C/2024/2197

27.3.2024

# Oversigt over EU-afgørelser om tilladelse til markedsføring af lægemidler fra 1. februar 2024 til 29. februar 2024

*(Offentliggjort i henhold til artikel 13 eller artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004 ([1]) eller artikel 5 i Europa-Parlamentets og Rådets forordning (EU) 2019/6 ([2]))*

(C/2024/2197)

([1]) EUT L 136 af 30.4.2004, s. 1.
([2]) EUT L 4 af 7.1.2019, s. 43.

— **Udstedelse af markedsføringstilladelse** (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004): **Godkendt**

| Dato for afgørelser | Lægemidlets navn | INN-navn (International Non-Proprietary Name) | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Lægemiddelform | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|---|---|---|---|---|---|---|---|
| 9.2.2024 | Casgevy | exagamglogen-autotemcel | Vertex Pharmaceuticals (Ireland) Limited<br>Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland | EU/1/23/1787 | Dispersion til infusion | B06AX | 12.2.2024 |
| 9.2.2024 | Mevlyq | eribulin | YES Pharmaceutical Development Services GmbH<br>Basler Strasse 7, 61352 Bad Homburg, Deutschland | EU/1/23/1789 | Injektionsvæske, opløsning | L01XX41 | 13.2.2024 |
| 9.2.2024 | Skyclarys | omaveloxolon | Reata Ireland Limited<br>Block A, George's Quay Plaza, George's Quay, Dublin 2, D02 E440, Ireland | EU/1/23/1786 | Kapsler, hårde | Pending | 12.2.2024 |
| 16.2.2024 | Ibuprofen Gen.Orph | Ibuprofen | Gen.Orph<br>185 Bureaux de la Colline, 92213 Saint Cloud Cedex, France | EU/1/23/1791 | Injektionsvæske, opløsning | C01EB16 | 21.2.2024 |
| 16.2.2024 | Pomalidomide Viatris | pomalidomide | Viatris Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/23/1785 | Kapsler, hårde | L04AX06 | 19.2.2024 |
| 16.2.2024 | Velsipity | etrasimod | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/23/1790 | Filmovertrukket tablet | L04AE05 | 19.2.2024 |
| 19.2.2024 | Dabigatran etexilate Leon Farma | dabigatran etexilate | Laboratorios Leon Farma S.A.<br>C/ La Vallina s/n, Polígono Industrial Navatejera, 24193 Villaquilambre León, España | EU/1/23/1769 | Kapsler, hårde | B01AE07 | 21.2.2024 |

| Dato for afgørelser | Lægemidlets navn | INN-navn (International Non-Proprietary Name) | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Lægemiddelform | ATC-kode (Anatomical Therapeutic Chemical Code) | Dato for notifikation |
|---|---|---|---|---|---|---|---|
| 22.2.2024 | Holoclar | Ex vivo-ekspanderede autologe, humane corneaepitelceller indeholdende stamceller | Holostem S.r.l.<br>Via Glauco Gottardi 100, 41125 Modena, Italia | EU/1/14/987 | Levende vævsækvivalent | S01XA19 | 23.2.2024 |

— **Ændring af markedsføringstilladelse** (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004): **Godkendt**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 1.2.2024 | Efavirenz Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/11/742 | 5.2.2024 |
| 1.2.2024 | Hexacima | Sanofi Pasteur<br>14 Espace Henry Vallée, 69007 Lyon, France | EU/1/13/828 | 5.2.2024 |
| 1.2.2024 | Hexyon | Sanofi Pasteur<br>14 Espace Henry Vallée, 69007 Lyon, France | EU/1/13/829 | 2.2.2024 |
| 1.2.2024 | Inrebic | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/20/1514 | 3.2.2024 |
| 1.2.2024 | Mirvaso | Galderma International<br>Tour Europlaza, 20 avenue André Prothin, La Défense 4, La Défense Cedex 92927, France | EU/1/13/904 | 6.2.2024 |
| 1.2.2024 | Mycamine | Astellas Pharma Europe B.V.<br>Sylviusweg 62, 2333 BE Leiden, Nederland | EU/1/08/448 | 5.2.2024 |
| 1.2.2024 | Simponi | Janssen Biologics B.V.<br>Einsteinweg 101, 2333 CB Leiden, Nederland | EU/1/09/546 | 6.2.2024 |
| 1.2.2024 | Tafinlar | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/13/865 | 2.2.2024 |
| 1.2.2024 | Thiotepa Riemser | Esteve Pharmaceuticals GmbH<br>Hohenzollerndamm 150-151, 14199 Berlin, Deutschland | EU/1/21/1536 | 5.2.2024 |
| 1.2.2024 | Tybost | Gilead Sciences Ireland UC<br>Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/13/872 | 5.2.2024 |
| 6.2.2024 | Abecma | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/21/1539 | 7.2.2024 |
| 6.2.2024 | Cegfila | Mundipharma Corporation (Ireland) Limited<br>United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland | EU/1/19/1409 | 7.2.2024 |
| 6.2.2024 | Intuniv | Takeda Pharmaceuticals International AG Ireland Branch<br>Block 2, Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland | EU/1/15/1040 | 8.2.2024 |
| 6.2.2024 | Keppra | UCB Pharma S.A.<br>Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België | EU/1/00/146 | 7.2.2024 |
| 6.2.2024 | Nyxoid | Mundipharma Corporation (Ireland) Limited<br>United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland | EU/1/17/1238 | 7.2.2024 |
| 6.2.2024 | Sixmo | L. Molteni & C. dei F.lli Alitti Società di .Esercizio .S.p.A<br>Strada Statale 67, Loc. Granatieri, 50018 Scandicci (Firenze), Italia | EU/1/19/1369 | 7.2.2024 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 6.2.2024 | SomaKit TOC | Advanced Accelerator Applications<br>8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France | EU/1/16/1141 | 8.2.2024 |
| 8.2.2024 | Clopidogrel Teva | Teva B.V.<br>Swensweg 5, 2031 GA Haarlem, Nederland | EU/1/09/540 | 9.2.2024 |
| 8.2.2024 | Coagadex | BPL Bioproducts Laboratory GmbH<br>Dornhofstrasse 34, 63263 Neu-Isenburg, Deutschland | EU/1/16/1087 | 12.2.2024 |
| 8.2.2024 | Dynastat | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/02/209 | 9.2.2024 |
| 8.2.2024 | QINLOCK | Deciphera Pharmaceuticals (Netherlands) B.V.<br>Atrium Building Floor 4th, Strawinskylaan 3051, Amsterdam, Noord-Holland, 1077 ZX, Nederland | EU/1/21/1569 | 12.2.2024 |
| 8.2.2024 | Scintimun | CIS bio international<br>Boîte Postale 32, 91192 Gif-sur-Yvette, France | EU/1/09/602 | 9.2.2024 |
| 8.2.2024 | Vaxzevria | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/21/1529 | 9.2.2024 |
| 8.2.2024 | VidPrevtyn Beta | Sanofi Pasteur<br>14 Espace Henry Vallée, 69007 Lyon, France | EU/1/21/1580 | 9.2.2024 |
| 8.2.2024 | Zypadhera | CHEPLAPHARM Registration GmbH<br>Weiler Straße 5e, 79540 Lörrach, Deutschland | EU/1/08/479 | 9.2.2024 |
| 8.2.2024 | Zyprexa | CHEPLAPHARM Registration GmbH<br>Weiler Straße 5e, 79540 Lörrach, Deutschland | EU/1/96/022 | 9.2.2024 |
| 8.2.2024 | Zyprexa Velotab | CHEPLAPHARM Registration GmbH<br>Weiler Straße 5e, 79540 Lörrach, Deutschland | EU/1/99/125 | 9.2.2024 |
| 9.2.2024 | Clopidogrel Krka d. d. | KRKA d d., Novo mesto<br>Šmarješka cesta 6, 8501 Novo mesto, Slovenija | EU/1/09/562 | 12.2.2024 |
| 9.2.2024 | Doptelet | Swedish Orphan Biovitrum AB (publ)<br>112 76 Stockholm, Sverige | EU/1/19/1373 | 14.2.2024 |
| 9.2.2024 | DuoPlavin | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/10/619 | 12.2.2024 |
| 9.2.2024 | Esperoct | Novo Nordisk A/S<br>Novo Allé, 2880 Bagsværd, Danmark | EU/1/19/1374 | 12.2.2024 |
| 9.2.2024 | Protopic | Leo Pharma A/S<br>Industriparken 55, 2750 Ballerup, Danmark | EU/1/02/201 | 13.2.2024 |
| 9.2.2024 | Rasilez | Noden Pharma DAC<br>D'Olier Chambers, 16A D'Olier Street, Dublin 2, Ireland | EU/1/07/405 | 12.2.2024 |
| 9.2.2024 | Translarna | PTC Therapeutics International Limited<br>5th Floor, 3 Grand Canal Plaza, Grand Canal Street Upper, Dublin 4, D04 EE70, Ireland | EU/1/13/902 | 12.2.2024 |
| 9.2.2024 | Viagra | Upjohn EESV<br>Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Nederland | EU/1/98/077 | 15.2.2024 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 16.2.2024 | Arixtra | Viatris Healthcare Limited<br>Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland | EU/1/02/206 | 19.2.2024 |
| 16.2.2024 | Azopt | Novartis Europharm Limited<br>Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland | EU/1/00/129 | 19.2.2024 |
| 16.2.2024 | Baqsimi | Amphastar France Pharmaceuticals<br>Usine Saint Charles, Eragny Sur Epte, 60590 France | EU/1/19/1406 | 20.2.2024 |
| 16.2.2024 | Briviact | UCB Pharma S.A.<br>Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België | EU/1/15/1073 | 19.2.2024 |
| 16.2.2024 | Bylvay | Ipsen Pharma<br>65 quai Georges Gorse, 92100 Boulogne-Billancourt, France | EU/1/21/1566 | 19.2.2024 |
| 16.2.2024 | Cayston | Gilead Sciences Ireland UC<br>Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/09/543 | 19.2.2024 |
| 16.2.2024 | Entyvio | Takeda Pharma A/S<br>Delta Park 45, 2665 Vallensbæk Strand, Danmark | EU/1/14/923 | 19.2.2024 |
| 16.2.2024 | Evoltra | Sanofi B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/06/334 | 19.2.2024 |
| 16.2.2024 | Fetcroja | Shionogi B.V.<br>Herengracht 464, 1017 CA, Amsterdam, Nederland | EU/1/20/1434 | 19.2.2024 |
| 16.2.2024 | Hemlibra | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/18/1271 | 20.2.2024 |
| 16.2.2024 | Herzuma | Celltrion Healthcare Hungary Kft.<br>Váci út 1-3. WestEnd Office Building B torony, 1062 Budapest, Magyarország | EU/1/17/1257 | 19.2.2024 |
| 16.2.2024 | Imfinzi | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/18/1322 | 19.2.2024 |
| 16.2.2024 | IMJUDO | AstraZeneca AB<br>151 85 Södertälje, Sverige | EU/1/22/1713 | 19.2.2024 |
| 16.2.2024 | Imraldi | Samsung Bioepis NL B.V.<br>Olof Palmestraat 10, 2616 LR Delft, Nederland | EU/1/17/1216 | 21.2.2024 |
| 16.2.2024 | Jylamvo | Therakind (Europe) Limited<br>Paramount Court, Corrig Road, Sandyford Business Park, Dublin 18, D18 R9C7, Ireland | EU/1/17/1172 | 27.2.2024 |
| 16.2.2024 | Kaftrio | Vertex Pharmaceuticals (Ireland) Limited<br>Unit 49, Block F2, Northwood Court, Santry, Dublin 9, D09 T665, Ireland | EU/1/20/1468 | 19.2.2024 |
| 16.2.2024 | Lupkynis | Otsuka Pharmaceutical Netherlands B.V.<br>Herikerbergweg 292, 1101 CT, Amsterdam, Nederland | EU/1/22/1678 | 20.2.2024 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 16.2.2024 | LysaKare | Advanced Accelerator Applications<br>8-10 Rue Henri Sainte-Claire Deville, 92500 Rueil-Malmaison, France | EU/1/19/1381 | 19.2.2024 |
| 16.2.2024 | Natpar | Takeda Pharmaceuticals International AG Ireland Branch<br>Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland | EU/1/15/1078 | 19.2.2024 |
| 16.2.2024 | Pemazyre | Incyte Biosciences Distribution B.V.<br>Paasheuvelweg 25, 1105 BP Amsterdam, Nederland | EU/1/21/1535 | 21.2.2024 |
| 16.2.2024 | Pregabalin Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/15/1027 | 19.2.2024 |
| 16.2.2024 | Sarclisa | Sanofi Winthrop Industrie<br>82 avenue Raspail, 94250 Gentilly, France | EU/1/20/1435 | 19.2.2024 |
| 16.2.2024 | Senshio | Shionogi B.V.<br>Herengracht 464, 1017 CA, Amsterdam, Nederland | EU/1/14/978 | 19.2.2024 |
| 16.2.2024 | Stayveer | Janssen-Cilag International NV<br>Turnhoutseweg 30, 2340 Beerse, België | EU/1/13/832 | 19.2.2024 |
| 16.2.2024 | Stocrin | Merck Sharp & Dohme B.V.<br>Waarderweg 39, 2031 BN Haarlem, Nederland | EU/1/99/111 | 19.2.2024 |
| 16.2.2024 | Truvada | Gilead Sciences Ireland UC<br>Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/04/305 | 19.2.2024 |
| 16.2.2024 | Viread | Gilead Sciences Ireland UC<br>Carrigtohill, County Cork, T45 DP77, Ireland | EU/1/01/200 | 19.2.2024 |
| 16.2.2024 | Vydura | Pfizer Europe MA EEIG<br>Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België | EU/1/22/1645 | 19.2.2024 |
| 16.2.2024 | Xagrid | Takeda Pharmaceuticals International AG Ireland Branch<br>Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, D02 HW68, Ireland | EU/1/04/295 | 19.2.2024 |
| 22.2.2024 | Deltyba | Otsuka Novel Products GmbH<br>Erika-Mann-Straße 21, 80636 München, Deutschland | EU/1/13/875 | 27.2.2024 |
| 22.2.2024 | Docetaxel Accord | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/12/769 | 26.2.2024 |
| 22.2.2024 | Ebvallo | Pierre Fabre Medicament<br>Les Cauquillous, 81500 Lavaur, France | EU/1/22/1700 | 26.2.2024 |
| 22.2.2024 | Pravafenix | LABORATOIRES SMB SA<br>26-28 rue de la Pastorale / 26-28 Herderslied-straat, 1080 Brussel/Bruxelles, Belgique/België | EU/1/11/679 | 23.2.2024 |
| 22.2.2024 | Skytrofa | Ascendis Pharma Endocrinology Division A/S<br>Tuborg Boulevard 12, 2900 Hellerup, Danmark | EU/1/21/1607 | 23.2.2024 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 22.2.2024 | Spectrila | medac Gesellschaft für klinische Spezialpräparate mbH<br>Theaterstraße 6, 22880 Wedel, Deutschland | EU/1/15/1072 | 26.2.2024 |
| 22.2.2024 | Strensiq | Alexion Europe SAS<br>103-105 rue Anatole France, 92300 Levallois-Perret, France | EU/1/15/1015 | 26.2.2024 |
| 22.2.2024 | Tecentriq | Roche Registration GmbH<br>Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Deutschland | EU/1/17/1220 | 23.2.2024 |
| 23.2.2024 | BLENREP | GlaxoSmithKline (Ireland) Limited<br>12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland | EU/1/20/1474 | 29.2.2024 |
| 26.2.2024 | Deltyba | Otsuka Novel Products GmbH<br>Erika-Mann-Straße 21, 80636 München, Deutschland | EU/1/13/875 | 28.2.2024 |
| 29.2.2024 | Capecitabine medac | medac Gesellschaft für klinische Spezialpräparate mbH<br>Theaterstraße 6, 22880 Wedel, Deutschland | EU/1/12/802 | 1.3.2024 |
| 29.2.2024 | Posaconazole AHCL | Accord Healthcare S.L.U.<br>World Trade Center, Moll de Barcelona, s/n, Edifici Est 6ª planta, 08039 Barcelona, España | EU/1/19/1380 | 1.3.2024 |
| 29.2.2024 | Retsevmo | Eli Lilly Nederland B.V.<br>Papendorpseweg 83, 3528 BJ Utrecht, Nederland | EU/1/20/1527 | 1.3.2024 |
| 29.2.2024 | Tevagrastim | Teva GmbH<br>Graf-Arco-Straße 3, 89079 Ulm, Deutschland | EU/1/08/445 | 4.3.2024 |
| 29.2.2024 | VidPrevtyn Beta | Sanofi Pasteur<br>14 Espace Henry Vallée, 69007 Lyon, France | EU/1/21/1580 | 1.3.2024 |

— **Tilbagekaldelse af markedsføringstilladelse** (artikel 13 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004)

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 1.2.2024 | Sustiva | Bristol-Myers Squibb Pharma EEIG<br>Plaza 254, Blanchardstown Corporate Park 2, D15 T867, Dublin 15, Ireland | EU/1/99/110 | 3.2.2024 |
| 9.2.2024 | Apealea | Inceptua AB<br>Gustavslundsv. 143, 16751 Bromma, Sverige | EU/1/18/1292 | 14.2.2024 |

— ***Ændring af markedsføringstilladelse*** (artikel 38 i Europa-Parlamentets og Rådets forordning (EF) nr. 726/2004; Artikel 5 i Europa-Parlamentets og Rådets forordning (EU) 2019/6): **Godkendt**

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 1.2.2024 | Solensia | Zoetis Belgium SA<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/20/269 | 2.2.2024 |
| 1.2.2024 | Solensia | Zoetis Belgium SA<br>Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgique | EU/2/20/269 | 2.2.2024 |

| Dato for afgørelser | Lægemidlets navn | Indehaver af markedsføringstilladelsen | Nummer i EF-registret | Dato for notifikation |
|---|---|---|---|---|
| 1.2.2024 | Zactran | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/08/082 | 6.2.2024 |
| 29.2.2024 | Metacam | Boehringer Ingelheim Vetmedica GmbH<br>D-55216 Ingelheim am Rhein, Deutschland | EU/2/97/004 | 1.3.2024 |
| 29.2.2024 | REXXOLIDE | Dechra Regulatory B.V.<br>Handelsweg 25, 5531 AE Bladel, Nederland | EU/2/20/263 | 6.3.2024 |

Alle interesserede kan ved henvendelse på nedenstående adresse få tilsendt den offentlige evalueringsrapport om de pågældende lægemidler og de afgørelser, der er truffet vedrørende disse:

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
NEDERLANDENE