

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
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
Crescent Pharma International Limited	Marketing authorisation application	27/05/2026	1
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
Adalvo Limited	Marketing authorisation application	16/04/2026	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
A09AA02 multienzymes (lipase, protease etc.) <i>Pancreas powder (porcine)</i>			
ADOH B.V.	Marketing authorisation application	11/06/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
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
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
Viartis Limited	Marketing authorisation application	26/05/2026	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			
Amarox Pharma GmbH	Marketing authorisation application	01/07/2025	1
Glenmark Arzneimittel GmbH	Marketing authorisation application	31/07/2025	1
A10BJ02 liraglutide Liraglutide			
Adalvo Limited	Marketing authorisation application	31/01/2023	1
Medical Valley Invest AB	Marketing authorisation application	30/12/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
Masuu Pharma Europe Limited	Marketing authorisation application	28/04/2026	1
Medical Valley Invest AB	Marketing authorisation application	26/05/2026	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
Masuu Pharma Europe Limited	Marketing authorisation application	28/04/2026	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
Medical Valley Invest AB	Marketing authorisation application	01/06/2026	2
A11CC03 alfalcidol <i>Alfalcidol</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
A16AA01 levocarnitine <i>Levocarnitine</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	05/01/2026	1

Applicant	Nature of the application	Application receipt date	Number of applications
A16AX08 teduglutide <i>Teduglutide</i>			
Adalvo Limited	Marketing authorisation application	05/09/2024	1
Advanz Pharma Limited	Marketing authorisation application	29/12/2025	2
Vivanta Generics s.r.o.	Marketing authorisation application	04/05/2026	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 selezipag <i>Selezipag</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>			
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
Accord Healthcare Ireland Limited	Marketing authorisation application	29/04/2026	3
B02AA02 tranexamic acid <i>Tranexamic acid</i>			
Hyloris	Marketing authorisation application	23/01/2026	2
B02BD06 von Willebrand factor and coagulation factor VIII in combination <i>Factor VIII (antihæmophilic 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
B03AC Iron, parenteral preparations <i>Ferric carboxymaltose, Iron (Fe)</i>			
Universal Farma S.L.	Marketing authorisation application	18/12/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
Tillomed Italia S.r.l.	Marketing authorisation application	29/04/2026	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
C02KX01 bosentan <i>Bosentan monohydrate</i>			
Abacus Medicine A/S	Parallel import	20/04/2026	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>			
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
C10AA04 fluvastatin Fluvastatin sodium			
Abacus Medicine A/S	Parallel import	30/04/2026	1
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
D06AX01 fusidic acid Fusidic acid			
Abacus Medicine A/S	Parallel import	22/05/2026	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
D10AD51 tretinoin, combinations Benzoyl peroxide, hydrous, Tretinoin			
Galenica AB	Marketing authorisation application	08/05/2026	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

Applicant	Nature of the application	Application receipt date	Number of applications
D10AE01 benzoyl peroxide <i>Benzoyl peroxide</i>			
Paranova Oy	Parallel import	03/12/2025	1
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
D11AX01 minoxidil <i>Minoxidil</i>			
STADA Arzneimittel AG	Marketing authorisation application	30/04/2026	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>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	26/11/2025	2
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

Applicant	Nature of the application	Application receipt date	Number of applications
G04BD04 oxybutynin <i>Oxybutynin hydrochloride</i>			
Farco-Pharma GmbH	Marketing authorisation application	09/12/2025	1
G04BD12 mirabegron <i>Mirabegron</i>			
Adalvo Limited	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
Viartis Limited	Marketing authorisation application	08/05/2026	2
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
H01CB02 octreotide <i>Octreotide</i>			
Orifarm Oy	Parallel import	28/05/2026	1
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

Applicant	Nature of the application	Application receipt date	Number of applications
H02AB04 methylprednisolone <i>Methylprednisolone hydrogen succinate</i>			
Noridem Enterprises Limited	Marketing authorisation application	03/02/2026	5
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
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
Vale Pharmaceuticals Limited	Marketing authorisation application	30/04/2026	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
J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i>			
Welding GmbH & Co. KG	Marketing authorisation application	25/06/2024	1
Noridem Enterprises Limited	Marketing authorisation application	27/12/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
J01XX05 methenamine <i>Methenamine hippurate</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	30/04/2025	1
Waymade B.V.	Marketing authorisation application	30/04/2026	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
Seacross Pharma (Europe) Limited	Marketing authorisation application	16/04/2026	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
J05AB11 valaciclovir <i>Valaciclovir hydrochloride monohydrate</i>			
Abacus Medicine A/S	Parallel import	27/05/2026	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
Medical Valley Invest AB	Marketing authorisation application	29/05/2026	1
J05AR03 tenofovir disoproxil and emtricitabine <i>Emtricitabine, Tenofovir disoproxil fumarate</i>			
Amarox Pharma B.V.	Marketing authorisation application	18/06/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
Stragen France	Marketing authorisation application	04/05/2026	1
L01CD01 paclitaxel <i>Paclitaxel</i>			
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
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
L01EA05 ponatinib <i>Ponatinib hydrochloride</i>			
Sandoz B.V.	Marketing authorisation application	04/05/2026	3
L01EE01 trametinib <i>Trametinib dimethyl sulfoxide</i>			
Teva GmbH	Marketing authorisation application	11/12/2025	2
L01EF01 palbociclib <i>Palbociclib</i>			
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>			
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
L01EX07 cabozantinib <i>Cabozantinib L-tartrate</i>			
Devatis GmbH	Marketing authorisation application	28/11/2025	3
L01EX07 cabozantinib <i>Cabozantinib fumarate</i>			
Adalvo Limited	Marketing authorisation application	02/02/2026	3

Applicant	Nature of the application	Application receipt date	Number of applications
L01EX08 lenvatinib <i>Lenvatinib besilate</i>			
Viatriis Limited	Marketing authorisation application	07/01/2026	2
Mylan Pharmaceuticals Limited	Marketing authorisation application	10/02/2026	2
L01EX08 lenvatinib <i>Lenvatinib mesylate</i>			
STADA Arzneimittel AG	Marketing authorisation application	22/11/2024	2
STADA Arzneimittel AG	Marketing authorisation application	22/11/2024	6
L01EX08 lenvatinib <i>Lenvatinib</i>			
PGF Pharma International d.o.o.	Marketing authorisation application	30/10/2025	2
L01EX09 nintedanib <i>Nintedanib esylate</i>			
PGF Pharma International d.o.o.	Marketing authorisation application	02/06/2025	2
L01XA01 cisplatin <i>Cisplatin</i>			
Amarox Pharma B.V.	Marketing authorisation application	30/05/2025	1
Amarox Pharma B.V.	Marketing authorisation application	27/05/2026	1
L01XA02 carboplatin <i>Carboplatin</i>			
Amarox Pharma GmbH	Marketing authorisation application	31/10/2025	1
L01XA03 oxaliplatin <i>Oxaliplatin</i>			
Amarox Pharma B.V.	Marketing authorisation application	29/07/2025	1
Tillomed Malta Limited	Marketing authorisation application	17/10/2025	1
L01XG01 bortezomib <i>Bortezomib</i>			
Sun Pharmaceuticals Germany GmbH	Marketing authorisation application	02/02/2026	1
L01XG02 carfilzomib <i>Carfilzomib</i>			
Reddy Holding GmbH	Marketing authorisation application	01/12/2025	3
Amarox Pharma B.V.	Marketing authorisation application	08/01/2026	3
L01XK01 olaparib <i>Olaparib</i>			
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 <i>Carfilzomib</i>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	30/01/2026	1
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
Orifarm Oy	Parallel import	15/04/2026	1
L02BX03 abiraterone <i>Abiraterone acetate</i>			
STADA Arzneimittel AG	Marketing authorisation application	03/11/2025	1
PGF Pharma International d.o.o.	Marketing authorisation application	30/04/2026	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
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
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	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
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

Applicant	Nature of the application	Application receipt date	Number of applications
M02AA15 diclofenac Diclofenac diethylamine			
Fysioline Oy	Marketing authorisation application	18/07/2025	1
Orifarm Healthcare A/S	Marketing authorisation application	08/06/2026	1
M02AA15 diclofenac Diclofenac sodium			
Haleon Denmark ApS	Marketing authorisation application	03/06/2025	1
M03AC09 rocuronium bromide Rocuronium bromide			
Amarox Pharma B.V.	Marketing authorisation application	02/06/2025	1
M03BX01 baclofen Baclofen			
2Care4 Generics ApS	Marketing authorisation application	31/10/2025	1
Strides Nordic ApS	Marketing authorisation application	01/04/2026	1
Crescent Pharma International Limited	Marketing authorisation application	15/05/2026	1
Orifarm Oy	Parallel import	03/06/2026	2
Orifarm Oy	Parallel import	08/06/2026	1
M04AC01 colchicine Colchicine			
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 Calcium carbonate, Cholecalciferol concentrate (powder form), Risedronate sodium			
Kappler Pharma Consult GmbH	Marketing authorisation application	27/12/2024	1
N01AH01 fentanyl Fentanyl citrate			
Laboratoire Aguettant	Marketing authorisation application	07/04/2026	1
N01AH06 remifentanil Remifentanil hydrochloride			
Kalceks AS	Marketing authorisation application	30/04/2025	3
Noridem Enterprises Limited	Marketing authorisation application	01/07/2025	3
N01AX10 propofol Propofol			
Troikaa Pharmaceuticals Europe s.r.o.	Marketing authorisation application	02/03/2026	2
N01BB02 lidocaine Lidocaine			
Orion Corporation	Marketing authorisation application	31/01/2025	1
Cresia Consulting S.L.	Marketing authorisation application	26/03/2026	1
N01BB09 ropivacaine Ropivacaine hydrochloride monohydrate			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	12/12/2024	4
N01BB51 bupivacaine, combinations Bupivacaine hydrochloride monohydrate, Adrenaline tartrate			
Macure Pharma ApS	Marketing authorisation application	11/04/2025	2
N02AA01 morphine Morphine hydrochloride trihydrate			
Dextreg	Marketing authorisation application	29/05/2026	1

Applicant	Nature of the application	Application receipt date	Number of applications
N02AB03 fentanyl <i>Fentanyl citrate</i>			
Welding GmbH & Co. KG	Marketing authorisation application	28/05/2026	1
N02BE01 paracetamol <i>Paracetamol</i>			
ratiopharm GmbH	Marketing authorisation application	15/07/2024	2
Noridem Enterprises Limited	Marketing authorisation application	24/03/2025	1
Orion Corporation	Marketing authorisation application	10/06/2026	2
N02BE51 paracetamol, combinations excl. psycholeptics <i>Ibuprofen, Paracetamol</i>			
Vale Pharmaceuticals Limited	Marketing authorisation application	09/10/2023	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
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
N03AB02 phenytoin <i>Phenytoin sodium</i>			
Hikma Farmacéutica (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
N03AF02 oxcarbazepine <i>Oxcarbazepine</i>			
Amarox Pharma GmbH	Marketing authorisation application	11/03/2025	3
N03AG01 valproic acid <i>Sodium valproate</i>			
Desitin Arzneimittel GmbH	Marketing authorisation application	30/04/2025	4
Macure Pharma ApS	Marketing authorisation application	27/11/2025	1
N03AX09 lamotrigine <i>Lamotrigine</i>			
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	08/01/2024	2
N03AX14 levetiracetam <i>Levetiracetam</i>			
Grindeks AS	Marketing authorisation application	01/08/2025	4
Neuraxpharm Pharmaceuticals S.L.	Marketing authorisation application	04/05/2026	4
N03AX18 lacosamide <i>Lacosamide</i>			
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

Applicant	Nature of the application	Application receipt date	Number of applications
N03AX23 brivaracetam <i>Brivaracetam</i>			
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 <i>Carbidopa, Levodopa</i>			
2Care4 Generics ApS	Marketing authorisation application	31/10/2025	2
N04BA02 levodopa and decarboxylase inhibitor <i>Levodopa, Benserazide hydrochloride</i>			
Orion Corporation	Marketing authorisation application	31/03/2026	3
N04BC09 rotigotine <i>Rotigotine</i>			
Orion Corporation	Marketing authorisation application	30/09/2024	6
N05AE05 lurasidone <i>Lurasidone hydrochloride</i>			
Amarox Pharma GmbH	Marketing authorisation application	18/11/2024	3
N05AH02 clozapine <i>Clozapine</i>			
Grindeks AS	Marketing authorisation application	27/09/2023	2
N05AH03 olanzapine <i>Olanzapine</i>			
Devatis GmbH	Marketing authorisation application	30/07/2025	6
Orifarm Oy	Parallel import	25/03/2026	1
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>			
Viatri 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

Applicant	Nature of the application	Application receipt date	Number of applications
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>			
Unimedica 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
N06AA10 nortriptyline <i>Nortriptyline hydrochloride</i>			
Orifarm Oy	Parallel import	18/05/2026	1
N06AB03 fluoxetine <i>Fluoxetine hydrochloride</i>			
Amarox Pharma B.V.	Marketing authorisation application	30/04/2026	5
N06AB06 sertraline <i>Sertraline hydrochloride</i>			
RIA Generics Limited	Marketing authorisation application	22/05/2023	2
N06AX11 mirtazapine <i>Mirtazapine</i>			
Devatis GmbH	Marketing authorisation application	08/04/2025	3
Omet Pharma AB	Marketing authorisation application	27/05/2026	3
N06AX12 bupropion <i>Bupropion hydrochloride</i>			
Amarox Pharma B.V.	Marketing authorisation application	30/01/2025	2
Aliud Pharma GmbH	Marketing authorisation application	04/05/2026	1
N06AX26 vortioxetine <i>Vortioxetine hydrobromide benzyl alcohol hemi-solvate</i>			
Orion Corporation	Marketing authorisation application	12/09/2025	4
N06AX26 vortioxetine <i>Vortioxetine hydrobromide</i>			
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
Biofarm Sp. z o.o.	Marketing authorisation application	01/06/2026	4
N06BA02 dexamfetamine <i>Dexamphetamine sulphate</i>			
2Care4 Generics ApS	Marketing authorisation application	03/03/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
N06BA04 methylphenidate <i>Methylphenidate hydrochloride</i>			
Viatriis Limited	Marketing authorisation application	01/12/2025	4
N06BA09 atomoxetine <i>Atomoxetine hydrochloride</i>			
Amarox Pharma GmbH	Marketing authorisation application	30/04/2025	7
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
N07BB01 disulfiram <i>Disulfiram</i>			
Macure Pharma ApS	Marketing authorisation application	25/03/2025	1
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
Ashish Life Science Holding B.V.	Marketing authorisation application	04/05/2026	4
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

Applicant	Nature of the application	Application receipt date	Number of applications
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>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	24/04/2026	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, 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 <i>Canine distemper virus, strain Lederle, Live, Canine adenovirus 2, strain Manhattan, Live, Canine parvovirus, strain Cornell, Live</i>			
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
QM01AE91 carprofen <i>Carprofen</i>			
Alfasan Nederland B.V.	Marketing authorisation application	07/12/2022	2

Applicant	Nature of the application	Application receipt date	Number of applications
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
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

Applicant	Nature of the application	Application receipt date	Number of applications
QN05CM92 xylazine Xylazine hydrochloride			
Forte Healthcare Licencing Limited	Marketing authorisation application	01/04/2025	1
V.M.D.	Marketing authorisation application	20/04/2026	1
QN51AA01 pentobarbital Pentobarbital sodium			
Wirtschaftsgenossenschaft deutscher Tieraerzte eG	Marketing authorisation application	21/08/2025	1
QP52AA51 praziquantel, combinations Praziquantel, Pyrantel embonate, Febantel			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	08/06/2023	2
QP53AC55 flumethrin, combinations Flumethrin, Imidacloprid, Titanium dioxide (E171)			
Beaphar B.V.	Marketing authorisation application	16/09/2024	1
QP53AC55 flumethrin, combinations Flumethrin, Imidacloprid			
Beaphar B.V.	Marketing authorisation application	16/09/2024	2
QP54AA51 ivermectin, combinations Ivermectin, Praziquantel			
Bioveta a.s.	Marketing authorisation application	10/01/2025	1
QP54AB51 milbemycin oxime, combinations Milbemycin oxime, Praziquantel			
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 Chloramphenicol			
Domes Pharma	Marketing authorisation application	24/06/2025	1
QS01CA01 dexamethasone and antiinfectives Framycetin sulfate, Dexamethasone sodium phosphate			
Domes Pharma	Marketing authorisation application	06/02/2026	1
QS02BA01 hydrocortisone Hydrocortisone aceponate			
Alfasan Nederland B.V.	Marketing authorisation application	07/04/2026	1
R01AD09 mometasone Mometasone furoate			
Orion Corporation	Marketing authorisation application	17/11/2025	1
R01AD58 fluticasone, combinations Azelastine hydrochloride, Fluticasone propionate			
Adalvo Limited	Marketing authorisation application	02/06/2025	2
Adalvo Limited	Marketing authorisation application	16/01/2026	3
R02AA03 dichlorobenzyl alcohol Amylmetacresol, 2,4-Dichlorobenzylalcohol			
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 Cetylpyridinium chloride, Lidocaine hydrochloride monohydrate			
Kappler Pharma Consult GmbH	Marketing authorisation application	22/04/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
Naiax Pharma S.L.	Marketing authorisation application	01/12/2025	1
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
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
R05X OTHER COLD PREPARATIONS <i>Gentiana lutea, Primula veris, Rumex crispus, Sambucus nigra (lat.), Verbena officinalis L.</i>			
Bionorica SE	Marketing authorisation application	13/05/2026	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

Applicant	Nature of the application	Application receipt date	Number of applications
R07AX02 ivacaftor <i>Ivacaftor</i>			
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
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
Viartis 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
S01XA18 ciclosporin <i>Ciclosporin</i>			
Devatis GmbH	Marketing authorisation application	28/04/2026	1

Applicant	Nature of the application	Application receipt date	Number of applications
V03AB34 fomepizole <i>Fomepizole</i>			
Waymade B.V.	Marketing authorisation application	19/09/2025	1
V04CL Tests for allergic diseases <i>Birch</i>			
ALK-Abello A/S	Marketing authorisation application	29/05/2026	1
V04CL Tests for allergic diseases <i>Timothy</i>			
ALK-Abello A/S	Marketing authorisation application	29/05/2026	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