

Sintesi delle decisioni dell'Unione europea relative alle autorizzazioni all'immissione in commercio di medicinali dal 1° ottobre 2021 al 31 ottobre 2021*[pubblicate a norma dell'articolo 13 o dell'articolo 38 del regolamento (CE) n. 726/2004 del Parlamento europeo e del Consiglio⁽¹⁾]*

(2021/C 478/01)

— **Modifica di un'autorizzazione all'immissione in commercio** [articolo 13 del regolamento (CE) n. 726/2004 del Parlamento europeo e del Consiglio]: **Accettate**

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
1.10.2021	COVID-19 Vaccine Janssen	Janssen-Cilag International NV Turnhoutseweg 30, 2340 Beerse, België	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, Deutschland	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

⁽¹⁾ GU L 136 del 30.4.2004, pag. 1.

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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	Onpatro	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

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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	Memantina Mylan	Mylan Pharmaceuticals Limited Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland	EU/1/13/827	20.10.2021
19.10.2021	Memantine LEK	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/13/826	21.10.2021
19.10.2021	Mirapexin	Boehringer Ingelheim International GmbH Binger Straße 173, 55216 Ingelheim am Rhein, Deutschland	EU/1/97/051	21.10.2021

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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	Viartis 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

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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, Du- blin 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, Neder- land	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

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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	Voriconazolo 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

— **Ritiro di un'autorizzazione all'immissione in commercio** [articolo 13 del regolamento (CE) n. 726/2004 del Parlamento europeo e del Consiglio]

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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

— **Modifica di un'autorizzazione all'immissione in commercio** (articolo 38 del regolamento (CE) n. 726/2004 del Parlamento europeo e del Consiglio): **Accettate**

Data della decisione	Denominazione del medicinale	Titolare dell'autorizzazione all'immissione in commercio	Numero d'iscrizione nel registro comunitario	Data di notifica
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

Per consultare la relazione pubblica di valutazione sui medicinali in questione e le correlate decisioni contattare:

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