

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

Applicant	Nature of the application	Application receipt date	Number of applications
<b>A09AA02 multienzymes (lipase, protease etc.) Pancreas powder (porcine)</b>			
ADOH B.V.	Marketing authorisation application	11/06/2025	3
<b>A09AA02 multienzymes (lipase, protease etc.) Pancreas powder</b>			
AVVA Pharmaceuticals Ltd.	Marketing authorisation application	14/07/2020	2
<b>A09AA02 multienzymes (lipase, protease etc.) Pancreatin</b>			
Strides Nordic ApS	Marketing authorisation application	31/10/2025	2
<b>A10BA02 metformin Metformin hydrochloride</b>			
Activase Pharmaceuticals Ltd.	Marketing authorisation application	29/02/2024	3
<b>A10BD07 metformin and sitagliptin Sitagliptin hydrochloride, Metformin hydrochloride</b>			
Vivanta Generics s.r.o.	Marketing authorisation application	22/06/2022	2
<b>A10BD07 metformin and sitagliptin Sitagliptin phosphate monohydrate, Metformin hydrochloride</b>			
Laboratorios Liconsa S.A.	Marketing authorisation application	02/02/2026	2
<b>A10BD08 metformin and vildagliptin Vildagliptin, Metformin hydrochloride</b>			
Vivanta Generics s.r.o.	Marketing authorisation application	02/08/2021	2
<b>A10BD11 metformin and linagliptin Linagliptin, Metformin hydrochloride</b>			
KRKA d.d. Novo mesto	Marketing authorisation application	23/12/2024	2
<b>A10BD15 metformin and dapagliflozin Dapagliflozin propanediol monohydrate, Metformin hydrochloride</b>			
Amarox Pharma B.V.	Marketing authorisation application	10/10/2025	2
STADA Arzneimittel AG	Marketing authorisation application	11/12/2025	2
<b>A10BD15 metformin and dapagliflozin Dapagliflozin, Metformin hydrochloride</b>			
Adalvo Limited	Marketing authorisation application	29/08/2025	2
<b>A10BD15 metformin and dapagliflozin Metformin hydrochloride, Dapagliflozin</b>			
ratiopharm Arzneimittel Vertriebs GmbH	Marketing authorisation application	29/09/2025	2
<b>A10BD20 metformin and empagliflozin Empagliflozin, Metformin hydrochloride</b>			
KRKA d.d. Novo mesto	Marketing authorisation application	03/02/2025	4
<b>A10BH01 sitagliptin Sitagliptin hydrochloride</b>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/09/2021	3
<b>A10BH01 sitagliptin Sitagliptin phosphate monohydrate</b>			
Pharmaceutical Innovation Services S.L.	Marketing authorisation application	01/08/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>A10BH05 linagliptin <i>Linagliptin</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	02/04/2024	1
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
<b>A10BJ02 liraglutide <i>Liraglutide</i></b>			
Adalvo Limited	Marketing authorisation application	31/01/2023	1
Medical Valley Invest AB	Marketing authorisation application	30/12/2024	1
<b>A10BJ06 semaglutide <i>Semaglutide</i></b>			
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
<b>A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	01/03/2024	2
G.L. Pharma GmbH	Marketing authorisation application	18/08/2025	2
Zentiva k.s.	Marketing authorisation application	18/08/2025	2
<b>A10BK01 dapagliflozin <i>Dapagliflozin</i></b>			
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
<b>A10BK03 empagliflozin <i>Empagliflozin</i></b>			
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
<b>A11CC03 alfalcidol <i>Alfalcidol</i></b>			
Strides Nordic ApS	Marketing authorisation application	02/12/2024	3
<b>A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i></b>			
Pemberton Laboratories Limited	Marketing authorisation application	21/11/2024	1
Orion Corporation	Marketing authorisation application	27/11/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>A16AA01 levocarnitine <i>Levocarnitine</i></b>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	05/01/2026	1
<b>A16AX06 miglustat <i>Miglustat</i></b>			
Waymade B.V.	Marketing authorisation application	29/07/2024	1
<b>A16AX08 teduglutide <i>Teduglutide</i></b>			
Adalvo Limited	Marketing authorisation application	05/09/2024	1
Advanz Pharma Limited	Marketing authorisation application	29/12/2025	2
<b>B01AB02 antithrombin <i>Antithrombine III humane</i></b>			
Octapharma AB	Marketing authorisation application	21/08/2025	1
<b>B01AB05 enoxaparin <i>Enoxaparin sodium</i></b>			
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
<b>B01AC04 clopidogrel <i>Clopidogrel hydrogen sulphate</i></b>			
Vale Pharmaceuticals Limited	Marketing authorisation application	21/01/2026	1
<b>B01AC21 treprostinil <i>Treprostinil sodium</i></b>			
Abacus Medicine A/S	Parallel import	10/12/2025	1
<b>B01AC25 cangrelor <i>Cangrelor Tetrasodium</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/07/2025	1
<b>B01AC27 selexipag <i>Selexipag</i></b>			
Devatis GmbH	Marketing authorisation application	16/10/2025	9
<b>B01AF01 rivaroxaban <i>Rivaroxaban</i></b>			
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
<b>B01AF02 apixaban <i>Apixaban</i></b>			
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
<b>B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i></b>			
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

Applicant	Nature of the application	Application receipt date	Number of applications
<b>B02AA02 tranexamic acid <i>Tranexamic acid</i></b>			
Hyloris	Marketing authorisation application	23/01/2026	2
<b>B02BB01 fibrinogen, human <i>Human fibrinogen</i></b>			
Octapharma Gmbh	Marketing authorisation application	20/05/2025	1
<b>B02BD06 von Willebrand factor and coagulation factor VIII in combination <i>Factor VIII (antihaemophilic factor), Human von Willebrand factor</i></b>			
CSL Behring GmbH	Marketing authorisation application	21/11/2025	1
<b>B02BX05 eltrombopag <i>Eltrombopag olamine</i></b>			
Coripharma ehf.	Marketing authorisation application	20/12/2024	3
<b>B03AB05 ferric oxide polymaltose complexes <i>Iron(III)-hydroxide polymaltose complex</i></b>			
Orifarm Oy	Parallel import	11/09/2024	1
<b>B03AC Iron, parenteral preparations <i>Ferric carboxymaltose, Iron (Fe)</i></b>			
Universal Farma S.L.	Marketing authorisation application	18/12/2025	1
<b>B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i></b>			
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
<b>B03BA01 cyanocobalamin <i>Cyanocobalamin</i></b>			
Orion Corporation	Marketing authorisation application	25/10/2024	1
<b>B05BA01 amino acids <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	31/07/2024	3
<b>B05BA02 fat emulsions <i>Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	06/02/2024	1
<b>B05BA03 carbohydrates <i>Glucose monohydrate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	30/08/2024	1
<b>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></b>			
Noridem Enterprises Limited	Marketing authorisation application	29/12/2025	3
<b>B05BB01 electrolytes <i>Potassium chloride, Sodium chloride</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	09/05/2025	2
<b>B05BB01 electrolytes <i>Potassium chloride</i></b>			
Baxter Holding B.V.	Marketing authorisation application	02/02/2026	3
<b>B05BB01 electrolytes <i>Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Sodium lactate solution</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	02/10/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>B05BB01 electrolytes Sodium chloride</b>			
Noridem Enterprises Limited	Marketing authorisation application	01/10/2024	1
<b>B05BC01 mannitol Mannitol</b>			
Noridem Enterprises Limited	Marketing authorisation application	01/07/2025	1
<b>B05DA Isotonic solutions ICODEXTRIN, Sodium chloride, Sodium (S)-lactate solution, Calcium chloride dihydrate, Magnesium chloride hexahydrate</b>			
Noridem Enterprises Limited	Marketing authorisation application	02/02/2024	1
<b>B05DA Isotonic solutions ICODEXTRIN, Sodium chloride, Sodium lactate, Calcium chloride dihydrate, Magnesium chloride hexahydrate</b>			
Fresenius Medical Care Deutschland GmbH	Marketing authorisation application	27/11/2025	1
<b>B05DB Hypertonic solutions Glucose monohydrate</b>			
Triomed AB	Marketing authorisation application	27/02/2026	1
<b>B05XA01 potassium chloride Potassium chloride</b>			
Noridem Enterprises Limited	Marketing authorisation application	18/03/2025	1
B. Braun Melsungen AG	Marketing authorisation application	20/03/2026	1
<b>B05XA31 electrolytes in combination with other drugs Ferric chloride hexahydrate, Zinc chloride, Manganese chloride tetrahydrate, Copper chloride dihydrate, Chromium chloride hexahydrate, Sodium selenite pentahydrate, Sodium molybdate dihydrate, Potassium iodide, Sodium fluoride</b>			
B. Braun Melsungen AG	Marketing authorisation application	10/04/2024	1
<b>C01AA05 digoxin Digoxin</b>			
Macure Pharma ApS	Marketing authorisation application	30/09/2025	1
<b>C01CA07 dobutamine Dobutamine hydrochloride</b>			
PANPHARMA	Marketing authorisation application	29/12/2023	1
<b>C01CA24 epinephrine Adrenaline tartrate</b>			
Meda Pharma GmbH & Co. KG	Marketing authorisation application	02/05/2024	2
<b>C02AB01 methyl dopa (levorotatory) Methyl dopa sesquihydrate</b>			
Macure Pharma ApS	Marketing authorisation application	01/04/2025	1
<b>C02AC01 clonidine Clonidine hydrochloride</b>			
Novumgen Limited	Marketing authorisation application	09/01/2026	1
<b>C02AC02 guanfacine Guanfacine hydrochloride</b>			
Sandoz GmbH	Marketing authorisation application	04/08/2025	4
Exeltis Healthcare S.L.	Marketing authorisation application	23/03/2026	4
<b>C02DC01 minoxidil Minoxidil</b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	08/01/2026	3
<b>C02DD01 nitroprusside Sodium nitroprusside dihydrate</b>			
Macure Pharma ApS	Marketing authorisation application	26/05/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>C02KX02 ambrisentan <i>Ambrisentan</i></b>			
Orifarm Oy	Parallel import	11/03/2026	1
Orifarm Oy	Parallel import	16/03/2026	1
<b>C02KX04 macitentan <i>Macitentan</i></b>			
Renata Pharmaceuticals (Ireland) Limited	Marketing authorisation application	29/12/2023	1
Vivanta Generics s.r.o.	Marketing authorisation application	30/04/2024	1
<b>C02KX05 riociguat <i>Riociguat</i></b>			
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
<b>C03CA01 furosemide <i>Furosemide</i></b>			
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
<b>C03DA01 spironolactone <i>Spironolactone</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	04/11/2024	3
<b>C03XA01 tolvaptan <i>Tolvaptan</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	31/07/2024	3
<b>C05AE03 diltiazem <i>Diltiazem hydrochloride</i></b>			
XGX Pharma ApS	Marketing authorisation application	27/01/2025	1
<b>C05CA03 diosmin <i>Diosmin</i></b>			
Orion Corporation	Marketing authorisation application	09/12/2025	1
<b>C07AA05 propranolol <i>Propranolol hydrochloride</i></b>			
2Care4 Generics ApS	Marketing authorisation application	27/09/2024	2
Omet Pharma AB	Marketing authorisation application	14/04/2025	2
<b>C07AB02 metoprolol <i>Metoprolol succinate, Metoprolol</i></b>			
Orion Corporation	Marketing authorisation application	04/04/2025	1
<b>C07AB02 metoprolol <i>Metoprolol succinate</i></b>			
Orion Corporation	Marketing authorisation application	04/04/2025	3
<b>C07AB03 atenolol <i>Atenolol</i></b>			
Teva GmbH	Marketing authorisation application	23/12/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>C09CA07 telmisartan <i>Telmisartan</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	28/02/2025	3
<b>C09DA03 valsartan and diuretics <i>Indapamide, Valsartan</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	16/06/2025	1
<b>C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan disodium</i></b>			
Vale Pharmaceuticals Limited	Marketing authorisation application	01/08/2025	3
Kappler Pharma Consult GmbH	Marketing authorisation application	21/08/2025	3
<b>C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	03/02/2025	3
<b>C09DX04 valsartan and sacubitril <i>Sacubitril valsartan sodium hydrate</i></b>			
Viatriis Limited	Marketing authorisation application	30/01/2024	3
Reddy Holding GmbH	Marketing authorisation application	07/08/2025	3
<b>C10AA05 atorvastatin <i>Atorvastatin</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	02/12/2024	4
<b>C10BA06 rosuvastatin and ezetimibe <i>Ezetimibe, Rosuvastatin calcium</i></b>			
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
<b>D02AX Other emollients and protectives <i>Propylene glycol E1520</i></b>			
Galenica AB	Marketing authorisation application	12/02/2026	1
<b>D05AX52 calcipotriol, combinations <i>Betamethasone dipropionate, Calcipotriol monohydrate</i></b>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	01/08/2024	1
<b>D06BA01 silver sulfadiazine <i>Silver sulfadiazine</i></b>			
Macure Pharma ApS	Marketing authorisation application	15/07/2025	1
<b>D07AB02 hydrocortisone butyrate <i>Hydrocortisone butyrate</i></b>			
Grindeks AS	Marketing authorisation application	30/05/2025	1
<b>D07AC01 betamethasone <i>Betamethasone valerate</i></b>			
Grindeks AS	Marketing authorisation application	01/04/2025	1
Grindeks AS	Marketing authorisation application	30/04/2025	1
<b>D07AC13 mometasone <i>Mometasone furoate</i></b>			
Grindeks AS	Marketing authorisation application	21/10/2022	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	13/10/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>D07AD01 clobetasol</b> <i>Clobetasol propionate</i>			
Grindeks AS	Marketing authorisation application	28/11/2024	1
Grindeks AS	Marketing authorisation application	28/03/2025	1
<b>D08AG02 povidone-iodine</b> <i>Polyvidone-iodine</i>			
Mundipharma Oy	Marketing authorisation application	18/07/2019	1
<b>D10AE01 benzoyl peroxide</b> <i>Benzoyl peroxide, hydrous</i>			
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
<b>D10AE01 benzoyl peroxide</b> <i>Benzoyl peroxide</i>			
Paranova Oy	Parallel import	03/12/2025	1
<b>D10BA01 isotretinoin</b> <i>Isotretinoin</i>			
Strides Nordic ApS	Marketing authorisation application	01/09/2025	2
<b>D11AH01 tacrolimus</b> <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
<b>G01AF02 clotrimazole</b> <i>Clotrimazole, Clotrimazole</i>			
Bayer Oy	Marketing authorisation application	30/01/2025	1
<b>G01AF02 clotrimazole</b> <i>Clotrimazole</i>			
Bayer Oy	Marketing authorisation application	03/04/2025	1
<b>G01AX66 octenidine, combinations</b> <i>Octenidine dihydrochloride, Phenoxyethanol</i>			
DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH	Marketing authorisation application	10/03/2026	1
<b>G02AD06 misoprostol</b> <i>Misoprostol</i>			
Inphena A/S	Marketing authorisation application	06/03/2024	1
<b>G02BB02 vaginal ring with progestogen</b> <i>Levonorgestrel</i>			
Exeltis Healthcare S.L.	Marketing authorisation application	02/03/2026	1
<b>G02CX Other gynecologicals</b> <i>Nifedipine</i>			
Laboratorio Reig Jofré S.A.	Marketing authorisation application	24/09/2024	1
<b>G03AA14 nomegestrol and estradiol</b> <i>Estradiol hemihydrate, Nomegestrol acetate</i>			
Exeltis Healthcare S.L.	Marketing authorisation application	25/02/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>G03AC09 desogestrel <i>Desogestrel</i></b>			
Orifarm Oy	Parallel import	08/12/2025	1
Abacus Medicine A/S	Parallel import	16/12/2025	1
<b>G03BA03 testosterone <i>Testosterone</i></b>			
Exeltis Healthcare S.L.	Marketing authorisation application	10/02/2025	1
Aspire Pharma (Malta) Limited	Marketing authorisation application	26/11/2025	2
<b>G03DC02 norethisterone <i>Norethisterone</i></b>			
Abacus Medicine A/S	Parallel import	02/12/2025	1
<b>G03XB51 mifepristone, combinations <i>Mifepristone, Misoprostol</i></b>			
ADOH B.V.	Marketing authorisation application	29/11/2024	1
<b>G04BD04 oxybutynin <i>Oxybutynin hydrochloride</i></b>			
Farco-Pharma GmbH	Marketing authorisation application	09/12/2025	1
<b>G04BD12 mirabegron <i>Mirabegron</i></b>			
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
<b>G04BE03 sildenafil <i>Sildenafil citrate</i></b>			
ADOH B.V.	Marketing authorisation application	01/12/2023	4
<b>G04BE08 tadalafil <i>Tadalafil</i></b>			
Amarox Pharma GmbH	Marketing authorisation application	30/10/2024	1
<b>G04CA54 tamsulosin and tadalafil <i>Tamsulosin hydrochloride, Tadalafil</i></b>			
Midas Pharma GmbH	Marketing authorisation application	06/10/2025	1
<b>H01BA01 vasopressin (argipressin) <i>Argipressin</i></b>			
EVER Valinject GmbH	Marketing authorisation application	30/01/2026	1
<b>H01BB02 oxytocin <i>Oxytocin</i></b>			
PANPHARMA	Marketing authorisation application	21/01/2025	1
Abacus Medicine A/S	Parallel import	07/03/2025	1
<b>H01BB03 carbetocin <i>Carbetocin</i></b>			
EVER Valinject GmbH	Marketing authorisation application	30/09/2024	1
<b>H01CB02 octreotide <i>Octreotide acetate</i></b>			
Qilu Pharma Spain S.L.	Marketing authorisation application	30/05/2025	3
STADA Arzneimittel AG	Marketing authorisation application	12/08/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>H01CB03 lanreotide <i>Lanreotide acetate</i></b>			
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
<b>H01CC01 ganirelix <i>Ganirelix acetate</i></b>			
Seacross Pharma (Europe) Limited	Marketing authorisation application	15/04/2025	1
<b>H02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	28/06/2024	1
<b>H02AB04 methylprednisolone <i>Methylprednisolone hydrogen succinate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	03/02/2026	5
<b>H02AB08 triamcinolone <i>Triamcinolone hexacetonide</i></b>			
Orifarm Oy	Parallel import	10/12/2025	1
<b>H02AB09 hydrocortisone <i>Hydrocortisone sodium succinate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	02/05/2025	6
<b>H02AB09 hydrocortisone <i>Hydrocortisone</i></b>			
Morningside Healthcare (Malta) Limited	Marketing authorisation application	01/03/2024	2
<b>J01CF02 cloxacillin <i>Cloxacillin sodium</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	31/07/2024	3
<b>J01CR02 amoxicillin and beta-lactamase inhibitor <i>Amoxicillin trihydrate, Potassium clavulanate diluted</i></b>			
PGF Pharma International d.o.o.	Marketing authorisation application	14/02/2025	4
<b>J01DC02 cefuroxime <i>Cefuroxime sodium</i></b>			
Hameln Pharma GmbH	Marketing authorisation application	24/03/2025	1
Noridem Enterprises Limited	Marketing authorisation application	10/09/2025	2
<b>J01DD02 ceftazidime <i>Ceftazidime pentahydrate</i></b>			
Navamedic ASA	Marketing authorisation application	01/10/2025	3
Noridem Enterprises Limited	Marketing authorisation application	06/10/2025	2
<b>J01DD04 ceftriaxone <i>Ceftriaxone sodium</i></b>			
Apta Medica Internacional d.o.o.	Marketing authorisation application	29/04/2025	2
<b>J01EE01 sulfamethoxazole and trimethoprim <i>Sulfamethoxazole, Trimethoprim</i></b>			
Laboratórios Basi Indústria Farmacêutica S.A.	Marketing authorisation application	01/12/2025	1
<b>J01FA09 clarithromycin <i>Clarithromycin</i></b>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	14/11/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>J01FA10 azithromycin <i>Azithromycin dihydrate</i></b>			
Gufic Ireland Limited	Marketing authorisation application	31/12/2024	1
<b>J01FF01 clindamycin <i>Clindamycin phosphate</i></b>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	02/01/2023	1
<b>J01MA02 ciprofloxacin <i>Ciprofloxacin lactate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	08/04/2025	1
<b>J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	27/12/2024	1
<b>J01XA04 dalbavancin <i>Dalbavancin</i></b>			
Welding GmbH & Co. KG	Marketing authorisation application	25/06/2024	1
<b>J01XX05 methenamine <i>Methenamine hippurate</i></b>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	30/04/2025	1
<b>J01XX09 daptomycin <i>Daptomycin</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	14/05/2025	2
<b>J02AA01 amphotericin <i>Amphotericin b</i></b>			
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
<b>J02AC04 posaconazole <i>Posaconazole</i></b>			
PGF Pharma International d.o.o.	Marketing authorisation application	30/07/2025	1
<b>J02AX05 micafungin <i>Micafungin sodium</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	22/04/2025	2
Noridem Enterprises Limited	Marketing authorisation application	30/05/2025	2
<b>J02AX06 anidulafungin <i>Anidulafungin</i></b>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	27/12/2024	1
<b>J05AB06 ganciclovir <i>Ganciclovir sodium</i></b>			
Bioglan AB	Marketing authorisation application	02/10/2024	1
<b>J05AB14 valganciclovir <i>Valganciclovir hydrochloride</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	02/10/2024	1
<b>J05AF13 tenofovir alafenamide <i>Tenofovir alafenamide fumarate</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	29/12/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>J05AJ01 raltegravir <i>Raltegravir potassium</i></b>			
Amarox Pharma GmbH	Marketing authorisation application	13/11/2024	1
Viartis Limited	Marketing authorisation application	13/05/2025	1
<b>J05AJ03 dolutegravir <i>Dolutegravir sodium</i></b>			
Zentiva k.s.	Marketing authorisation application	22/10/2025	1
<b>J05AR03 tenofovir disoproxil and emtricitabine <i>Emtricitabine, Tenofovir disoproxil fumarate</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	18/06/2025	1
<b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide fumarate</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	16/12/2024	2
<b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide succinate</i></b>			
Lupin Europe GmbH	Marketing authorisation application	30/01/2025	2
<b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide</i></b>			
Medical Valley Invest AB	Marketing authorisation application	03/02/2025	2
<b>J05AR19 emtricitabine, tenofovir alafenamide and rilpivirine <i>Emtricitabine, Rilpivirine hydrochloride, Tenofovir alafenamide monofumarate</i></b>			
Accord Healthcare S.L.U.	Marketing authorisation application	02/06/2025	1
<b>L01AX03 temozolomide <i>Temozolomide</i></b>			
PGF Pharma International d.o.o.	Marketing authorisation application	28/03/2025	6
<b>L01BC02 fluorouracil <i>Fluorouracil</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	11/09/2025	1
<b>L01BC07 azacitidine <i>Azacitidine</i></b>			
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
<b>L01BC08 decitabine <i>Decitabine</i></b>			
EVER Valinject GmbH	Marketing authorisation application	25/09/2024	1
<b>L01CD01 paclitaxel <i>Paclitaxel</i></b>			
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
<b>L01CD02 docetaxel <i>Docetaxel trihydrate</i></b>			
Tillomed Malta Limited	Marketing authorisation application	02/02/2026	1
<b>L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i></b>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	30/06/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L01DC03 mitomycin <i>Mitomycin</i></b>			
Accord Healthcare S.L.U.	Marketing authorisation application	22/09/2025	1
<b>L01EA01 imatinib <i>Imatinib mesylate</i></b>			
Grindeks AS	Marketing authorisation application	30/04/2024	2
Sandoz B.V.	Marketing authorisation application	03/05/2024	2
<b>L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate, Nilotinib dihydrochloride dihydrate</i></b>			
Devatis GmbH	Marketing authorisation application	27/11/2024	1
<b>L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate</i></b>			
Devatis GmbH	Marketing authorisation application	27/11/2024	2
<b>L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i></b>			
Hetero Europe S.L.	Marketing authorisation application	26/02/2025	3
<b>L01EA03 nilotinib <i>Nilotinib hydrochloride monohydrate</i></b>			
Helm Pharmaceuticals GmbH	Marketing authorisation application	31/07/2024	2
<b>L01EA03 nilotinib <i>Nilotinib</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	31/01/2025	3
Vivanta Generics s.r.o.	Marketing authorisation application	31/07/2025	3
<b>L01EE01 trametinib <i>Trametinib dimethyl sulfoxide</i></b>			
Teva GmbH	Marketing authorisation application	11/12/2025	2
<b>L01EF01 palbociclib <i>Palbociclib</i></b>			
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
<b>L01EJ01 ruxolitinib <i>Ruxolitinib dihydrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	21/02/2025	5
<b>L01EJ01 ruxolitinib <i>Ruxolitinib hemifumarate</i></b>			
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
<b>L01EJ01 ruxolitinib <i>Ruxolitinib hydrochloride</i></b>			
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

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L01EX02 sorafenib Sorafenib tosilate</b>			
Devatis GmbH	Marketing authorisation application	31/07/2025	1
<b>L01EX07 cabozantinib Cabozantinib L-tartrate</b>			
Devatis GmbH	Marketing authorisation application	28/11/2025	3
<b>L01EX07 cabozantinib Cabozantinib fumarate</b>			
Adalvo Limited	Marketing authorisation application	02/02/2026	3
<b>L01EX08 lenvatinib Lenvatinib besilate</b>			
Viatrix Limited	Marketing authorisation application	07/01/2026	2
Mylan Pharmaceuticals Limited	Marketing authorisation application	10/02/2026	2
<b>L01EX08 lenvatinib Lenvatinib mesylate</b>			
STADA Arzneimittel AG	Marketing authorisation application	22/11/2024	2
STADA Arzneimittel AG	Marketing authorisation application	22/11/2024	6
<b>L01EX08 lenvatinib Lenvatinib</b>			
PGF Pharma International d.o.o.	Marketing authorisation application	30/10/2025	2
<b>L01EX09 nintedanib Nintedanib esylate</b>			
ratiopharm GmbH	Marketing authorisation application	26/09/2024	2
PGF Pharma International d.o.o.	Marketing authorisation application	02/06/2025	2
Laboratorios Cinfa S.A.	Marketing authorisation application	09/09/2025	2
<b>L01XA01 cisplatin Cisplatin</b>			
Amarox Pharma B.V.	Marketing authorisation application	30/05/2025	1
<b>L01XA02 carboplatin Carboplatin</b>			
Amarox Pharma GmbH	Marketing authorisation application	31/10/2025	1
<b>L01XA03 oxaliplatin Oxaliplatin</b>			
Amarox Pharma B.V.	Marketing authorisation application	29/07/2025	1
Tillomed Malta Limited	Marketing authorisation application	17/10/2025	1
<b>L01XG01 bortezomib Bortezomib</b>			
Sun Pharmaceuticals Germany GmbH	Marketing authorisation application	02/02/2026	1
<b>L01XG02 carfilzomib Carfilzomib</b>			
Reddy Holding GmbH	Marketing authorisation application	01/12/2025	3
Amarox Pharma B.V.	Marketing authorisation application	08/01/2026	3
<b>L01XK01 olaparib Olaparib</b>			
Sandoz B.V.	Marketing authorisation application	22/12/2025	2
Vivanta Generics s.r.o.	Marketing authorisation application	02/02/2026	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L01XX Other antineoplastic agents <i>Carfilzomib</i></b>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	30/01/2026	1
<b>L01XX41 eribulin <i>Eribulin mesylate</i></b>			
Tillomed Malta Limited	Marketing authorisation application	02/10/2023	1
Accord Healthcare B.V.	Marketing authorisation application	04/01/2024	1
<b>L02BA03 fulvestrant <i>Fulvestrant</i></b>			
Orion Corporation	Marketing authorisation application	03/11/2023	1
<b>L02BB04 enzalutamide <i>Enzalutamide</i></b>			
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
<b>L02BG04 letrozole <i>Letrozole</i></b>			
Tarbis Farma S.L.	Marketing authorisation application	02/12/2024	1
<b>L02BX03 abiraterone <i>Abiraterone acetate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	03/11/2025	1
<b>L04AA06 mycophenolic acid <i>Mycophenolate mofetil</i></b>			
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
<b>L04AA18 everolimus <i>Everolimus</i></b>			
Ascend GmbH	Marketing authorisation application	02/02/2026	4
<b>L04AA31 teriflunomide <i>Teriflunomide</i></b>			
Heaton k.s.	Marketing authorisation application	20/12/2023	1
<b>L04AA32 apremilast <i>Apremilast</i></b>			
Bioglan AB	Marketing authorisation application	31/10/2024	2
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

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L04AA40 cladribine <i>Cladribine</i></b>			
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
<b>L04AD02 tacrolimus <i>Tacrolimus monohydrate</i></b>			
Orifarm Healthcare A/S	Marketing authorisation application	29/11/2023	4
Ascend GmbH	Marketing authorisation application	11/02/2026	3
<b>L04AF01 tofacitinib <i>Tofacitinib citrate</i></b>			
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
<b>L04AK02 teriflunomide <i>Teriflunomide</i></b>			
STADA Nordic ApS	Marketing authorisation application	13/12/2024	2
<b>L04AX03 methotrexate <i>Methotrexate</i></b>			
Gebro Pharma GmbH	Marketing authorisation application	24/03/2026	1
<b>L04AX05 pirfenidone <i>Pirfenidone</i></b>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	03/03/2025	2
<b>L04AX06 pomalidomide <i>Pomalidomide</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	03/10/2024	4
<b>L04AX07 dimethyl fumarate <i>Dimethyl fumarate</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	22/10/2024	2
<b>M01AE01 ibuprofen <i>Ibuprofen</i></b>			
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

Applicant	Nature of the application	Application receipt date	Number of applications
<b>M01AE51 ibuprofen, combinations <i>Ibuprofen, Caffeine</i></b>			
Teva B.V.	Marketing authorisation application	09/12/2024	1
Alfred E. Tiefenbacher (GmbH & Co. KG)	Marketing authorisation application	21/02/2025	1
<b>M01AE52 naproxen and esomeprazole <i>Naproxen, Esomeprazole magnesium trihydrate</i></b>			
Orion Corporation	Marketing authorisation application	29/04/2025	1
<b>M01AH04 parecoxib <i>Parecoxib sodium</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	01/07/2025	1
<b>M01AX25 chondroitin sulfate <i>Chondroitin sulfate sodium</i></b>			
IBSA Farmaceutici Italia S.r.l	Marketing authorisation application	07/02/2025	1
Schmid Pharma B.V.	Marketing authorisation application	28/02/2025	1
<b>M02AA07 piroxicam <i>Piroxicam</i></b>			
Haleon Denmark ApS	Marketing authorisation application	28/03/2025	1
<b>M02AA13 ibuprofen <i>Ibuprofen lysine</i></b>			
Laboratorio Italiano Biochimico Farmaceutico Lisapharma S.p.A.	Marketing authorisation application	27/02/2026	1
<b>M02AA15 diclofenac <i>Diclofenac diethylamine</i></b>			
Fysioline Oy	Marketing authorisation application	18/07/2025	1
<b>M02AA15 diclofenac <i>Diclofenac sodium</i></b>			
Haleon Denmark ApS	Marketing authorisation application	03/06/2025	1
<b>M03AC09 rocuronium bromide <i>Rocuronium bromide</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	07/06/2024	1
Amarox Pharma B.V.	Marketing authorisation application	02/06/2025	1
<b>M03AC11 cisatracurium <i>Cisatracurium besilate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	24/02/2025	1
<b>M03BX01 baclofen <i>Baclofen</i></b>			
2Care4 Generics ApS	Marketing authorisation application	31/01/2025	1
2Care4 Generics ApS	Marketing authorisation application	31/10/2025	1
<b>M04AC01 colchicine <i>Colchicine</i></b>			
Abacus Medicine A/S	Parallel import	10/02/2026	1
Orifarm Oy	Parallel import	27/02/2026	1
<b>M05BB04 risedronic acid, calcium and colecalciferol, sequential <i>Calcium carbonate, Cholecalciferol concentrate (powder form), Risedronate sodium</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	27/12/2024	1
<b>N01AH06 remifentanil <i>Remifentanil hydrochloride</i></b>			
Kalceks AS	Marketing authorisation application	30/04/2025	3
Noridem Enterprises Limited	Marketing authorisation application	01/07/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N01AX10 propofol <i>Propofol</i></b>			
Troikaa Pharmaceuticals Europe s.r.o.	Marketing authorisation application	02/03/2026	2
<b>N01BB02 lidocaine <i>Lidocaine</i></b>			
Orion Corporation	Marketing authorisation application	31/01/2025	1
Cresia Consulting S.L.	Marketing authorisation application	26/03/2026	1
<b>N01BB09 ropivacaine <i>Ropivacaine hydrochloride monohydrate</i></b>			
Hikma Farmacéutica (Portugal) S.A.	Marketing authorisation application	12/12/2024	4
Noridem Enterprises Limited	Marketing authorisation application	20/01/2025	5
<b>N01BB51 bupivacaine, combinations <i>Bupivacaine hydrochloride monohydrate, Adrenaline tartrate</i></b>			
Macure Pharma ApS	Marketing authorisation application	11/04/2025	2
<b>N01BB58 articaine, combinations <i>Articaine hydrochloride, Adrenaline</i></b>			
Laboratorios Normon S.A.	Marketing authorisation application	25/03/2025	2
<b>N02BE01 paracetamol <i>Paracetamol</i></b>			
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
<b>N02BE51 paracetamol, combinations excl. psycholeptics <i>Ibuprofen, Paracetamol</i></b>			
Vale Pharmaceuticals Limited	Marketing authorisation application	09/10/2023	1
Fysioline Oy	Marketing authorisation application	10/04/2025	1
<b>N02BE51 paracetamol, combinations excl. psycholeptics <i>Paracetamol, Caffeine</i></b>			
Haleon Denmark ApS	Marketing authorisation application	17/12/2024	1
<b>N02BF01 gabapentin <i>Gabapentin</i></b>			
Amarox Pharma B.V.	Marketing authorisation application	19/12/2025	2
<b>N02BF02 pregabalin <i>Pregabalin</i></b>			
Grindeks AS	Marketing authorisation application	01/08/2024	6
<b>N02CC01 sumatriptan <i>Sumatriptan</i></b>			
Medical Valley Invest AB	Marketing authorisation application	09/12/2024	2
<b>N02CC03 zolmitriptan <i>Zolmitriptan</i></b>			
Medical Valley Invest AB	Marketing authorisation application	26/02/2026	2
<b>N02CX02 clonidine <i>Clonidine hydrochloride</i></b>			
Macure Pharma ApS	Marketing authorisation application	28/08/2024	1
<b>N03AA03 primidone <i>Primidone</i></b>			
2Care4 Generics ApS	Marketing authorisation application	01/10/2024	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N03AB02 phenytoin <i>Phenytoin sodium</i></b>			
Hikma Farmacéutica (Portugal) S.A.	Marketing authorisation application	03/03/2025	1
<b>N03AD01 ethosuximide <i>Ethosuximide</i></b>			
Neuraxpharm Arzneimittel GmbH	Marketing authorisation application	23/05/2025	1
<b>N03AF02 oxcarbazepine <i>Oxcarbazepine</i></b>			
Amarox Pharma GmbH	Marketing authorisation application	11/03/2025	3
<b>N03AG01 valproic acid <i>Sodium valproate</i></b>			
Desitin Arzneimittel GmbH	Marketing authorisation application	30/04/2025	4
Macure Pharma ApS	Marketing authorisation application	27/11/2025	1
<b>N03AX09 lamotrigine <i>Lamotrigine</i></b>			
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	08/01/2024	2
<b>N03AX14 levetiracetam <i>Levetiracetam</i></b>			
Grindeks AS	Marketing authorisation application	01/08/2025	4
<b>N03AX18 lacosamide <i>Lacosamide</i></b>			
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
<b>N03AX22 perampanel <i>Perampanel hydrate (4:3)</i></b>			
Orion Corporation	Marketing authorisation application	31/05/2024	6
<b>N03AX23 brivaracetam <i>Brivaracetam</i></b>			
Desitin Arzneimittel GmbH	Marketing authorisation application	31/07/2024	1
Desitin Arzneimittel GmbH	Marketing authorisation application	11/02/2026	1
<b>N04BA02 levodopa and decarboxylase inhibitor <i>Carbidopa, Levodopa</i></b>			
2Care4 Generics ApS	Marketing authorisation application	31/10/2025	2
<b>N04BB01 amantadine <i>Amantadine hydrochloride</i></b>			
Macure Pharma ApS	Marketing authorisation application	28/11/2024	1
<b>N04BC09 rotigotine <i>Rotigotine</i></b>			
Orion Corporation	Marketing authorisation application	30/09/2024	6
<b>N05AE05 lurasidone <i>Lurasidone hydrochloride</i></b>			
Amarox Pharma GmbH	Marketing authorisation application	18/11/2024	3
<b>N05AH02 clozapine <i>Clozapine</i></b>			
Grindeks AS	Marketing authorisation application	27/09/2023	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N05AH03 olanzapine <i>Olanzapine</i></b>			
Devatis GmbH	Marketing authorisation application	30/07/2025	6
Orifarm Oy	Parallel import	25/03/2026	1
<b>N05AH04 quetiapine <i>Quetiapine fumarate</i></b>			
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
<b>N05AL05 amisulpride <i>Amisulpride</i></b>			
Ailon Pharma Oy	Marketing authorisation application	20/10/2025	3
<b>N05AX Other antipsychotics <i>Sodium valproate</i></b>			
Desitin Arzneimittel GmbH	Marketing authorisation application	30/04/2025	4
<b>N05AX08 risperidone <i>Risperidone</i></b>			
Orion Corporation	Marketing authorisation application	31/10/2025	3
<b>N05AX12 aripiprazole <i>Aripiprazole</i></b>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	22/04/2024	4
<b>N05AX13 paliperidone <i>Paliperidone palmitate</i></b>			
Viatriis Limited	Marketing authorisation application	25/10/2024	8
Advanz Pharma Limited	Marketing authorisation application	03/03/2025	4
<b>N05AX15 cariprazine <i>Cariprazine hydrochloride</i></b>			
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
<b>N05BA01 diazepam <i>Diazepam</i></b>			
Macure Pharma ApS	Marketing authorisation application	01/11/2024	1
<b>N05CD08 midazolam <i>Midazolam maleate</i></b>			
SERB S.A.	Marketing authorisation application	27/02/2025	1
<b>N05CD08 midazolam <i>Midazolam</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	18/12/2025	2
<b>N05CF02 zolpidem <i>Zolpidem Tartrate</i></b>			
Unimedica Pharma AB	Marketing authorisation application	20/10/2025	2
<b>N05CH01 melatonin <i>Melatonin</i></b>			
Vitalbans Oy	Marketing authorisation application	26/09/2025	3
Owlpharma Consulting LDA	Marketing authorisation application	31/10/2025	1
ACE Pharmaceuticals BV	Marketing authorisation application	13/11/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N05CM18 dexmedetomidine</b> <i>Dexmedetomidine hydrochloride</i>			
Noridem Enterprises Limited	Marketing authorisation application	21/10/2024	1
<b>N06AA09 amitriptyline</b> <i>Amitriptyline hydrochloride</i>			
Neuraxpharm Sweden AB	Marketing authorisation application	03/04/2024	1
<b>N06AB06 sertraline</b> <i>Sertraline hydrochloride</i>			
RIA Generics Limited	Marketing authorisation application	22/05/2023	2
<b>N06AX11 mirtazapine</b> <i>Mirtazapine</i>			
Devatis GmbH	Marketing authorisation application	08/04/2025	3
<b>N06AX12 bupropion</b> <i>Bupropion hydrochloride</i>			
Amarox Pharma B.V.	Marketing authorisation application	30/01/2025	2
<b>N06AX26 vortioxetine</b> <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
<b>N06AX26 vortioxetine</b> <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
<b>N06BA02 dexamfetamine</b> <i>Dexamphetamine sulphate</i>			
2Care4 Generics ApS	Marketing authorisation application	03/03/2025	3
<b>N06BA04 methylphenidate</b> <i>Methylphenidate hydrochloride</i>			
Viartis Limited	Marketing authorisation application	01/12/2025	4
<b>N06BA09 atomoxetine</b> <i>Atomoxetine hydrochloride</i>			
Amarox Pharma GmbH	Marketing authorisation application	30/04/2025	7
2Care4 Generics ApS	Marketing authorisation application	31/07/2025	1
<b>N06BA12 lisdexamfetamine</b> <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
<b>N06DA03 rivastigmine</b> <i>Rivastigmine</i>			
Sandoz A/S	Marketing authorisation application	01/07/2024	3
Strides Nordic ApS	Marketing authorisation application	02/09/2024	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N07BB01 disulfiram</b> <i>Disulfiram</i>			
Macure Pharma ApS	Marketing authorisation application	25/03/2025	1
<b>N07XX08 tafamidis</b> <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
<b>P02CF01 ivermectin</b> <i>Ivermectin</i>			
Zentiva k.s.	Marketing authorisation application	30/10/2025	1
Devatis GmbH	Marketing authorisation application	25/02/2026	1
<b>QA02BC01 omeprazole</b> <i>Omeprazole</i>			
Boehringer Ingelheim Vetmedica GmbH	Marketing authorisation application	20/10/2025	1
<b>QA04AD90 Maropitant</b> <i>Maropitant citrate monohydrate</i>			
Alfasan Nederland B.V.	Marketing authorisation application	10/11/2025	1
<b>QA06AD11 lactulose</b> <i>Lactulose</i>			
Alfasan Nederland B.V.	Marketing authorisation application	03/02/2025	1
<b>QC01CE90 pimobendane</b> <i>Pimobendan</i>			
VetViva Richter GmbH	Marketing authorisation application	04/11/2025	4
<b>QC03CA01 furosemide</b> <i>Furosemide</i>			
Alfasan Nederland B.V.	Marketing authorisation application	22/09/2025	1
<b>QD08AG03 iodine</b> <i>Iodine</i>			
Delaval	Marketing authorisation application	11/12/2024	2
<b>QG52X VARIOUS PRODUCTS FOR THE CARE OF TEATS AND UDDER</b> <i>Hydrocortisone aceponate</i>			
Virbac	Marketing authorisation application	26/11/2024	1
<b>QH02AB02 dexamethasone</b> <i>Dexamethasone sodium phosphate</i>			
Alfasan Nederland B.V.	Marketing authorisation application	20/07/2020	1
<b>QH02AB06 prednisolone</b> <i>Prednisolone</i>			
Axience	Marketing authorisation application	02/04/2025	1
<b>QH02CA01 trilostane</b> <i>Trilostane</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	24/10/2025	5
<b>QH03BB02 thiamazole</b> <i>Thiamazole</i>			
Virbac	Marketing authorisation application	28/08/2024	1
<b>QI02AE05 mycoplasma</b> <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
<b>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></b>			
Bioveta a.s.	Marketing authorisation application	15/11/2024	1
<b>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></b>			
Bioveta a.s.	Marketing authorisation application	15/11/2024	1
<b>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></b>			
Bioveta a.s.	Marketing authorisation application	20/03/2026	1
<b>QJ01CR02 amoxicillin and enzyme inhibitor <i>Amoxicillin trihydrate, Potassium clavulanate</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	14/03/2023	3
<b>QJ01EW10 sulfadiazine and trimethoprim, incl. derivatives <i>Trimethoprim, Sulfadiazine</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	28/05/2025	2
<b>QM01AC06 meloxicam <i>Meloxicam</i></b>			
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
<b>QM01AE03 ketoprofen <i>Ketoprofen</i></b>			
VetViva Richter GmbH	Marketing authorisation application	20/03/2025	1
<b>QM01AE91 carprofen <i>Carprofen</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	07/12/2022	2
<b>QM01AH91 robenacoxib <i>Robenacoxib</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	25/04/2025	1
KRKA d.d. Novo mesto	Marketing authorisation application	28/04/2025	1
<b>QM01AX90 pentosan polysulphate <i>Pentosan polysulfate sodium</i></b>			
Forte Healthcare Licencing Limited	Marketing authorisation application	05/03/2025	1
<b>QN01AX95 levomenthol <i>Levomenthol</i></b>			
Scanvacc AS	Marketing authorisation application	30/01/2026	1
<b>QN01AX99 other general anesthetics, combinations <i>Tiletamine hydrochloride, Zolazepam hydrochloride</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	18/06/2025	1
<b>QN01BA52 procaine, combinations <i>Procaine hydrochloride, Adrenaline tartrate</i></b>			
Forte Healthcare Licencing Limited	Marketing authorisation application	04/02/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>QN02AC52 methadone, combinations excl. psycholeptics</b> <i>Levomethadone hydrochloride, Fenpipramide hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	28/02/2022	2
<b>QN02AE01 buprenorphine</b> <i>Buprenorphine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	14/02/2025	1
<b>QN02AF01 butorphanol</b> <i>Butorphanol Tartrate</i>			
Alfasan Nederland B.V.	Marketing authorisation application	08/04/2025	1
<b>QN02AX02 tramadol</b> <i>Tramadol hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	05/12/2022	6
<b>QN03AA02 phenobarbital</b> <i>Phenobarbital</i>			
Alfasan Nederland B.V.	Marketing authorisation application	13/09/2023	3
<b>QN04BC02 Pergolide</b> <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
<b>QN05AA04 acepromazine</b> <i>Acepromazine maleate</i>			
Floris Holding B.V.	Marketing authorisation application	21/01/2026	1
<b>QN05CD08 midazolam</b> <i>Midazolam</i>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	04/11/2025	1
<b>QN05CM18 Dexmedetomidine</b> <i>Dexmedetomidine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	15/09/2022	1
<b>QN05CM90 detomidine</b> <i>Detomidine hydrochloride for veterinary use</i>			
Alfasan Nederland B.V.	Marketing authorisation application	14/04/2022	1
<b>QN05CM91 medetomidine</b> <i>Medetomidine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	15/09/2022	1
<b>QN05CM92 xylazine</b> <i>Xylazine hydrochloride</i>			
Forte Healthcare Licencing Limited	Marketing authorisation application	01/04/2025	1
<b>QN51AA01 pentobarbital</b> <i>Pentobarbital sodium</i>			
Wirtschaftsgenossenschaft deutscher Tieraerzte eG	Marketing authorisation application	21/08/2025	1
<b>QP52AA51 praziquantel, combinations</b> <i>Praziquantel, Pyrantel embonate, Febantel</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	08/06/2023	2
<b>QP53AC55 flumethrin, combinations</b> <i>Flumethrin, Imidacloprid, Titanium dioxide</i>			
Beaphar B.V.	Marketing authorisation application	16/09/2024	1
<b>QP53AC55 flumethrin, combinations</b> <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
<b>QP53AC55 flumethrin, combinations <i>Imidacloprid, Flumethrin</i></b>			
Virbac	Marketing authorisation application	03/07/2024	3
<b>QP54AA51 ivermectin, combinations <i>Ivermectin, Praziquantel</i></b>			
Bioveta a.s.	Marketing authorisation application	10/01/2025	1
<b>QP54AB51 milbemycin oxime, combinations <i>Milbemycin oxime, Praziquantel</i></b>			
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
<b>QS01AA01 chloramphenicol <i>Chloramphenicol</i></b>			
Domes Pharma	Marketing authorisation application	24/06/2025	1
<b>QS01CA01 dexamethasone and antiinfectives <i>Framycetin sulfate, Dexamethasone sodium phosphate</i></b>			
Domes Pharma	Marketing authorisation application	06/02/2026	1
<b>R01AA07 xylometazoline <i>Xylometazoline hydrochloride</i></b>			
Vianex S.A.	Marketing authorisation application	01/11/2024	2
<b>R01AD09 mometasone <i>Mometasone furoate</i></b>			
Orion Corporation	Marketing authorisation application	17/11/2025	1
<b>R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Fluticasone propionate</i></b>			
Adalvo Limited	Marketing authorisation application	02/06/2025	2
Adalvo Limited	Marketing authorisation application	16/01/2026	3
<b>R02AA03 dichlorobenzyl alcohol <i>Amylmetacresol, 2,4-Dichlorobenzylalcohol</i></b>			
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
<b>R02AA06 cetylpyridinium <i>Cetylpyridinium chloride, Lidocaine hydrochloride monohydrate</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	22/04/2025	1
<b>R02AX01 flurbiprofen <i>Flurbiprofen</i></b>			
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
<b>R03AC02 salbutamol <i>Salbutamol sulfate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	20/02/2025	3
<b>R03AK06 salmeterol and fluticasone <i>Salmeterol, Fluticasone</i></b>			
PGF Pharma International d.o.o.	Marketing authorisation application	17/07/2025	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>R03AK08 formoterol and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate</i></b>			
Devatis GmbH	Marketing authorisation application	30/10/2025	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	19/02/2026	2
<b>R03AL02 salbutamol and ipratropium bromide <i>Ipratropium bromide, Salbutamol sulfate</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	30/09/2025	1
<b>R03AL04 indacaterol and glycopyrronium bromide <i>Indacaterol maleate, Glycopyrronium bromide</i></b>			
Genetic S.p.A.	Marketing authorisation application	24/07/2024	1
<b>R03AL09 formoterol, glycopyrronium bromide and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate, Glycopyrronium bromide</i></b>			
Elpen Pharmaceutical Co. Inc.	Marketing authorisation application	29/12/2025	2
<b>R03BB01 ipratropium bromide <i>Ipratropium bromide</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	21/11/2025	2
<b>R06AA04 clemastine <i>Clemastine fumarate</i></b>			
Macure Healthcare Limited	Marketing authorisation application	17/01/2025	1
<b>R06AE03 cyclizine <i>Cyclizine lactate</i></b>			
2Care4 Generics ApS	Marketing authorisation application	28/02/2025	1
<b>R06AX26 fexofenadine <i>Fexofenadine hydrochloride</i></b>			
Haleon Denmark ApS	Marketing authorisation application	17/12/2024	1
<b>R06AX27 desloratadine <i>Desloratadine</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	31/08/2023	1
ratiopharm GmbH	Marketing authorisation application	20/08/2025	1
<b>R06AX29 bilastine <i>Bilastine monohydrate</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	30/08/2024	1
<b>R07AX02 ivacaftor <i>Ivacaftor</i></b>			
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
<b>S01BA01 dexamethasone <i>Dexamethasone sodium phosphate</i></b>			
Pharmathen S.A.	Marketing authorisation application	20/05/2025	1
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
<b>S01BC04 flurbiprofen <i>Flurbiprofen sodium dihydrate</i></b>			
Horus Pharma	Marketing authorisation application	28/08/2025	1
<b>S01BC11 bromfenac <i>Bromfenac sodium sesquihydrate</i></b>			
Blumont Ofta Trading Limited	Marketing authorisation application	02/09/2024	1
Laboratorios Salvat S.A.	Marketing authorisation application	17/09/2024	1
<b>S01EA05 brimonidine <i>Brimonidine tartrate</i></b>			
Blumont Ofta Trading Limited	Marketing authorisation application	19/02/2026	1
<b>S01EC54 brinzolamide, combinations <i>Brinzolamide, Brimonidine tartrate</i></b>			
Pharmaselect International Beteiligungs GmbH	Marketing authorisation application	01/04/2025	1
<b>S01ED51 timolol, combinations <i>Dorzolamide hydrochloride, Timolol maleate</i></b>			
Genetic S.p.A.	Marketing authorisation application	26/04/2024	1
<b>S01ED51 timolol, combinations <i>Latanoprost, Timolol</i></b>			
Creative Pharma Solutions s.r.o.	Marketing authorisation application	30/06/2025	1
Sandoz A/S	Marketing authorisation application	01/07/2025	1
<b>S01EE01 latanoprost <i>Latanoprost</i></b>			
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
<b>S01EE03 bimatoprost <i>Bimatoprost</i></b>			
GHN Pharma Nordic AB	Marketing authorisation application	24/02/2025	1
<b>S01XA12 dexpanthenol <i>Dexpanthenol</i></b>			
Dr. Gerhard Mann Chem.-Pharm. fabrik GmbH	Marketing authorisation application	25/06/2024	1
<b>V01AA02 grass pollen <i>Timothy</i></b>			
ALK-Abello A/S	Marketing authorisation application	06/10/2025	1
<b>V03AB34 fomepizole <i>Fomepizole</i></b>			
Waymade B.V.	Marketing authorisation application	19/09/2025	1
<b>V04CX01 indocyanine green <i>Indocyanine green</i></b>			
Provepharm	Marketing authorisation application	07/10/2024	1
<b>V07AB Solvents and diluting agents, incl. irrigating solutions <i>Water for injection</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	29/11/2024	1
<b>V09GX Other cardiovascular system diagnostic radiopharmaceuticals <i>Strontium (82Sr) dichloride, Rubidium (82 Rb)</i></b>			
Jubilant Pharmaceuticals nv	Marketing authorisation application	08/12/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
V09IX14 gallium (68Ga) gozetotide <i>Gozetotide</i>			
Billev Pharma ApS	Marketing authorisation application	10/10/2025	1