

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| A02AC01 calcium carbonate <i>Calcium carbonate</i> | | | |
| Bayer Oy | Marketing authorisation application | 22/01/2025 | 1 |
| A02AD04 hydrotalcite <i>Hydrotalcite</i> | | | |
| Bayer Austria Ges.m.b.H. | Marketing authorisation application | 16/09/2024 | 1 |
| A02BC02 pantoprazole <i>Pantoprazole sodium</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 30/04/2025 | 2 |
| A02BC05 esomeprazole <i>Esomeprazole magnesium trihydrate</i> | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 20/02/2025 | 2 |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 28/11/2025 | 3 |
| A02BD08 bismuth subcitrate, metronidazole and tetracycline <i>Bismuth subcitrate potassium, Metronidazole, Tetracycline hydrochloride</i> | | | |
| Laboratoires Juvise Pharmaceuticals | Marketing authorisation application | 08/09/2025 | 1 |
| A03AB02 glycopyrronium bromide <i>Glycopyrronium bromide</i> | | | |
| Laboratoire Aguettant | Marketing authorisation application | 30/01/2026 | 1 |
| A03BA01 atropine <i>Atropine sulfate</i> | | | |
| Dextreg | Marketing authorisation application | 26/05/2025 | 2 |
| 2care4 ApS | Parallel import | 30/01/2026 | 1 |
| A04AA01 ondansetron <i>Ondansetron hydrochloride dihydrate</i> | | | |
| Laboratoire Aguettant | Marketing authorisation application | 30/04/2025 | 1 |
| A04AA02 granisetron <i>Granisetron hydrochloride</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 29/05/2024 | 2 |
| A05AA02 ursodeoxycholic acid <i>Ursodeoxycholic acid</i> | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 31/03/2026 | 2 |
| A06AG11 laurilsulfate, incl. combinations <i>Trisodium citrate dihydrate, Sodium lauryl sulfoacetate, Sorbitol, liquid (crystallising)</i> | | | |
| Laboratorios Liconsa S.A. | Marketing authorisation application | 22/01/2024 | 1 |
| A07AA09 vancomycin <i>Vancomycin hydrochloride</i> | | | |
| Xeolas Pharmaceuticals Limited | Marketing authorisation application | 21/03/2025 | 2 |
| A07AA12 fidaxomicin <i>Fidaxomicin</i> | | | |
| Adalvo Limited | Marketing authorisation application | 07/07/2025 | 1 |
| A07EA06 budesonide <i>Budesonide</i> | | | |
| Orion Corporation | Marketing authorisation application | 11/04/2025 | 1 |
| QP Nordic ehf. | Marketing authorisation application | 30/03/2026 | 1 |
| A07EC02 mesalazine <i>Mesalazine</i> | | | |
| Faes Farma S.A. | Marketing authorisation application | 25/04/2025 | 1 |

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|---|-------------------------------------|--------------------------|------------------------|
| A09AA02 multienzymes (lipase, protease etc.) Pancreas powder (porcine) | | | |
| ADOH B.V. | Marketing authorisation application | 11/06/2025 | 3 |
| A09AA02 multienzymes (lipase, protease etc.) Pancreatin | | | |
| Strides Nordic ApS | Marketing authorisation application | 31/10/2025 | 2 |
| A10BA02 metformin Metformin hydrochloride | | | |
| Activase Pharmaceuticals Ltd. | Marketing authorisation application | 29/02/2024 | 3 |
| A10BD07 metformin and sitagliptin Sitagliptin hydrochloride, Metformin hydrochloride | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 22/06/2022 | 2 |
| A10BD07 metformin and sitagliptin Sitagliptin phosphate monohydrate, Metformin hydrochloride | | | |
| Laboratorios Liconsa S.A. | Marketing authorisation application | 02/02/2026 | 2 |
| A10BD08 metformin and vildagliptin Vildagliptin, Metformin hydrochloride | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 02/08/2021 | 2 |
| A10BD11 metformin and linagliptin Linagliptin, Metformin hydrochloride | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 23/12/2024 | 2 |
| A10BD15 metformin and dapagliflozin Dapagliflozin propanediol monohydrate, Metformin hydrochloride | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 10/10/2025 | 2 |
| STADA Arzneimittel AG | Marketing authorisation application | 11/12/2025 | 2 |
| A10BD15 metformin and dapagliflozin Dapagliflozin, Metformin hydrochloride | | | |
| Adalvo Limited | Marketing authorisation application | 29/08/2025 | 2 |
| A10BD15 metformin and dapagliflozin Metformin hydrochloride, Dapagliflozin | | | |
| ratiopharm Arzneimittel Vertriebs GmbH | Marketing authorisation application | 29/09/2025 | 2 |
| A10BD20 metformin and empagliflozin Empagliflozin, Metformin hydrochloride | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 03/02/2025 | 4 |
| A10BH01 sitagliptin Sitagliptin hydrochloride | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 01/09/2021 | 3 |
| A10BH01 sitagliptin Sitagliptin phosphate monohydrate | | | |
| Pharmaceutical Innovation Services S.L. | Marketing authorisation application | 01/08/2025 | 3 |
| A10BH05 linagliptin Linagliptin | | | |
| Galenicum Health S.L.U | Marketing authorisation application | 31/01/2025 | 1 |
| Amarox Pharma GmbH | Marketing authorisation application | 01/07/2025 | 1 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 31/07/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| A10BJ02 liraglutide <i>Liraglutide</i> | | | |
| Adalvo Limited | Marketing authorisation application | 31/01/2023 | 1 |
| Medical Valley Invest AB | Marketing authorisation application | 30/12/2024 | 1 |
| A10BJ06 semaglutide <i>Semaglutide</i> | | | |
| Zentiva Portugal Lda. | Marketing authorisation application | 16/02/2026 | 4 |
| iPharMed | Marketing authorisation application | 16/02/2026 | 5 |
| KRKA d.d. Novo mesto | Marketing authorisation application | 26/02/2026 | 2 |
| Cipla Europe NV | Marketing authorisation application | 27/02/2026 | 4 |
| A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i> | | | |
| G.L. Pharma GmbH | Marketing authorisation application | 18/08/2025 | 2 |
| Zentiva k.s. | Marketing authorisation application | 18/08/2025 | 2 |
| Gedeon Richter Romania S.A. | Marketing authorisation application | 02/04/2026 | 2 |
| A10BK01 dapagliflozin <i>Dapagliflozin</i> | | | |
| Genepharma S.A. | Marketing authorisation application | 01/08/2024 | 2 |
| Accord Healthcare B.V. | Marketing authorisation application | 27/12/2024 | 2 |
| Glenmark Pharmaceuticals s.r.o. | Marketing authorisation application | 30/06/2025 | 2 |
| Strides Nordic ApS | Marketing authorisation application | 02/02/2026 | 1 |
| A10BK03 empagliflozin <i>Empagliflozin</i> | | | |
| Avansor Pharma Oy | Marketing authorisation application | 29/07/2024 | 2 |
| Reddy Holding GmbH | Marketing authorisation application | 11/04/2025 | 2 |
| KRKA d.d. Novo mesto | Marketing authorisation application | 23/06/2025 | 2 |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 01/08/2025 | 2 |
| Sandoz Pharmaceuticals d.d. | Marketing authorisation application | 30/09/2025 | 2 |
| Mylan Germany GmbH | Marketing authorisation application | 31/10/2025 | 2 |
| Orion Corporation | Marketing authorisation application | 16/02/2026 | 2 |
| Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. z o.o. | Marketing authorisation application | 19/03/2026 | 2 |
| A11CC03 alfacalcidol <i>Alfacalcidol</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 02/12/2024 | 3 |
| A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i> | | | |
| Pemberton Laboratories Limited | Marketing authorisation application | 21/11/2024 | 1 |
| Orion Corporation | Marketing authorisation application | 27/11/2025 | 1 |
| A16AA01 levocarnitine <i>Levocarnitine</i> | | | |
| Aspire Pharma (Malta) Limited | Marketing authorisation application | 05/01/2026 | 1 |
| A16AX06 miglustat <i>Miglustat</i> | | | |
| Waymade B.V. | Marketing authorisation application | 29/07/2024 | 1 |

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|---|-------------------------------------|--------------------------|------------------------|
| A16AX08 teduglutide <i>Teduglutide</i> | | | |
| Adalvo Limited | Marketing authorisation application | 05/09/2024 | 1 |
| Advanz Pharma Limited | Marketing authorisation application | 29/12/2025 | 2 |
| B01AB05 enoxaparin <i>Enoxaparin sodium</i> | | | |
| Changshan Europe S.r.l. | Marketing authorisation application | 03/03/2025 | 5 |
| PGF Pharma International d.o.o. | Marketing authorisation application | 03/03/2025 | 5 |
| B01AC04 clopidogrel <i>Clopidogrel hydrogen sulphate</i> | | | |
| Vale Pharmaceuticals Limited | Marketing authorisation application | 21/01/2026 | 1 |
| B01AC25 cangrelor <i>Cangrelor Tetrasodium</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 01/07/2025 | 1 |
| B01AC27 selexipag <i>Selexipag</i> | | | |
| Devatis GmbH | Marketing authorisation application | 16/10/2025 | 9 |
| B01AF01 rivaroxaban <i>Rivaroxaban</i> | | | |
| Tillomed Pharma GmbH | Marketing authorisation application | 30/01/2023 | 5 |
| ratiopharm GmbH | Marketing authorisation application | 12/08/2024 | 4 |
| Amarox Pharma B.V. | Marketing authorisation application | 31/01/2025 | 4 |
| Abacus Medicine A/S | Parallel import | 24/02/2026 | 1 |
| B01AF02 apixaban <i>Apixaban</i> | | | |
| Indoco Remedies Czech s.r.o. | Marketing authorisation application | 15/08/2022 | 2 |
| PGF Pharma International d.o.o. | Marketing authorisation application | 25/06/2025 | 2 |
| B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i> | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 03/02/2025 | 3 |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 02/05/2025 | 3 |
| Amarox Pharma GmbH | Marketing authorisation application | 23/09/2025 | 3 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 07/11/2025 | 3 |
| Orion Corporation | Marketing authorisation application | 09/04/2026 | 3 |
| B02AA02 tranexamic acid <i>Tranexamic acid</i> | | | |
| Hyloris | Marketing authorisation application | 23/01/2026 | 2 |
| B02BB01 fibrinogen, human <i>Human fibrinogen</i> | | | |
| Octapharma GmbH | Marketing authorisation application | 20/05/2025 | 1 |
| B02BD06 von Willebrand factor and coagulation factor VIII in combination <i>Factor VIII (antihemophilic factor), Human von Willebrand factor</i> | | | |
| CSL Behring GmbH | Marketing authorisation application | 21/11/2025 | 1 |
| B02BX05 eltrombopag <i>Eltrombopag olamine</i> | | | |
| Coripharma ehf. | Marketing authorisation application | 20/12/2024 | 3 |

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| B03AB05 ferric oxide polymaltose complexes <i>Iron(III)-hydroxide polymaltose complex</i> | | | |
| Orifarm Oy | Parallel import | 11/09/2024 | 1 |
| B03AC Iron, parenteral preparations <i>Ferric carboxymaltose, Iron (Fe)</i> | | | |
| Universal Farma S.L. | Marketing authorisation application | 18/12/2025 | 1 |
| B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i> | | | |
| Orion Corporation | Marketing authorisation application | 06/05/2024 | 1 |
| Seacross Pharma (Europe) Limited | Marketing authorisation application | 31/07/2024 | 1 |
| Medical Valley Invest AB | Marketing authorisation application | 27/12/2024 | 1 |
| Devatis GmbH | Marketing authorisation application | 11/08/2025 | 1 |
| B03BA01 cyanocobalamin <i>Cyanocobalamin</i> | | | |
| Orion Corporation | Marketing authorisation application | 25/10/2024 | 1 |
| B05BA01 amino acids <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 31/07/2024 | 3 |
| B05BA02 fat emulsions <i>Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 06/02/2024 | 1 |
| B05BA03 carbohydrates <i>Glucose monohydrate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 30/08/2024 | 1 |
| B05BA10 combinations <i>Glucose monohydrate, Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Calcium chloride dihydrate, Sodium glycerophosphate hydrate, Magnesium sulfate heptahydrate, Potassium chloride, Sodium acetate trihydrate, Zinc sulfate heptahydrate, Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 29/12/2025 | 3 |
| B05BB01 electrolytes <i>Potassium chloride, Sodium chloride</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 09/05/2025 | 2 |
| B05BB01 electrolytes <i>Potassium chloride</i> | | | |
| Baxter Holding B.V. | Marketing authorisation application | 02/02/2026 | 3 |
| B05BB01 electrolytes <i>Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Sodium lactate solution</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 02/10/2024 | 1 |
| B05BB01 electrolytes <i>Sodium chloride</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 01/10/2024 | 1 |
| B05BC01 mannitol <i>Mannitol</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 01/07/2025 | 1 |
| B05DA Isotonic solutions <i>ICODEXTRIN, Sodium chloride, Sodium (S)-lactate solution, Calcium chloride dihydrate, Magnesium chloride hexahydrate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 02/02/2024 | 1 |
| B05DA Isotonic solutions <i>ICODEXTRIN, Sodium chloride, Sodium lactate, Calcium chloride dihydrate, Magnesium chloride hexahydrate</i> | | | |
| Fresenius Medical Care Deutschland GmbH | Marketing authorisation application | 27/11/2025 | 1 |

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|---|-------------------------------------|--------------------------|------------------------|
| B05DB Hypertonic solutions <i>Glucose monohydrate</i> | | | |
| Triomed AB | Marketing authorisation application | 27/02/2026 | 1 |
| B05XA01 potassium chloride <i>Potassium chloride</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 18/03/2025 | 1 |
| B05XA31 electrolytes in combination with other drugs <i>Ferric chloride hexahydrate, Zinc chloride, Manganese chloride tetrahydrate, Copper chloride dihydrate, Chromium chloride hexahydrate, Sodium selenite pentahydrate, Sodium molybdate dihydrate, Potassium iodide, Sodium fluoride</i> | | | |
| B. Braun Melsungen AG | Marketing authorisation application | 10/04/2024 | 1 |
| C01AA05 digoxin <i>Digoxin</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 30/09/2025 | 1 |
| C01CA07 dobutamine <i>Dobutamine hydrochloride</i> | | | |
| PANPHARMA | Marketing authorisation application | 29/12/2023 | 1 |
| C02AB01 methyldopa (levorotatory) <i>Methyldopa sesquihydrate</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 01/04/2025 | 1 |
| C02AC01 clonidine <i>Clonidine hydrochloride</i> | | | |
| Novumgen Limited | Marketing authorisation application | 09/01/2026 | 1 |
| C02AC02 guanfacine <i>Guanfacine hydrochloride</i> | | | |
| Sandoz GmbH | Marketing authorisation application | 04/08/2025 | 4 |
| Exeltis Healthcare S.L. | Marketing authorisation application | 23/03/2026 | 4 |
| C02DC01 minoxidil <i>Minoxidil</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 08/01/2026 | 3 |
| C02DD01 nitroprusside <i>Sodium nitroprusside dihydrate</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 26/05/2025 | 1 |
| C02KX02 ambrisentan <i>Ambrisentan</i> | | | |
| Orifarm Oy | Parallel import | 11/03/2026 | 1 |
| Orifarm Oy | Parallel import | 16/03/2026 | 1 |
| C02KX04 macitentan <i>Macitentan</i> | | | |
| Renata Pharmaceuticals (Ireland) Limited | Marketing authorisation application | 29/12/2023 | 1 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 30/04/2024 | 1 |
| C02KX05 riociguat <i>Riociguat</i> | | | |
| Olpha AS | Marketing authorisation application | 28/08/2025 | 5 |
| STADA Arzneimittel AG | Marketing authorisation application | 30/09/2025 | 5 |
| Hexal A/S | Marketing authorisation application | 24/10/2025 | 5 |
| Sandoz A/S | Marketing authorisation application | 24/10/2025 | 5 |
| Devatis GmbH | Marketing authorisation application | 28/11/2025 | 5 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| C03CA01 furosemide <i>Furosemide</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 30/08/2024 | 2 |
| Noridem Enterprises Limited | Marketing authorisation application | 04/12/2024 | 1 |
| Kalceks AS | Marketing authorisation application | 20/12/2024 | 1 |
| C03DA01 spironolactone <i>Spironolactone</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 04/11/2024 | 3 |
| C03XA01 tolvaptan <i>Tolvaptan</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 31/07/2024 | 3 |
| C05AE03 diltiazem <i>Diltiazem hydrochloride</i> | | | |
| XGX Pharma ApS | Marketing authorisation application | 27/01/2025 | 1 |
| C05CA03 diosmin <i>Diosmin</i> | | | |
| Orion Corporation | Marketing authorisation application | 09/12/2025 | 1 |
| C07AA05 propranolol <i>Propranolol hydrochloride</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 27/09/2024 | 2 |
| Omet Pharma AB | Marketing authorisation application | 14/04/2025 | 2 |
| C07AB02 metoprolol <i>Metoprolol succinate, Metoprolol</i> | | | |
| Orion Corporation | Marketing authorisation application | 04/04/2025 | 1 |
| C07AB02 metoprolol <i>Metoprolol succinate</i> | | | |
| Orion Corporation | Marketing authorisation application | 04/04/2025 | 3 |
| C07AB03 atenolol <i>Atenolol</i> | | | |
| Teva GmbH | Marketing authorisation application | 23/12/2025 | 3 |
| C08CA04 nicardipine <i>Nicardipine hydrochloride</i> | | | |
| Laboratoire Aguettant | Marketing authorisation application | 08/04/2026 | 1 |
| C09CA07 telmisartan <i>Telmisartan</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 28/02/2025 | 3 |
| C09DA03 valsartan and diuretics <i>Indapamide, Valsartan</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 16/06/2025 | 1 |
| C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan disodium</i> | | | |
| Vale Pharmaceuticals Limited | Marketing authorisation application | 01/08/2025 | 3 |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 21/08/2025 | 3 |
| C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 03/02/2025 | 3 |

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|--|-------------------------------------|--------------------------|------------------------|
| C09DX04 valsartan and sacubitril Sacubitril valsartan sodium hydrate | | | |
| Viatriis Limited | Marketing authorisation application | 30/01/2024 | 3 |
| Reddy Holding GmbH | Marketing authorisation application | 07/08/2025 | 3 |
| C10AA05 atorvastatin Atorvastatin | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 02/12/2024 | 4 |
| C10BA06 rosuvastatin and ezetimibe Ezetimibe, Rosuvastatin calcium | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 17/06/2024 | 4 |
| Hennig Arzneimittel GmbH&Co KG | Marketing authorisation application | 26/02/2026 | 4 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 26/02/2026 | 4 |
| D02AX Other emollients and protectives Propylene glycol E1520 | | | |
| Galenica AB | Marketing authorisation application | 12/02/2026 | 1 |
| D05AX52 calcipotriol, combinations Betamethasone dipropionate, Calcipotriol monohydrate | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 01/08/2024 | 1 |
| D06BA01 silver sulfadiazine Silver sulfadiazine | | | |
| Macure Pharma ApS | Marketing authorisation application | 15/07/2025 | 1 |
| D07AB02 hydrocortisone butyrate Hydrocortisone butyrate | | | |
| Grindeks AS | Marketing authorisation application | 30/05/2025 | 1 |
| D07AC01 betamethasone Betamethasone valerate | | | |
| Grindeks AS | Marketing authorisation application | 01/04/2025 | 1 |
| Grindeks AS | Marketing authorisation application | 30/04/2025 | 1 |
| D07AC13 mometasone Mometasone furoate | | | |
| Grindeks AS | Marketing authorisation application | 21/10/2022 | 2 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 13/10/2025 | 1 |
| D07AD01 clobetasol Clobetasol propionate | | | |
| Grindeks AS | Marketing authorisation application | 28/11/2024 | 1 |
| Grindeks AS | Marketing authorisation application | 28/03/2025 | 1 |
| D08AG02 povidone-iodine Polyvidone-iodine | | | |
| Mundipharma Oy | Marketing authorisation application | 18/07/2019 | 1 |
| D10AE01 benzoyl peroxide Benzoyl peroxide, hydrous | | | |
| Galenica AB | Marketing authorisation application | 07/03/2025 | 1 |
| MagnaPharm Trading Slovakia s.r.o. | Marketing authorisation application | 07/03/2025 | 1 |
| Laboratoires MEDGEN | Marketing authorisation application | 10/03/2025 | 1 |
| D10AE01 benzoyl peroxide Benzoyl peroxide | | | |
| Paranova Oy | Parallel import | 03/12/2025 | 1 |

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|--|-------------------------------------|--------------------------|------------------------|
| D10BA01 isotretinoin <i>Isotretinoin</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 01/09/2025 | 2 |
| D11AH01 tacrolimus <i>Tacrolimus monohydrate</i> | | | |
| Adalvo Limited | Marketing authorisation application | 02/01/2025 | 2 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 02/01/2025 | 2 |
| Adalvo Limited | Marketing authorisation application | 29/10/2025 | 2 |
| Winmed A/S | Marketing authorisation application | 29/10/2025 | 2 |
| G01AF02 clotrimazole <i>Clotrimazole, Clotrimazole</i> | | | |
| Bayer Oy | Marketing authorisation application | 30/01/2025 | 1 |
| G01AF02 clotrimazole <i>Clotrimazole</i> | | | |
| Bayer Oy | Marketing authorisation application | 03/04/2025 | 1 |
| G01AX66 octenidine, combinations <i>Octenidine dihydrochloride, Phenoxyethanol</i> | | | |
| DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH | Marketing authorisation application | 10/03/2026 | 1 |
| G02AD06 misoprostol <i>Misoprostol</i> | | | |
| Inphena A/S | Marketing authorisation application | 06/03/2024 | 1 |
| G02BB02 vaginal ring with progestogen <i>Levonorgestrel</i> | | | |
| Exeltis Healthcare S.L. | Marketing authorisation application | 02/03/2026 | 1 |
| G02CX Other gynecologicals <i>Nifedipine</i> | | | |
| Laboratorio Reig Jofré S.A. | Marketing authorisation application | 24/09/2024 | 1 |
| G03AA14 nomegestrol and estradiol <i>Estradiol hemihydrate, Nomegestrol acetate</i> | | | |
| Exeltis Healthcare S.L. | Marketing authorisation application | 25/02/2025 | 1 |
| G03AC09 desogestrel <i>Desogestrel</i> | | | |
| Orifarm Oy | Parallel import | 08/12/2025 | 1 |
| G03BA03 testosterone <i>Testosterone</i> | | | |
| Exeltis Healthcare S.L. | Marketing authorisation application | 10/02/2025 | 1 |
| Aspire Pharma (Malta) Limited | Marketing authorisation application | 26/11/2025 | 2 |
| G03DC02 norethisterone <i>Norethisterone</i> | | | |
| Abacus Medicine A/S | Parallel import | 02/12/2025 | 1 |
| G03XB51 mifepristone, combinations <i>Mifepristone, Misoprostol</i> | | | |
| ADOH B.V. | Marketing authorisation application | 29/11/2024 | 1 |
| Nordic Group B.V. | Marketing authorisation application | 01/04/2026 | 1 |
| G04BD04 oxybutynin <i>Oxybutynin hydrochloride</i> | | | |
| Farco-Pharma GmbH | Marketing authorisation application | 09/12/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| G04BD12 mirabegron <i>Mirabegron</i> | | | |
| Adalvo Limited | Marketing authorisation application | 02/07/2024 | 1 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 02/07/2024 | 1 |
| Zentiva k.s. | Marketing authorisation application | 02/07/2024 | 1 |
| Sandoz B.V. | Marketing authorisation application | 07/10/2025 | 2 |
| Teva GmbH | Marketing authorisation application | 03/11/2025 | 1 |
| G04BE03 sildenafil <i>Sildenafil citrate</i> | | | |
| ADOH B.V. | Marketing authorisation application | 01/12/2023 | 4 |
| G04BE08 tadalafil <i>Tadalafil</i> | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 30/10/2024 | 1 |
| Zentiva Pharma GmbH | Marketing authorisation application | 01/04/2026 | 3 |
| G04CA54 tamsulosin and tadalafil <i>Tamsulosin hydrochloride, Tadalafil</i> | | | |
| Midas Pharma GmbH | Marketing authorisation application | 06/10/2025 | 1 |
| H01BA01 vasopressin (argipressin) <i>Argipressin</i> | | | |
| EVER Valinject GmbH | Marketing authorisation application | 30/01/2026 | 1 |
| H01BB02 oxytocin <i>Oxytocin</i> | | | |
| PANPHARMA | Marketing authorisation application | 21/01/2025 | 1 |
| Abacus Medicine A/S | Parallel import | 07/03/2025 | 1 |
| H01BB03 carbetocin <i>Carbetocin</i> | | | |
| EVER Valinject GmbH | Marketing authorisation application | 30/09/2024 | 1 |
| H01CB02 octreotide <i>Octreotide acetate</i> | | | |
| Qilu Pharma Spain S.L. | Marketing authorisation application | 30/05/2025 | 3 |
| STADA Arzneimittel AG | Marketing authorisation application | 12/08/2025 | 3 |
| H01CB03 lanreotide <i>Lanreotide acetate</i> | | | |
| Seacross Pharma (Europe) Limited | Marketing authorisation application | 31/01/2025 | 3 |
| STADA Arzneimittel AG | Marketing authorisation application | 30/05/2025 | 3 |
| Amneal EU Limited | Marketing authorisation application | 10/10/2025 | 3 |
| H01CC01 ganirelix <i>Ganirelix acetate</i> | | | |
| Seacross Pharma (Europe) Limited | Marketing authorisation application | 15/04/2025 | 1 |
| H02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 28/06/2024 | 1 |
| H02AB04 methylprednisolone <i>Methylprednisolone hydrogen succinate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 03/02/2026 | 5 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| H02AB08 triamcinolone <i>Triamcinolone hexacetonide</i> | | | |
| Orifarm Oy | Parallel import | 10/12/2025 | 1 |
| H02AB09 hydrocortisone <i>Hydrocortisone sodium succinate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 02/05/2025 | 6 |
| Hameln Pharma GmbH | Marketing authorisation application | 30/03/2026 | 1 |
| H02AB09 hydrocortisone <i>Hydrocortisone</i> | | | |
| Morningside Healthcare (Malta) Limited | Marketing authorisation application | 01/03/2024 | 2 |
| J01CF02 cloxacillin <i>Cloxacillin sodium</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 31/07/2024 | 3 |
| J01CR02 amoxicillin and beta-lactamase inhibitor <i>Amoxicillin trihydrate, Potassium clavulanate diluted</i> | | | |
| PGF Pharma International d.o.o. | Marketing authorisation application | 14/02/2025 | 4 |
| J01CR05 piperacillin and beta-lactamase inhibitor <i>Piperacillin sodium, Tazobactam sodium</i> | | | |
| Stragen Nordic A/S | Marketing authorisation application | 07/04/2026 | 1 |
| J01DC02 cefuroxime <i>Cefuroxime sodium</i> | | | |
| Hameln Pharma GmbH | Marketing authorisation application | 24/03/2025 | 1 |
| Noridem Enterprises Limited | Marketing authorisation application | 10/09/2025 | 2 |
| J01DD02 ceftazidime <i>Ceftazidime pentahydrate</i> | | | |
| Navamedic ASA | Marketing authorisation application | 01/10/2025 | 3 |
| Noridem Enterprises Limited | Marketing authorisation application | 06/10/2025 | 2 |
| J01DD04 ceftriaxone <i>Ceftriaxone sodium</i> | | | |
| Apta Medica Internacional d.o.o. | Marketing authorisation application | 29/04/2025 | 2 |
| J01EE01 sulfamethoxazole and trimethoprim <i>Sulfamethoxazole, Trimethoprim</i> | | | |
| Laboratórios Basi Indústria Farmacêutica S.A. | Marketing authorisation application | 01/12/2025 | 1 |
| J01FA09 clarithromycin <i>Clarithromycin</i> | | | |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 14/11/2024 | 1 |
| J01FA10 azithromycin <i>Azithromycin dihydrate</i> | | | |
| Gufic Ireland Limited | Marketing authorisation application | 31/12/2024 | 1 |
| Abacus Medicine A/S | Parallel import | 31/03/2026 | 1 |
| J01FF01 clindamycin <i>Clindamycin phosphate</i> | | | |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 02/01/2023 | 1 |
| J01MA02 ciprofloxacin <i>Ciprofloxacin lactate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 08/04/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 27/12/2024 | 1 |
| J01XA04 dalbavancin <i>Dalbavancin</i> | | | |
| Welding GmbH & Co. KG | Marketing authorisation application | 25/06/2024 | 1 |
| J01XX05 methenamine <i>Methenamine hippurate</i> | | | |
| Aspire Pharma (Malta) Limited | Marketing authorisation application | 30/04/2025 | 1 |
| J01XX09 daptomycin <i>Daptomycin</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 14/05/2025 | 2 |
| J02AA01 amphotericin <i>Amphotericin b</i> | | | |
| TLC Biopharmaceuticals B.V. | Marketing authorisation application | 24/10/2022 | 1 |
| Qilu Pharma Spain S.L. | Marketing authorisation application | 30/09/2024 | 1 |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 11/02/2025 | 1 |
| STADA Arzneimittel AG | Marketing authorisation application | 18/07/2025 | 1 |
| Masuu Pharma Europe Limited | Marketing authorisation application | 01/10/2025 | 1 |
| J02AC04 posaconazole <i>Posaconazole</i> | | | |
| PGF Pharma International d.o.o. | Marketing authorisation application | 30/07/2025 | 1 |
| J02AX05 micafungin <i>Micafungin sodium</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 22/04/2025 | 2 |
| Noridem Enterprises Limited | Marketing authorisation application | 30/05/2025 | 2 |
| J02AX06 anidulafungin <i>Anidulafungin</i> | | | |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 27/12/2024 | 1 |
| J05AB06 ganciclovir <i>Ganciclovir sodium</i> | | | |
| Bioglan AB | Marketing authorisation application | 02/10/2024 | 1 |
| J05AB14 valganciclovir <i>Valganciclovir hydrochloride</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 02/10/2024 | 1 |
| J05AF13 tenofovir alafenamide <i>Tenofovir alafenamide fumarate</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 29/12/2025 | 1 |
| J05AJ01 raltegravir <i>Raltegravir potassium</i> | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 13/11/2024 | 1 |
| Viartis Limited | Marketing authorisation application | 13/05/2025 | 1 |
| J05AJ03 dolutegravir <i>Dolutegravir sodium</i> | | | |
| Zentiva k.s. | Marketing authorisation application | 22/10/2025 | 1 |
| Cipla Europe NV | Marketing authorisation application | 01/04/2026 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| J05AR03 tenofovir disoproxil and emtricitabine <i>Emtricitabine, Tenofovir disoproxil fumarate</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 18/06/2025 | 1 |
| J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide fumarate</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 16/12/2024 | 2 |
| J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide succinate</i> | | | |
| Lupin Europe GmbH | Marketing authorisation application | 30/01/2025 | 2 |
| J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide</i> | | | |
| Medical Valley Invest AB | Marketing authorisation application | 03/02/2025 | 2 |
| J05AR19 emtricitabine, tenofovir alafenamide and rilpivirine <i>Emtricitabine, Rilpivirine hydrochloride, Tenofovir alafenamide monofumarate</i> | | | |
| Accord Healthcare S.L.U. | Marketing authorisation application | 02/06/2025 | 1 |
| L01AX03 temozolomide <i>Temozolomide</i> | | | |
| PGF Pharma International d.o.o. | Marketing authorisation application | 28/03/2025 | 6 |
| L01BC02 fluorouracil <i>Fluorouracil</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 11/09/2025 | 1 |
| L01BC07 azacitidine <i>Azacitidine</i> | | | |
| Tarchomińskie Zakłady Farmaceutyczne, Polfa S.A. | Marketing authorisation application | 26/11/2021 | 1 |
| ELC GROUP S.R.O. | Marketing authorisation application | 28/06/2023 | 1 |
| L01BC08 decitabine <i>Decitabine</i> | | | |
| EVER Valinject GmbH | Marketing authorisation application | 25/09/2024 | 1 |
| L01CD01 paclitaxel <i>Paclitaxel</i> | | | |
| Panacea Biotec Germany GmbH | Marketing authorisation application | 01/08/2023 | 1 |
| Qilu Pharma Spain S.L. | Marketing authorisation application | 16/10/2023 | 1 |
| Hexal AG | Marketing authorisation application | 02/12/2024 | 1 |
| Orion Corporation | Marketing authorisation application | 30/05/2025 | 1 |
| Amarox Pharma B.V. | Marketing authorisation application | 07/08/2025 | 1 |
| L01CD02 docetaxel <i>Docetaxel trihydrate</i> | | | |
| Tillomed Malta Limited | Marketing authorisation application | 02/02/2026 | 1 |
| L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i> | | | |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 30/06/2025 | 1 |
| L01DC03 mitomycin <i>Mitomycin</i> | | | |
| Accord Healthcare S.L.U. | Marketing authorisation application | 22/09/2025 | 1 |
| L01EA01 imatinib <i>Imatinib mesylate</i> | | | |
| Grindeks AS | Marketing authorisation application | 30/04/2024 | 2 |
| Sandoz B.V. | Marketing authorisation application | 03/05/2024 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate, Nilotinib dihydrochloride dihydrate</i> | | | |
| Devatis GmbH | Marketing authorisation application | 27/11/2024 | 1 |
| L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate</i> | | | |
| Devatis GmbH | Marketing authorisation application | 27/11/2024 | 2 |
| L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i> | | | |
| Hetero Europe S.L. | Marketing authorisation application | 26/02/2025 | 3 |
| L01EA03 nilotinib <i>Nilotinib hydrochloride monohydrate</i> | | | |
| Helm Pharmaceuticals GmbH | Marketing authorisation application | 31/07/2024 | 2 |
| L01EA03 nilotinib <i>Nilotinib</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 31/01/2025 | 3 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 31/07/2025 | 3 |
| L01EE01 trametinib <i>Trametinib dimethyl sulfoxide</i> | | | |
| Teva GmbH | Marketing authorisation application | 11/12/2025 | 2 |
| L01EF01 palbociclib <i>Palbociclib</i> | | | |
| Synthon B.V. | Marketing authorisation application | 12/11/2024 | 3 |
| STADA Arzneimittel AG | Marketing authorisation application | 30/04/2025 | 3 |
| Teva GmbH | Marketing authorisation application | 30/05/2025 | 3 |
| Devatis GmbH | Marketing authorisation application | 31/03/2026 | 3 |
| L01EJ01 ruxolitinib <i>Ruxolitinib dihydrate</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 21/02/2025 | 5 |
| L01EJ01 ruxolitinib <i>Ruxolitinib hemifumarate</i> | | | |
| Devatis GmbH | Marketing authorisation application | 19/02/2025 | 4 |
| G.L. Pharma GmbH | Marketing authorisation application | 27/02/2025 | 8 |
| Genepharma S.A. | Marketing authorisation application | 27/02/2025 | 4 |
| Reddy Holding GmbH | Marketing authorisation application | 28/08/2025 | 4 |
| Accord Healthcare B.V. | Marketing authorisation application | 27/03/2026 | 4 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 01/04/2026 | 4 |
| Advanz Pharma Limited | Marketing authorisation application | 10/04/2026 | 4 |
| L01EJ01 ruxolitinib <i>Ruxolitinib hydrochloride</i> | | | |
| Orion Corporation | Marketing authorisation application | 27/06/2024 | 4 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 01/08/2024 | 4 |
| Sandoz A/S | Marketing authorisation application | 03/02/2025 | 4 |
| L01EX02 sorafenib <i>Sorafenib tosilate</i> | | | |
| Devatis GmbH | Marketing authorisation application | 31/07/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| L01EX07 cabozantinib Cabozantinib L-tartrate | | | |
| Devatis GmbH | Marketing authorisation application | 28/11/2025 | 3 |
| L01EX07 cabozantinib Cabozantinib fumarate | | | |
| Adalvo Limited | Marketing authorisation application | 02/02/2026 | 3 |
| L01EX08 lenvatinib Lenvatinib besilate | | | |
| Viatriis Limited | Marketing authorisation application | 07/01/2026 | 2 |
| Mylan Pharmaceuticals Limited | Marketing authorisation application | 10/02/2026 | 2 |
| L01EX08 lenvatinib Lenvatinib mesylate | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 22/11/2024 | 2 |
| STADA Arzneimittel AG | Marketing authorisation application | 22/11/2024 | 6 |
| L01EX08 lenvatinib Lenvatinib | | | |
| PGF Pharma International d.o.o. | Marketing authorisation application | 30/10/2025 | 2 |
| L01EX09 nintedanib Nintedanib esylate | | | |
| ratiopharm GmbH | Marketing authorisation application | 26/09/2024 | 2 |
| PGF Pharma International d.o.o. | Marketing authorisation application | 02/06/2025 | 2 |
| L01XA01 cisplatin Cisplatin | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 30/05/2025 | 1 |
| L01XA02 carboplatin Carboplatin | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 31/10/2025 | 1 |
| L01XA03 oxaliplatin Oxaliplatin | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 29/07/2025 | 1 |
| Tillomed Malta Limited | Marketing authorisation application | 17/10/2025 | 1 |
| L01XG01 bortezomib Bortezomib | | | |
| Sun Pharmaceuticals Germany GmbH | Marketing authorisation application | 02/02/2026 | 1 |
| L01XG02 carfilzomib Carfilzomib | | | |
| Reddy Holding GmbH | Marketing authorisation application | 01/12/2025 | 3 |
| Amarox Pharma B.V. | Marketing authorisation application | 08/01/2026 | 3 |
| L01XK01 olaparib Olaparib | | | |
| Sandoz B.V. | Marketing authorisation application | 22/12/2025 | 2 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 02/02/2026 | 2 |
| L01XX Other antineoplastic agents Carfilzomib | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 30/01/2026 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| L01XX41 eribulin <i>Eribulin mesylate</i> | | | |
| Tillomed Malta Limited | Marketing authorisation application | 02/10/2023 | 1 |
| Accord Healthcare B.V. | Marketing authorisation application | 04/01/2024 | 1 |
| L02BA03 fulvestrant <i>Fulvestrant</i> | | | |
| Orion Corporation | Marketing authorisation application | 03/11/2023 | 1 |
| L02BB04 enzalutamide <i>Enzalutamide</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 02/07/2025 | 2 |
| Qilu Pharma Spain S.L. | Marketing authorisation application | 31/07/2025 | 2 |
| Reddy Holding GmbH | Marketing authorisation application | 27/02/2026 | 2 |
| L02BG04 letrozole <i>Letrozole</i> | | | |
| Tarbis Farma S.L. | Marketing authorisation application | 02/12/2024 | 1 |
| L02BX03 abiraterone <i>Abiraterone acetate</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 03/11/2025 | 1 |
| L04AA06 mycophenolic acid <i>Mycophenolate mofetil</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 23/06/2025 | 1 |
| Ascend GmbH | Marketing authorisation application | 03/02/2026 | 1 |
| Ascend GmbH | Marketing authorisation application | 04/03/2026 | 1 |
| L04AA18 everolimus <i>Everolimus</i> | | | |
| Ascend GmbH | Marketing authorisation application | 02/02/2026 | 4 |
| L04AA31 teriflunomide <i>Teriflunomide</i> | | | |
| Heaton k.s. | Marketing authorisation application | 20/12/2023 | 1 |
| L04AA32 apremilast <i>Apremilast</i> | | | |
| Sandoz B.V. | Marketing authorisation application | 28/03/2025 | 2 |
| Pharmathen S.A. | Marketing authorisation application | 31/03/2025 | 2 |
| Devatis GmbH | Marketing authorisation application | 30/10/2025 | 2 |
| L04AA40 cladribine <i>Cladribine</i> | | | |
| Sandoz B.V. | Marketing authorisation application | 25/08/2025 | 1 |
| STADA Arzneimittel AG | Marketing authorisation application | 26/08/2025 | 1 |
| Sumar Pharma ehf. | Marketing authorisation application | 26/08/2025 | 1 |
| Msn Labs Europe Limited | Marketing authorisation application | 18/12/2025 | 1 |
| Devatis GmbH | Marketing authorisation application | 22/12/2025 | 1 |
| Zentiva k.s. | Marketing authorisation application | 26/02/2026 | 1 |
| Accord Healthcare B.V. | Marketing authorisation application | 27/02/2026 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| L04AD02 tacrolimus <i>Tacrolimus monohydrate</i> | | | |
| Orifarm Healthcare A/S | Marketing authorisation application | 29/11/2023 | 4 |
| Ascend GmbH | Marketing authorisation application | 11/02/2026 | 3 |
| L04AF01 tofacitinib <i>Tofacitinib citrate</i> | | | |
| Teva B.V. | Marketing authorisation application | 26/03/2025 | 2 |
| STADA Arzneimittel AG | Marketing authorisation application | 28/03/2025 | 4 |
| Amarox Pharma B.V. | Marketing authorisation application | 31/03/2025 | 2 |
| Devatis GmbH | Marketing authorisation application | 09/04/2025 | 2 |
| Adalvo Limited | Marketing authorisation application | 30/04/2025 | 1 |
| Devatis GmbH | Marketing authorisation application | 31/03/2026 | 1 |
| L04AK02 teriflunomide <i>Teriflunomide</i> | | | |
| STADA Nordic ApS | Marketing authorisation application | 13/12/2024 | 2 |
| L04AX03 methotrexate <i>Methotrexate</i> | | | |
| Gebro Pharma GmbH | Marketing authorisation application | 24/03/2026 | 1 |
| L04AX05 pirfenidone <i>Pirfenidone</i> | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 03/03/2025 | 2 |
| L04AX06 pomalidomide <i>Pomalidomide</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 03/10/2024 | 4 |
| L04AX07 dimethyl fumarate <i>Dimethyl fumarate</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 22/10/2024 | 2 |
| M01AE01 ibuprofen <i>Ibuprofen</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 02/04/2024 | 3 |
| Sandoz A/S | Marketing authorisation application | 13/12/2024 | 2 |
| Sandoz A/S | Marketing authorisation application | 13/12/2024 | 4 |
| Strides Nordic ApS | Marketing authorisation application | 08/10/2025 | 3 |
| Fysioline Oy | Marketing authorisation application | 13/10/2025 | 1 |
| Strides Nordic ApS | Marketing authorisation application | 26/11/2025 | 1 |
| M01AE51 ibuprofen, combinations <i>Ibuprofen, Caffeine</i> | | | |
| Teva B.V. | Marketing authorisation application | 09/12/2024 | 1 |
| Alfred E. Tiefenbacher (GmbH & Co. KG) | Marketing authorisation application | 21/02/2025 | 1 |
| M01AE52 naproxen and esomeprazole <i>Naproxen, Esomeprazole magnesium trihydrate</i> | | | |
| Orion Corporation | Marketing authorisation application | 29/04/2025 | 1 |
| M01AH04 parecoxib <i>Parecoxib sodium</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 01/07/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| M01AX25 chondroitin sulfate <i>Chondroitin sulfate sodium</i> | | | |
| IBSA Farmaceutici Italia S.r.l | Marketing authorisation application | 07/02/2025 | 1 |
| Schmid Pharma B.V. | Marketing authorisation application | 28/02/2025 | 1 |
| M02AA07 piroxicam <i>Piroxicam</i> | | | |
| Haleon Denmark ApS | Marketing authorisation application | 28/03/2025 | 1 |
| M02AA13 ibuprofen <i>Ibuprofen lysine</i> | | | |
| Laboratorio Italiano Biochimico Farmaceutico Lisapharma S.p.A. | Marketing authorisation application | 27/02/2026 | 1 |
| M02AA15 diclofenac <i>Diclofenac diethylamine</i> | | | |
| Fysioline Oy | Marketing authorisation application | 18/07/2025 | 1 |
| M02AA15 diclofenac <i>Diclofenac sodium</i> | | | |
| Haleon Denmark ApS | Marketing authorisation application | 03/06/2025 | 1 |
| M03AC09 rocuronium bromide <i>Rocuronium bromide</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 02/06/2025 | 1 |
| M03BX01 baclofen <i>Baclofen</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 31/01/2025 | 1 |
| 2Care4 Generics ApS | Marketing authorisation application | 31/10/2025 | 1 |
| Strides Nordic ApS | Marketing authorisation application | 01/04/2026 | 1 |
| M04AC01 colchicine <i>Colchicine</i> | | | |
| Abacus Medicine A/S | Parallel import | 10/02/2026 | 1 |
| Orifarm Oy | Parallel import | 27/02/2026 | 1 |
| M05BB04 risedronic acid, calcium and colecalciferol, sequential <i>Calcium carbonate, Cholecalciferol concentrate (powder form), Risedronate sodium</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 27/12/2024 | 1 |
| N01AH01 fentanyl <i>Fentanyl citrate</i> | | | |
| Laboratoire Aguettant | Marketing authorisation application | 07/04/2026 | 1 |
| N01AH06 remifentanil <i>Remifentanil hydrochloride</i> | | | |
| Kalceks AS | Marketing authorisation application | 30/04/2025 | 3 |
| Noridem Enterprises Limited | Marketing authorisation application | 01/07/2025 | 3 |
| N01AX10 propofol <i>Propofol</i> | | | |
| Troikaa Pharmaceuticals Europe s.r.o. | Marketing authorisation application | 02/03/2026 | 2 |
| N01BB02 lidocaine <i>Lidocaine</i> | | | |
| Orion Corporation | Marketing authorisation application | 31/01/2025 | 1 |
| Cresia Consulting S.L. | Marketing authorisation application | 26/03/2026 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| N01BB09 ropivacaine <i>Ropivacaine hydrochloride monohydrate</i> | | | |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 12/12/2024 | 4 |
| Noridem Enterprises Limited | Marketing authorisation application | 20/01/2025 | 5 |
| N01BB51 bupivacaine, combinations <i>Bupivacaine hydrochloride monohydrate, Adrenaline tartrate</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 11/04/2025 | 2 |
| N01BB58 articaïne, combinations <i>Articaïne hydrochloride, Adrenaline</i> | | | |
| Laboratorios Normon S.A. | Marketing authorisation application | 25/03/2025 | 2 |
| N02BE01 paracetamol <i>Paracetamol</i> | | | |
| ratiopharm GmbH | Marketing authorisation application | 15/07/2024 | 2 |
| Noridem Enterprises Limited | Marketing authorisation application | 24/03/2025 | 1 |
| Fresenius Kabi Deutschland GmbH | Marketing authorisation application | 08/04/2025 | 1 |
| N02BE51 paracetamol, combinations excl. psycholeptics <i>Ibuprofen, Paracetamol</i> | | | |
| Vale Pharmaceuticals Limited | Marketing authorisation application | 09/10/2023 | 1 |
| Fysioline Oy | Marketing authorisation application | 10/04/2025 | 1 |
| N02BE51 paracetamol, combinations excl. psycholeptics <i>Paracetamol, Caffeine</i> | | | |
| Haleon Denmark ApS | Marketing authorisation application | 17/12/2024 | 1 |
| N02BF01 gabapentin <i>Gabapentin</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 19/12/2025 | 2 |
| N02BF02 pregabalin <i>Pregabalin</i> | | | |
| Grindeks AS | Marketing authorisation application | 01/08/2024 | 6 |
| N02CC01 sumatriptan <i>Sumatriptan</i> | | | |
| Medical Valley Invest AB | Marketing authorisation application | 09/12/2024 | 2 |
| N02CC03 zolmitriptan <i>Zolmitriptan</i> | | | |
| Medical Valley Invest AB | Marketing authorisation application | 26/02/2026 | 2 |
| N02CX02 clonidine <i>Clonidine hydrochloride</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 28/08/2024 | 1 |
| N03AA03 primidone <i>Primidone</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 01/10/2024 | 3 |
| N03AB02 phenytoin <i>Phenytoin sodium</i> | | | |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 03/03/2025 | 1 |
| N03AD01 ethosuximide <i>Ethosuximide</i> | | | |
| Neuraxpharm Arzneimittel GmbH | Marketing authorisation application | 23/05/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| N03AF02 oxcarbazepine Oxcarbazepine | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 11/03/2025 | 3 |
| N03AG01 valproic acid Sodium valproate | | | |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 30/04/2025 | 4 |
| Macure Pharma ApS | Marketing authorisation application | 27/11/2025 | 1 |
| N03AX09 lamotrigine Lamotrigine | | | |
| Ptr Pharma Consulting Unipessoal Lda. | Marketing authorisation application | 08/01/2024 | 2 |
| N03AX14 levetiracetam Levetiracetam | | | |
| Grindeks AS | Marketing authorisation application | 01/08/2025 | 4 |
| N03AX18 lacosamide Lacosamide | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 08/05/2025 | 1 |
| Amarox Pharma B.V. | Marketing authorisation application | 01/09/2025 | 4 |
| Orion Corporation | Marketing authorisation application | 23/01/2026 | 4 |
| N03AX22 perampanel Perampanel hydrate (4:3) | | | |
| Orion Corporation | Marketing authorisation application | 31/05/2024 | 6 |
| N03AX23 brivaracetam Brivaracetam | | | |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 31/07/2024 | 1 |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 11/02/2026 | 1 |
| N04BA02 levodopa and decarboxylase inhibitor Carbidopa, Levodopa | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 31/10/2025 | 2 |
| N04BA02 levodopa and decarboxylase inhibitor Levodopa, Benserazide hydrochloride | | | |
| Orion Corporation | Marketing authorisation application | 31/03/2026 | 3 |
| N04BB01 amantadine Amantadine hydrochloride | | | |
| Macure Pharma ApS | Marketing authorisation application | 28/11/2024 | 1 |
| N04BC09 rotigotine Rotigotine | | | |
| Orion Corporation | Marketing authorisation application | 30/09/2024 | 6 |
| N05AE05 lurasidone Lurasidone hydrochloride | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 18/11/2024 | 3 |
| N05AH02 clozapine Clozapine | | | |
| Grindeks AS | Marketing authorisation application | 27/09/2023 | 2 |
| N05AH03 olanzapine Olanzapine | | | |
| Devatis GmbH | Marketing authorisation application | 30/07/2025 | 6 |
| Orifarm Oy | Parallel import | 25/03/2026 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| N05AH04 quetiapine <i>Quetiapine fumarate</i> | | | |
| Grindeks AS | Marketing authorisation application | 07/10/2022 | 4 |
| Grindeks AS | Marketing authorisation application | 10/10/2022 | 5 |
| Amarox Pharma B.V. | Marketing authorisation application | 09/10/2025 | 7 |
| N05AL05 amisulpride <i>Amisulpride</i> | | | |
| Ailon Pharma Oy | Marketing authorisation application | 20/10/2025 | 3 |
| N05AX08 risperidone <i>Risperidone</i> | | | |
| Orion Corporation | Marketing authorisation application | 31/10/2025 | 3 |
| N05AX12 aripiprazole <i>Aripiprazole</i> | | | |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 22/04/2024 | 4 |
| N05AX13 paliperidone <i>Paliperidone palmitate</i> | | | |
| Viartis Limited | Marketing authorisation application | 25/10/2024 | 8 |
| Advanz Pharma Limited | Marketing authorisation application | 03/03/2025 | 4 |
| N05AX15 cariprazine <i>Cariprazine hydrochloride</i> | | | |
| Devatis GmbH | Marketing authorisation application | 31/07/2025 | 4 |
| KRKA d.d. Novo mesto | Marketing authorisation application | 30/09/2025 | 4 |
| Adalvo Limited | Marketing authorisation application | 12/12/2025 | 4 |
| N05BA01 diazepam <i>Diazepam</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 01/11/2024 | 1 |
| N05CD08 midazolam <i>Midazolam maleate</i> | | | |
| SERB S.A. | Marketing authorisation application | 27/02/2025 | 1 |
| N05CD08 midazolam <i>Midazolam</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 18/12/2025 | 2 |
| N05CF02 zolpidem <i>Zolpidem Tartrate</i> | | | |
| Unimedic Pharma AB | Marketing authorisation application | 20/10/2025 | 2 |
| N05CH01 melatonin <i>Melatonin</i> | | | |
| Owlpharma Consulting LDA | Marketing authorisation application | 31/10/2025 | 1 |
| ACE Pharmaceuticals BV | Marketing authorisation application | 13/11/2025 | 3 |
| N05CM18 dexmedetomidine <i>Dexmedetomidine hydrochloride</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 21/10/2024 | 1 |
| N06AA09 amitriptyline <i>Amitriptyline hydrochloride</i> | | | |
| Neuraxpharm Sweden AB | Marketing authorisation application | 03/04/2024 | 1 |
| N06AB06 sertraline <i>Sertraline hydrochloride</i> | | | |
| RIA Generics Limited | Marketing authorisation application | 22/05/2023 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| N06AX11 mirtazapine <i>Mirtazapine</i> | | | |
| Devatis GmbH | Marketing authorisation application | 08/04/2025 | 3 |
| N06AX12 bupropion <i>Bupropion hydrochloride</i> | | | |
| Amarox Pharma B.V. | Marketing authorisation application | 30/01/2025 | 2 |
| N06AX26 vortioxetine <i>Vortioxetine hydrobromide benzyl alcohol hemi-solvate</i> | | | |
| Orion Corporation | Marketing authorisation application | 16/01/2025 | 4 |
| Orion Corporation | Marketing authorisation application | 12/09/2025 | 4 |
| N06AX26 vortioxetine <i>Vortioxetine hydrobromide</i> | | | |
| Biofarm Sp.z.o.o | Marketing authorisation application | 07/02/2025 | 2 |
| Accord Healthcare Ireland Limited | Marketing authorisation application | 28/02/2025 | 4 |
| STADA Arzneimittel AG | Marketing authorisation application | 16/05/2025 | 4 |
| Sandoz Pharmaceuticals d.d. | Marketing authorisation application | 01/09/2025 | 4 |
| Teva GmbH | Marketing authorisation application | 01/09/2025 | 4 |
| N06BA02 dexamfetamine <i>Dexamphetamine sulphate</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 03/03/2025 | 3 |
| N06BA04 methylphenidate <i>Methylphenidate hydrochloride</i> | | | |
| Viartis Limited | Marketing authorisation application | 01/12/2025 | 4 |
| N06BA09 atomoxetine <i>Atomoxetine hydrochloride</i> | | | |
| Amarox Pharma GmbH | Marketing authorisation application | 30/04/2025 | 7 |
| 2Care4 Generics ApS | Marketing authorisation application | 31/07/2025 | 1 |
| N06BA12 lisdexamfetamine <i>Lisdexamfetamine dimesylate</i> | | | |
| Aspire Pharma (Malta) Limited | Marketing authorisation application | 21/01/2025 | 6 |
| Sandoz A/S | Marketing authorisation application | 21/01/2025 | 6 |
| Rontis Hellas Medical and Pharmaceutical Products S.A. | Marketing authorisation application | 30/12/2025 | 6 |
| Unimedic Pharma AB | Marketing authorisation application | 30/12/2025 | 1 |
| Pharmaplot P.C. | Marketing authorisation application | 31/12/2025 | 6 |
| N06DA03 rivastigmine <i>Rivastigmine</i> | | | |
| Sandoz A/S | Marketing authorisation application | 01/07/2024 | 3 |
| Strides Nordic ApS | Marketing authorisation application | 02/09/2024 | 3 |
| N07BB01 disulfiram <i>Disulfiram</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 25/03/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| N07XX08 tafamidis <i>Tafamidis</i> | | | |
| Cipla Europe NV | Marketing authorisation application | 28/03/2025 | 1 |
| Adalvo Limited | Marketing authorisation application | 29/07/2025 | 1 |
| Adalvo Limited | Marketing authorisation application | 27/02/2026 | 1 |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 30/03/2026 | 1 |
| P02CF01 ivermectin <i>Ivermectin</i> | | | |
| Zentiva k.s. | Marketing authorisation application | 30/10/2025 | 1 |
| Devatis GmbH | Marketing authorisation application | 25/02/2026 | 1 |
| QA02BC01 omeprazole <i>Omeprazole</i> | | | |
| Boehringer Ingelheim Vetmedica GmbH | Marketing authorisation application | 20/10/2025 | 1 |
| QA04AD90 Maropitant <i>Maropitant citrate monohydrate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 10/11/2025 | 1 |
| QA06AD11 lactulose <i>Lactulose</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 03/02/2025 | 1 |
| QC01CE90 pimobendane <i>Pimobendan</i> | | | |
| VetViva Richter GmbH | Marketing authorisation application | 04/11/2025 | 4 |
| QC03CA01 furosemide <i>Furosemide</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 22/09/2025 | 1 |
| QD08AG03 iodine <i>Iodine</i> | | | |
| Delaval | Marketing authorisation application | 11/12/2024 | 2 |
| QG52X VARIOUS PRODUCTS FOR THE CARE OF TEATS AND UDDER <i>Hydrocortisone aceponate</i> | | | |
| Virbac | Marketing authorisation application | 26/11/2024 | 1 |
| QH02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 20/07/2020 | 1 |
| QH02AB06 prednisolone <i>Prednisolone</i> | | | |
| Axience | Marketing authorisation application | 02/04/2025 | 1 |
| QH02CA01 trilostane <i>Trilostane</i> | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 24/10/2025 | 5 |
| QH03BB02 thiamazole <i>Thiamazole</i> | | | |
| Virbac | Marketing authorisation application | 28/08/2024 | 1 |
| QI02AE05 mycoplasma <i>Mycoplasma bovis, strain N2805-1, live</i> | | | |
| Zoetis Animal Health ApS | Marketing authorisation application | 09/07/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| QI05AA01 Equine influenza virus vaccine <i>Equine Influenza virus H3N8, A/Equine/Limerick/2010, Inactivated, Equine influenza virus H3N8, A/Equine/Brno/08, Inactivated, Tetanus toxoid</i> | | | |
| Bioveta a.s. | Marketing authorisation application | 15/11/2024 | 1 |
| QI05AA01 Equine influenza virus vaccine <i>Equine Influenza virus H3N8, A/Equine/Limerick/2010, Inactivated, Equine influenza virus H3N8, A/Equine/Brno/08, Inactivated</i> | | | |
| Bioveta a.s. | Marketing authorisation application | 15/11/2024 | 1 |
| QI05AA04 Equine rhinopneumonitis virus vaccine + Equine influenza virus vaccine <i>Equine Influenza virus H3N8, A/Equine/Limerick/2010, Inactivated, Equine influenza virus H3N8, A/Equine/Brno/08, Inactivated, Equine herpesvirus 1, strain BIO 82, Inactivated</i> | | | |
| Bioveta a.s. | Marketing authorisation application | 20/03/2026 | 1 |
| QI07AD02 Canine distemper virus vaccine + Canine adenovirus vaccine + Canine parvovirus vaccine | | | |
| Virbac | Marketing authorisation application | 09/04/2026 | 1 |
| QJ01CR02 amoxicillin and enzyme inhibitor <i>Amoxicillin trihydrate, Potassium clavulanate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 14/03/2023 | 3 |
| QJ01EW10 sulfadiazine and trimethoprim, incl. derivatives <i>Trimethoprim, Sulfadiazine</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 28/05/2025 | 2 |
| QM01AC06 meloxicam <i>Meloxicam</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 13/09/2021 | 1 |
| Alfasan Nederland B.V. | Marketing authorisation application | 21/09/2021 | 1 |
| Alfasan Nederland B.V. | Marketing authorisation application | 08/10/2021 | 1 |
| Alfasan Nederland B.V. | Marketing authorisation application | 11/11/2021 | 1 |
| Alfasan Nederland B.V. | Marketing authorisation application | 03/11/2022 | 2 |
| Cyton AH Biosciences GmbH | Marketing authorisation application | 22/10/2024 | 1 |
| QM01AE91 carprofen <i>Carprofen</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/12/2022 | 2 |
| QM01AH91 robenacoxib <i>Robenacoxib</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 25/04/2025 | 1 |
| KRKA d.d. Novo mesto | Marketing authorisation application | 28/04/2025 | 1 |
| QM01AX90 pentosan polysulphate <i>Pentosan polysulfate sodium</i> | | | |
| Forte Healthcare Licencing Limited | Marketing authorisation application | 05/03/2025 | 1 |
| QN01AX95 levomenthol <i>Levomenthol</i> | | | |
| Scanvacc AS | Marketing authorisation application | 30/01/2026 | 1 |
| QN01AX99 other general anesthetics, combinations <i>Tiletamine hydrochloride, Zolazepam hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 18/06/2025 | 1 |
| QN01BA52 procaine, combinations <i>Procaine hydrochloride, Adrenaline tartrate</i> | | | |
| Forte Healthcare Licencing Limited | Marketing authorisation application | 04/02/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| QN02AC52 methadone, combinations excl. psycholeptics <i>Levomethadone hydrochloride, Fenpipramide hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 28/02/2022 | 2 |
| QN02AE01 buprenorphine <i>Buprenorphine hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 14/02/2025 | 1 |
| QN02AF01 butorphanol <i>Butorphanol Tartrate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 08/04/2025 | 1 |
| QN02AX02 tramadol <i>Tramadol hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 05/12/2022 | 6 |
| QN03AA02 phenobarbital <i>Phenobarbital</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 13/09/2023 | 3 |
| QN04BC02 Pergolide <i>Pergolide mesilate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 12/04/2023 | 3 |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/01/2025 | 1 |
| QN05AA04 acepromazine <i>Acepromazine maleate</i> | | | |
| Floris Holding B.V. | Marketing authorisation application | 21/01/2026 | 1 |
| QN05CD08 midazolam <i>Midazolam</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 04/11/2025 | 1 |
| QN05CM18 Dexmedetomidine <i>Dexmedetomidine hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 15/09/2022 | 1 |
| QN05CM90 detomidine <i>Detomidine hydrochloride for veterinary use</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 14/04/2022 | 1 |
| QN05CM91 medetomidine <i>Medetomidine hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 15/09/2022 | 1 |
| QN05CM92 xylazine <i>Xylazine hydrochloride</i> | | | |
| Forte Healthcare Licencing Limited | Marketing authorisation application | 01/04/2025 | 1 |
| QN51AA01 pentobarbital <i>Pentobarbital sodium</i> | | | |
| Wirtschaftsgenossenschaft deutscher Tieraerzte eG | Marketing authorisation application | 21/08/2025 | 1 |
| QP52AA51 praziquantel, combinations <i>Praziquantel, Pyrantel embonate, Febantel</i> | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 08/06/2023 | 2 |
| QP53AC55 flumethrin, combinations <i>Flumethrin, Imidacloprid, Titanium dioxide</i> | | | |
| Beaphar B.V. | Marketing authorisation application | 16/09/2024 | 1 |
| QP53AC55 flumethrin, combinations <i>Flumethrin, Imidacloprid</i> | | | |
| Beaphar B.V. | Marketing authorisation application | 16/09/2024 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| QP53AC55 flumethrin, combinations <i>Imidacloprid, Flumethrin</i> | | | |
| Virbac | Marketing authorisation application | 03/07/2024 | 3 |
| QP54AA51 ivermectin, combinations <i>Ivermectin, Praziquantel</i> | | | |
| Bioveta a.s. | Marketing authorisation application | 10/01/2025 | 1 |
| QP54AB51 milbemycin oxime, combinations <i>Milbemycin oxime, Praziquantel</i> | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 27/10/2017 | 1 |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 23/01/2024 | 1 |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 29/01/2024 | 2 |
| QS01AA01 chloramphenicol <i>Chloramphenicol</i> | | | |
| Domes Pharma | Marketing authorisation application | 24/06/2025 | 1 |
| QS01CA01 dexamethasone and antiinfectives <i>Framycetin sulfate, Dexamethasone sodium phosphate</i> | | | |
| Domes Pharma | Marketing authorisation application | 06/02/2026 | 1 |
| QS02BA01 hydrocortisone <i>Hydrocortisone aceponate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/04/2026 | 1 |
| R01AA07 xylometazoline <i>Xylometazoline hydrochloride</i> | | | |
| Vianex S.A. | Marketing authorisation application | 01/11/2024 | 2 |
| R01AD09 mometasone <i>Mometasone furoate</i> | | | |
| Orion Corporation | Marketing authorisation application | 17/11/2025 | 1 |
| R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Fluticasone propionate</i> | | | |
| Adalvo Limited | Marketing authorisation application | 02/06/2025 | 2 |
| Adalvo Limited | Marketing authorisation application | 16/01/2026 | 3 |
| R02AA03 dichlorobenzyl alcohol <i>Amylmetacresol, 2,4-Dichlorobenzylalcohol</i> | | | |
| Mapaex Consumer Healthcare (Ireland) Private Limited | Marketing authorisation application | 03/10/2025 | 2 |
| Mapaex Consumer Healthcare (Ireland) Private Limited | Marketing authorisation application | 06/10/2025 | 1 |
| R02AA06 cetylpyridinium <i>Cetylpyridinium chloride, Lidocaine hydrochloride monohydrate</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 22/04/2025 | 1 |
| R02AX01 flurbiprofen <i>Flurbiprofen</i> | | | |
| Naiax Pharma S.L. | Marketing authorisation application | 28/08/2024 | 1 |
| Naiax Pharma S.L. | Marketing authorisation application | 29/08/2024 | 1 |
| STADA Arzneimittel AG | Marketing authorisation application | 01/12/2025 | 2 |
| R03AC02 salbutamol <i>Salbutamol sulfate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 20/02/2025 | 3 |
| R03AK06 salmeterol and fluticasone <i>Salmeterol, Fluticasone</i> | | | |
| PGF Pharma International d.o.o. | Marketing authorisation application | 17/07/2025 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| R03AK08 formoterol and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate</i> | | | |
| Devatis GmbH | Marketing authorisation application | 30/10/2025 | 2 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 19/02/2026 | 2 |
| R03AL02 salbutamol and ipratropium bromide <i>Ipratropium bromide, Salbutamol sulfate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 30/09/2025 | 1 |
| R03AL04 indacaterol and glycopyrronium bromide <i>Indacaterol maleate, Glycopyrronium bromide</i> | | | |
| Genetic S.p.A. | Marketing authorisation application | 24/07/2024 | 1 |
| R03AL09 formoterol, glycopyrronium bromide and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate, Glycopyrronium bromide</i> | | | |
| Elpen Pharmaceutical Co. Inc. | Marketing authorisation application | 29/12/2025 | 2 |
| R03BB01 ipratropium bromide <i>Ipratropium bromide</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 21/11/2025 | 2 |
| R06AA04 clemastine <i>Clemastine fumarate</i> | | | |
| Macure Healthcare Limited | Marketing authorisation application | 17/01/2025 | 1 |
| R06AE03 cyclizine <i>Cyclizine lactate</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 28/02/2025 | 1 |
| R06AX26 fexofenadine <i>Fexofenadine hydrochloride</i> | | | |
| Haleon Denmark ApS | Marketing authorisation application | 17/12/2024 | 1 |
| R06AX27 desloratadine <i>Desloratadine</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 31/08/2023 | 1 |
| ratiopharm GmbH | Marketing authorisation application | 20/08/2025 | 1 |
| R06AX29 bilastine <i>Bilastine monohydrate</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 30/08/2024 | 1 |
| R07AX02 ivacaftor <i>Ivacaftor</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 02/05/2024 | 1 |
| STADA Arzneimittel AG | Marketing authorisation application | 30/09/2024 | 1 |
| Lupin Europe GmbH | Marketing authorisation application | 31/01/2025 | 2 |
| Sandoz B.V. | Marketing authorisation application | 02/05/2025 | 1 |
| Genepharma S.A. | Marketing authorisation application | 12/05/2025 | 2 |
| Amarox Pharma GmbH | Marketing authorisation application | 05/01/2026 | 2 |
| Elpen Pharmaceutical Co. Inc. | Marketing authorisation application | 30/01/2026 | 2 |
| S01BA01 dexamethasone <i>Dexamethasone sodium phosphate</i> | | | |
| Pharmaselect International Beteiligungs GmbH | Marketing authorisation application | 01/12/2025 | 1 |
| 1 A Pharma GmbH | Marketing authorisation application | 02/12/2025 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| S01BC04 flurbiprofen <i>Flurbiprofen sodium dihydrate</i> | | | |
| Horus Pharma | Marketing authorisation application | 28/08/2025 | 1 |
| S01BC11 bromfenac <i>Bromfenac sodium sesquihydrate</i> | | | |
| Blumont Ofta Trading Limited | Marketing authorisation application | 02/09/2024 | 1 |
| Laboratorios Salvat S.A. | Marketing authorisation application | 17/09/2024 | 1 |
| S01EA05 brimonidine <i>Brimonidine tartrate</i> | | | |
| Blumont Ofta Trading Limited | Marketing authorisation application | 19/02/2026 | 1 |
| S01EC54 brinzolamide, combinations <i>Brinzolamide, Brimonidine tartrate</i> | | | |
| Pharmaselect International Beteiligungs GmbH | Marketing authorisation application | 01/04/2025 | 1 |
| S01ED51 timolol, combinations <i>Dorzolamide hydrochloride, Timolol maleate</i> | | | |
| Genetic S.p.A. | Marketing authorisation application | 26/04/2024 | 1 |
| S01ED51 timolol, combinations <i>Latanoprost, Timolol</i> | | | |
| Creative Pharma Solutions s.r.o. | Marketing authorisation application | 30/06/2025 | 1 |
| Sandoz A/S | Marketing authorisation application | 01/07/2025 | 1 |
| S01EE01 latanoprost <i>Latanoprost</i> | | | |
| Genetic S.p.A. | Marketing authorisation application | 21/03/2025 | 2 |
| Laboratorios Salvat S.A. | Marketing authorisation application | 09/05/2025 | 1 |
| Viatrix Pharma GmbH | Marketing authorisation application | 06/11/2025 | 1 |
| AshCure Pharma B.V. | Marketing authorisation application | 07/02/2026 | 1 |
| S01EE03 bimatoprost <i>Bimatoprost</i> | | | |
| GHN Pharma Nordic AB | Marketing authorisation application | 24/02/2025 | 1 |
| S01XA12 dexpanthenol <i>Dexpanthenol</i> | | | |
| Dr. Gerhard Mann Chem.-Pharm. fabrik GmbH | Marketing authorisation application | 25/06/2024 | 1 |
| V03AB34 fomepizole <i>Fomepizole</i> | | | |
| Waymade B.V. | Marketing authorisation application | 19/09/2025 | 1 |
| V04CX01 indocyanine green <i>Indocyanine green</i> | | | |
| Provepharm | Marketing authorisation application | 07/10/2024 | 1 |
| V07AB Solvents and diluting agents, incl. irrigating solutions <i>Water for injection</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 29/11/2024 | 1 |
| V09GX Other cardiovascular system diagnostic radiopharmaceuticals <i>Strontium (82Sr) dichloride, Rubidium (82 Rb)</i> | | | |
| Jubilant Pharmaceuticals nv | Marketing authorisation application | 08/12/2025 | 1 |