

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
A02AH Antacids with sodium bicarbonate <i>Sodium hydrogen carbonate</i>			
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	28/02/2024	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
A02BC05 esomeprazole <i>Esomeprazole sodium</i>			
Demo S.A.	Marketing authorisation application	15/07/2024	1
A03BA01 atropine <i>Atropine sulfate</i>			
Dextreg	Marketing authorisation application	26/05/2025	2
A04AA01 ondansetron <i>Ondansetron hydrochloride dihydrate</i>			
Noridem Enterprises Limited	Marketing authorisation application	27/09/2024	1
Laboratoire Aguettant	Marketing authorisation application	30/04/2025	1
A04AA01 ondansetron <i>Ondansetron</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	16/02/2023	2
A04AA02 granisetron <i>Granisetron hydrochloride</i>			
STADA Arzneimittel AG	Marketing authorisation application	29/05/2024	4
A06AG11 laurilsulfate, incl. combinations <i>Trisodium citrate dihydrate, Sodium lauryl sulfoacetate, Sorbitol, liquid (crystallising)</i>			
Laboratorios Liconsa S.A.	Marketing authorisation application	22/01/2024	1
A07AA09 vancomycin <i>Vancomycin hydrochloride</i>			
Xeolas Pharmaceuticals Limited	Marketing authorisation application	21/03/2025	2
A07AA12 fidaxomicin <i>Fidaxomicin</i>			
Adalvo Limited	Marketing authorisation application	07/07/2025	1
A07EA06 budesonide <i>Budesonide</i>			
Orion Corporation	Marketing authorisation application	11/04/2025	1
A07EC02 mesalazine <i>Mesalazine</i>			
Faes Farma S.A.	Marketing authorisation application	25/04/2025	1
A07FA02 saccharomyces boulardii <i>Saccharomyces boulardii</i>			
Paranova Oy	Parallel import	12/10/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
A09AA02 multienzymes (lipase, protease etc.) <i>Pancreas powder (porcine)</i>			
ADOH B.V.	Marketing authorisation application	11/06/2025	3
A09AA02 multienzymes (lipase, protease etc.) <i>Pancreas powder</i>			
AVVA Pharmaceuticals Ltd.	Marketing authorisation application	14/07/2020	2
A10BA02 metformin <i>Metformin hydrochloride</i>			
Activase Pharmaceuticals Ltd.	Marketing authorisation application	29/02/2024	3
A10BD07 metformin and sitagliptin <i>Sitagliptin hydrochloride, Metformin hydrochloride</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	22/06/2022	2
A10BD08 metformin and vildagliptin <i>Vildagliptin, Metformin hydrochloride</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	02/08/2021	2
A10BD11 metformin and linagliptin <i>Linagliptin, Metformin hydrochloride</i>			
KRKA d.d. Novo mesto	Marketing authorisation application	23/12/2024	2
A10BD15 metformin and dapagliflozin <i>Dapagliflozin propanediol monohydrate, Metformin hydrochloride</i>			
KRKA d.d. Novo mesto	Marketing authorisation application	29/04/2024	2
A10BD15 metformin and dapagliflozin <i>Dapagliflozin, Metformin hydrochloride</i>			
Adalvo Limited	Marketing authorisation application	29/08/2025	2
A10BD20 metformin and empagliflozin <i>Empagliflozin, Metformin hydrochloride</i>			
KRKA d.d. Novo mesto	Marketing authorisation application	03/02/2025	4
A10BH01 sitagliptin <i>Sitagliptin hydrochloride</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/09/2021	3
AshCure Pharma B.V.	Marketing authorisation application	20/05/2025	3
A10BH01 sitagliptin <i>Sitagliptin phosphate monohydrate</i>			
Morningside Healthcare (Malta) Limited	Marketing authorisation application	22/11/2023	3
Devatis GmbH	Marketing authorisation application	30/08/2024	3
Pharmaceutical Innovation Services S.L.	Marketing authorisation application	01/08/2025	3
A10BH05 linagliptin <i>Linagliptin</i>			
Galenicum Health S.L.U	Marketing authorisation application	21/10/2022	1
Orion Corporation	Marketing authorisation application	01/09/2023	1
Accord Healthcare B.V.	Marketing authorisation application	02/04/2024	1
Teva B.V.	Marketing authorisation application	20/12/2024	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

Applicant	Nature of the application	Application receipt date	Number of applications
A10BJ02 liraglutide <i>Liraglutide</i>			
Adalvo Limited	Marketing authorisation application	31/01/2023	1
Cipla Europe NV	Marketing authorisation application	09/03/2023	1
Medical Valley Invest AB	Marketing authorisation application	30/12/2024	1
A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i>			
STADA Arzneimittel AG	Marketing authorisation application	01/03/2024	2
Orion Corporation	Marketing authorisation application	25/04/2024	2
G.L. Pharma GmbH	Marketing authorisation application	18/08/2025	2
Zentiva k.s.	Marketing authorisation application	18/08/2025	2
A10BK01 dapagliflozin <i>Dapagliflozin</i>			
Sandoz A/S	Marketing authorisation application	24/06/2024	2
Genepharm 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
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
A11CC03 alfacalcidol <i>Alfacalcidol</i>			
Strides Nordic ApS	Marketing authorisation application	02/12/2024	3
A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i>			
Fresenius Kabi AB	Marketing authorisation application	19/10/2023	1
Pemberton Laboratories Limited	Marketing authorisation application	21/11/2024	1
A16AX06 miglustat <i>Miglustat</i>			
Waymade B.V.	Marketing authorisation application	29/07/2024	1
Orifarm Oy	Parallel import	24/04/2025	1
A16AX08 teduglutide <i>Teduglutide</i>			
Adalvo Limited	Marketing authorisation application	05/09/2024	1
B01AB02 antithrombin <i>Antithrombine III humane</i>			
Octapharma AB	Marketing authorisation application	21/08/2025	1
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

Applicant	Nature of the application	Application receipt date	Number of applications
B01AC16 eptifibatide <i>Eptifibatide</i>			
Ctruz ApS	Marketing authorisation application	25/03/2025	2
B01AC24 ticagrelor <i>Ticagrelor</i>			
Devatis GmbH	Marketing authorisation application	09/07/2024	2
B01AC25 cangrelor <i>Cangrelor Tetrasodium</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/07/2025	1
B01AD02 alteplase <i>Alteplase</i>			
2care4 ApS	Parallel import	18/06/2025	1
B01AE07 dabigatran etexilate <i>Dabigatran etexilate mesilate</i>			
Gedeon Richter Plc	Marketing authorisation application	02/05/2024	2
B01AF01 rivaroxaban <i>Rivaroxaban</i>			
Tillomed Pharma GmbH	Marketing authorisation application	30/01/2023	5
Indoco Remedies Czech s.r.o.	Marketing authorisation application	03/08/2023	5
ratiopharm GmbH	Marketing authorisation application	12/08/2024	5
Amarox Pharma B.V.	Marketing authorisation application	31/01/2025	4
B01AF02 apixaban <i>Apixaban</i>			
Indoco Remedies Czech s.r.o.	Marketing authorisation application	15/08/2022	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	20/12/2024	2
PGF Pharma International d.o.o.	Marketing authorisation application	25/06/2025	2
B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i>			
Synthon B.V.	Marketing authorisation application	21/03/2024	3
Glenmark Arzneimittel GmbH	Marketing authorisation application	03/02/2025	3
Kappler Pharma Consult GmbH	Marketing authorisation application	02/05/2025	3
B02AA02 tranexamic acid <i>Tranexamic acid</i>			
Tillomed Pharma GmbH	Marketing authorisation application	14/02/2023	1
B02BB01 fibrinogen, human <i>Human fibrinogen</i>			
CSL Behring GmbH	Marketing authorisation application	12/12/2024	1
Octapharma GmbH	Marketing authorisation application	20/05/2025	1
B02BD06 von Willebrand factor and coagulation factor VIII in combination <i>Factor VIII (antihaemophilic factor), Human von Willebrand factor</i>			
Abacus Medicine A/S	Parallel import	28/10/2024	1
B02BX05 eltrombopag <i>Eltrombopag olamine</i>			
Coripharma ehf.	Marketing authorisation application	20/12/2024	3

Applicant	Nature of the application	Application receipt date	Number of applications
B03AB05 ferric oxide polymaltose complexes <i>Iron(III)-hydroxide polymaltose complex</i>			
Paranova Oy	Parallel import	27/08/2024	2
Orifarm Oy	Parallel import	11/09/2024	1
B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i>			
Orion Corporation	Marketing authorisation application	06/05/2024	1
Seacross Pharma (Europe) Limited	Marketing authorisation application	31/07/2024	1
Medical Valley Invest AB	Marketing authorisation application	27/12/2024	1
Devatis GmbH	Marketing authorisation application	11/08/2025	1
B03BA01 cyanocobalamin <i>Cyanocobalamin</i>			
Orion Corporation	Marketing authorisation application	25/10/2024	1
B05BA01 amino acids <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine</i>			
Noridem Enterprises Limited	Marketing authorisation application	31/07/2024	3
B05BA02 fat emulsions <i>Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids</i>			
Noridem Enterprises Limited	Marketing authorisation application	06/02/2024	1
B05BA03 carbohydrates <i>Glucose monohydrate</i>			
Noridem Enterprises Limited	Marketing authorisation application	30/08/2024	1
B05BA10 combinations <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Glucose monohydrate, Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids, Methionine, Phenylalanine, Proline, Aspartic acid, Cysteine, Glutamic acid, Lysine monohydrate</i>			
Fresenius Kabi AB	Marketing authorisation application	16/11/2023	1
B05BA10 combinations <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Sodium glycerophosphate hydrate, Magnesium sulfate heptahydrate, Glucose monohydrate, Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids, Methionine, Phenylalanine, Potassium chloride, Proline, Aspartic acid, Calcium gluconate monohydrate, Cysteine, Glutamic acid, Lysine monohydrate, Sodium acetate trihydrate</i>			
Fresenius Kabi AB	Marketing authorisation application	16/11/2023	1
B05BA10 combinations <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Sodium glycerophosphate hydrate, Magnesium sulfate heptahydrate, Glucose monohydrate, Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids, Methionine, Phenylalanine, Potassium chloride, Proline, Aspartic acid, Calcium gluconate monohydrate, Cysteine, Glutamic acid, Lysine monohydrate</i>			
Fresenius Kabi AB	Marketing authorisation application	16/11/2023	1
B05BB01 electrolytes <i>Potassium chloride, Sodium chloride</i>			
Noridem Enterprises Limited	Marketing authorisation application	09/05/2025	2
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

Applicant	Nature of the application	Application receipt date	Number of applications
B05DA Isotonic solutions ICODEXTRIN, Sodium chloride, Sodium (S)-lactate solution, Calcium chloride dihydrate, Magnesium chloride hexahydrate			
Noridem Enterprises Limited	Marketing authorisation application	02/02/2024	1
B05XA01 potassium chloride Potassium chloride			
Noridem Enterprises Limited	Marketing authorisation application	18/03/2025	1
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. Braun Melsungen AG	Marketing authorisation application	10/04/2024	1
C01BB01 lidocaine Lidocaine hydrochloride monohydrate			
Noridem Enterprises Limited	Marketing authorisation application	21/03/2024	1
C01CA07 dobutamine Dobutamine hydrochloride			
PANPHARMA	Marketing authorisation application	29/12/2023	1
C01CA24 epinephrine Adrenaline tartrate			
Viatriis AB	Marketing authorisation application	02/05/2024	2
C01EA01 alprostadil Alprostadil			
Oresund Pharma ApS (Øresund Pharma)	Marketing authorisation application	09/04/2025	1
C01EB10 adenosine Adenosine			
Orifarm Oy	Parallel import	10/03/2023	1
Macure Healthcare Limited	Marketing authorisation application	30/09/2024	1
C02AB02 methyldopa (racemic) Methyldopa sesquihydrate			
Macure Pharma ApS	Marketing authorisation application	01/04/2025	1
C02AC02 guanfacine Guanfacine hydrochloride			
Sandoz GmbH	Marketing authorisation application	04/08/2025	4
C02DD01 nitroprusside Sodium nitroprusside dihydrate			
Macure Pharma ApS	Marketing authorisation application	26/05/2025	1
C02KX01 bosentan Bosentan monohydrate			
Accord Healthcare B.V.	Marketing authorisation application	27/12/2023	1
Paranova Oy	Parallel import	16/07/2025	1
C02KX04 macitentan Macitentan			
Zentiva k.s.	Marketing authorisation application	22/12/2023	1
Renata Pharmaceuticals (Ireland) Limited	Marketing authorisation application	29/12/2023	1
STADA Arzneimittel AG	Marketing authorisation application	04/01/2024	1
Vivanta Generics s.r.o.	Marketing authorisation application	30/04/2024	1
Sandoz A/S	Marketing authorisation application	02/05/2024	1
Viatriis Limited	Marketing authorisation application	09/08/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
C02KX05 riociguat <i>Riociguat</i>			
Olpha AS	Marketing authorisation application	28/08/2025	5
C03CA01 furosemide <i>Furosemide</i>			
Omet Pharma AB	Marketing authorisation application	15/05/2024	2
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
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>			
Omet Pharma AB	Marketing authorisation application	14/05/2024	3
C07AB07 bisoprolol <i>Bisoprolol fumarate</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	28/12/2023	6
C08CA01 amlodipine <i>Amlodipine besylate</i>			
Teva B.V.	Marketing authorisation application	04/06/2024	2
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

Applicant	Nature of the application	Application receipt date	Number of applications
C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan disodium</i>			
Accord Healthcare B.V.	Marketing authorisation application	24/11/2023	3
STADA Arzneimittel AG	Marketing authorisation application	24/11/2023	3
axunio Pharma GmbH	Marketing authorisation application	24/11/2023	3
Teva GmbH	Marketing authorisation application	04/12/2023	3
Glenmark Arzneimittel GmbH	Marketing authorisation application	07/02/2025	3
axunio Pharma GmbH	Marketing authorisation application	25/04/2025	3
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>			
KRKA d.d. Novo mesto	Marketing authorisation application	29/04/2024	3
Amarox Pharma B.V.	Marketing authorisation application	03/02/2025	3
C09DX04 valsartan and sacubitril <i>Sacubitril valsartan sodium hydrate</i>			
Viartis Limited	Marketing authorisation application	30/01/2024	3
Reddy Holding GmbH	Marketing authorisation application	07/08/2025	3
C10AA05 atorvastatin <i>Atorvastatin</i>			
Amarox Pharma B.V.	Marketing authorisation application	02/12/2024	4
C10BA06 rosuvastatin and ezetimibe <i>Ezetimibe, Rosuvastatin calcium</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	17/06/2024	4
C10BA06 rosuvastatin and ezetimibe <i>Rosuvastatin calcium, Ezetimibe</i>			
KRKA d.d. Novo mesto	Marketing authorisation application	10/09/2024	2
D05AX52 calcipotriol, combinations <i>Betamethasone dipropionate, Calcipotriol hydrate</i>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	01/08/2024	1
D06AX01 fusidic acid <i>Fusidic acid</i>			
Strides Nordic ApS	Marketing authorisation application	01/12/2023	1
D06BA01 silver sulfadiazine <i>Silver sulfadiazine</i>			
Macure Pharma ApS	Marketing authorisation application	15/07/2025	1
D07AB02 hydrocortisone butyrate <i>Hydrocortisone butyrate</i>			
Grindeks AS	Marketing authorisation application	30/05/2025	1
D07AC01 betamethasone <i>Betamethasone valerate</i>			
Grindeks AS	Marketing authorisation application	01/04/2025	1
Grindeks AS	Marketing authorisation application	30/04/2025	1
D07AC13 mometasone <i>Mometasone furoate</i>			
Grindeks AS	Marketing authorisation application	21/10/2022	2

Applicant	Nature of the application	Application receipt date	Number of applications
D07AD01 clobetasol <i>Clobetasol propionate</i>			
Grindeks AS	Marketing authorisation application	28/11/2024	1
Grindeks AS	Marketing authorisation application	28/03/2025	1
D07CC01 betamethasone and antibiotics <i>Fusidic acid, Betamethasone valerate</i>			
Strides Nordic ApS	Marketing authorisation application	01/12/2023	1
D08AG02 povidone-iodine <i>Polyvidone-iodine</i>			
Mundipharma Oy	Marketing authorisation application	18/07/2019	1
D10AD53 adapalene, combinations <i>Adapalene, Benzoyl peroxide</i>			
STADA Arzneimittel AG	Marketing authorisation application	27/03/2024	2
D10AD53 adapalene, combinations <i>Clindamycin phosphate, Adapalene, Benzoyl peroxide, hydrous</i>			
Bausch Health Ireland Limited	Marketing authorisation application	30/05/2024	1
D10AE01 benzoyl peroxide <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
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
G01AF01 metronidazole <i>Metronidazole</i>			
Abacus Medicine A/S	Parallel import	16/08/2024	1
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
G02AD06 misoprostol <i>Misoprostol</i>			
Inphena A/S	Marketing authorisation application	06/03/2024	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
G03AC10 drospirenone <i>Drospirenone</i>			
Exeltis Healthcare S.L.	Marketing authorisation application	30/08/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
G03BA03 testosterone Testosterone undecanoate			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	28/07/2023	1
G03BA03 testosterone Testosterone			
The Simple Pharma Company Limited	Marketing authorisation application	19/12/2023	1
Exeltis Healthcare S.L.	Marketing authorisation application	10/02/2025	1
G03CA03 estradiol Estradiol hemihydrate			
Paranova Oy	Parallel import	10/07/2025	1
G03GA02 human menopausal gonadotrophin Menotropine			
Paranova Oy	Parallel import	27/04/2022	2
G03XB51 mifepristone, combinations Mifepristone, Misoprostol			
ADOH B.V.	Marketing authorisation application	29/11/2024	1
ADOH B.V.	Marketing authorisation application	31/03/2025	1
G04BD12 mirabegron Mirabegron			
Glenmark Arzneimittel GmbH	Marketing authorisation application	02/07/2024	1
STADA Arzneimittel AG	Marketing authorisation application	02/07/2024	1
Zentiva k.s.	Marketing authorisation application	02/07/2024	1
G04BE03 sildenafil Sildenafil citrate			
ADOH B.V.	Marketing authorisation application	01/12/2023	4
Apc Pharmlog Sp. z o.o.	Marketing authorisation application	11/04/2025	1
G04BE08 tadalafil Tadalafil			
Amarox Pharma GmbH	Marketing authorisation application	30/10/2024	1
G04CA02 tamsulosin Tamsulosin hydrochloride			
Viartis Limited	Marketing authorisation application	27/03/2025	1
H01BA04 terlipressin Terlipressin acetate			
Orifarm Oy	Parallel import	09/04/2025	1
H01BB02 oxytocin Oxytocin			
PANPHARMA	Marketing authorisation application	21/01/2025	1
Abacus Medicine A/S	Parallel import	07/03/2025	1
H01BB03 carbetocin Carbetocin			
EVER Valinject GmbH	Marketing authorisation application	30/09/2024	1
H01CB02 octreotide Octreotide acetate			
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
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
H01CC01 ganirelix <i>Ganirelix acetate</i>			
Seacross Pharma (Europe) Limited	Marketing authorisation application	15/04/2025	1
H02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i>			
PANPHARMA	Marketing authorisation application	24/01/2024	1
Noridem Enterprises Limited	Marketing authorisation application	28/06/2024	1
H02AB04 methylprednisolone <i>Methylprednisolone sodium succinate</i>			
Abacus Medicine A/S	Parallel import	05/03/2025	3
H02AB09 hydrocortisone <i>Hydrocortisone sodium succinate</i>			
Noridem Enterprises Limited	Marketing authorisation application	02/05/2025	6
H02AB09 hydrocortisone <i>Hydrocortisone</i>			
Morningside Healthcare (Malta) Limited	Marketing authorisation application	01/03/2024	2
H03AA01 levothyroxine sodium <i>Levothyroxine sodium</i>			
Sandoz A/S	Marketing authorisation application	26/03/2025	2
J01AA02 doxycycline <i>Doxycycline hyclate</i>			
Macure Healthcare Limited	Marketing authorisation application	27/03/2024	1
J01CA01 ampicillin <i>Ampicillin sodium</i>			
Demo S.A.	Marketing authorisation application	30/11/2023	3
J01CE01 benzylpenicillin <i>Benzylpenicillin sodium</i>			
Noridem Enterprises Limited	Marketing authorisation application	30/06/2023	4
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 monohydrate, Tazobactam</i>			
B. Braun Melsungen AG	Marketing authorisation application	13/12/2024	1
J01CR05 piperacillin and beta-lactamase inhibitor <i>Piperacillin sodium, Tazobactam sodium</i>			
Noridem Enterprises Limited	Marketing authorisation application	09/12/2024	2
J01DB04 cefazolin <i>Cefazoline sodium</i>			
Noridem Enterprises Limited	Marketing authorisation application	03/02/2025	2

Applicant	Nature of the application	Application receipt date	Number of applications
J01DC02 cefuroxime <i>Cefuroxime sodium</i>			
Hameln Pharma GmbH	Marketing authorisation application	24/03/2025	1
J01DD02 ceftazidime <i>Ceftazidime pentahydrate</i>			
Farmaprojects, S.A.U.	Marketing authorisation application	25/03/2024	3
J01DD04 ceftriaxone <i>Ceftriaxone sodium</i>			
Farmaprojects, S.A.U.	Marketing authorisation application	26/01/2024	2
Apta Medica Internacional d.o.o.	Marketing authorisation application	29/04/2025	2
J01DH51 imipenem and cilastatin <i>Imipenem monohydrate, Cilastatin sodium</i>			
Noridem Enterprises Limited	Marketing authorisation application	10/01/2025	1
J01FA09 clarithromycin <i>Clarithromycin</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	14/11/2024	1
J01FA10 azithromycin <i>Azithromycin dihydrate</i>			
Orifarm Oy	Parallel import	26/10/2023	1
Gufic Ireland Limited	Marketing authorisation application	31/12/2024	1
J01FF01 clindamycin <i>Clindamycin phosphate</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	02/01/2023	1
J01GB03 gentamicin <i>Gentamicin sulfate</i>			
Macure Healthcare Limited	Marketing authorisation application	01/11/2023	4
J01GB06 amikacin <i>Amikacin sulfate</i>			
2Care4 Generics ApS	Marketing authorisation application	28/06/2024	1
J01MA02 ciprofloxacin <i>Ciprofloxacin lactate</i>			
Noridem Enterprises Limited	Marketing authorisation application	08/04/2025	1
J01XA01 vancomycin <i>Vancomycin hydrochloride</i>			
Noridem Enterprises Limited	Marketing authorisation application	03/02/2025	2
J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i>			
Noridem Enterprises Limited	Marketing authorisation application	27/12/2024	1
J01XA04 dalbavancin <i>Dalbavancin</i>			
Welding GmbH & Co. KG	Marketing authorisation application	25/06/2024	1
J01XB01 colistin <i>Colistimethate sodium</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	28/05/2025	2
J01XX05 methenamine <i>Methenamine hippurate</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	30/04/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
J02AC04 posaconazole <i>Posaconazole</i>			
PGF Pharma International d.o.o.	Marketing authorisation application	30/07/2025	1
J02AX05 micafungin <i>Micafungin sodium</i>			
Amarox Pharma B.V.	Marketing authorisation application	22/04/2025	2
Noridem Enterprises Limited	Marketing authorisation application	30/05/2025	2
J02AX06 anidulafungin <i>Anidulafungin</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	27/12/2024	1
J05AB06 ganciclovir <i>Ganciclovir sodium</i>			
Bioglan AB	Marketing authorisation application	02/10/2024	1
J05AB14 valganciclovir <i>Valganciclovir hydrochloride</i>			
Amarox Pharma B.V.	Marketing authorisation application	02/10/2024	1
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
J05AR03 tenofovir disoproxil and emtricitabine <i>Emtricitabine, Tenofovir disoproxil fumarate</i>			
Amarox Pharma B.V.	Marketing authorisation application	18/06/2025	1
J05AR06 emtricitabine, tenofovir disoproxil and efavirenz <i>Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate</i>			
Aliud Pharma GmbH	Marketing authorisation application	20/12/2024	1
J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide fumarate</i>			
Amarox Pharma B.V.	Marketing authorisation application	16/12/2024	2
J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide succinate</i>			
Lupin Europe GmbH	Marketing authorisation application	30/01/2025	2
J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide</i>			
Medical Valley Invest AB	Marketing authorisation application	03/02/2025	2
J05AR19 emtricitabine, tenofovir alafenamide and rilpivirine <i>Emtricitabine, Rilpivirine hydrochloride, Tenofovir alafenamide monofumarate</i>			
Accord Healthcare S.L.U.	Marketing authorisation application	02/06/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
L01AA01 cyclophosphamide <i>Cyclophosphamide monohydrate</i>			
Baxter Oy	Marketing authorisation application	02/04/2025	2
L01AA06 ifosfamide <i>Ifosfamide</i>			
Baxter Oy	Marketing authorisation application	14/02/2025	2
L01AX03 temozolomide <i>Temozolomide</i>			
PGF Pharma International d.o.o.	Marketing authorisation application	28/03/2025	6
L01BC07 azacitidine <i>Azacitidine</i>			
Tarchomińskie Zakłady Farmaceutyczne, Polfa S.A.	Marketing authorisation application	26/11/2021	1
ELC GROUP S.R.O.	Marketing authorisation application	28/06/2023	1
L01BC08 decitabine <i>Decitabine</i>			
EVER Valinject GmbH	Marketing authorisation application	25/09/2024	1
L01CD01 paclitaxel <i>Paclitaxel</i>			
Panacea Biotec Germany GmbH	Marketing authorisation application	01/08/2023	1
Qilu Pharma Spain S.L.	Marketing authorisation application	16/10/2023	1
Seacross Pharma (Europe) Limited	Marketing authorisation application	02/05/2024	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
L01CD04 cabazitaxel <i>Cabazitaxel</i>			
Amarox Pharma B.V.	Marketing authorisation application	04/08/2025	1
L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	30/06/2025	1
L01DB02 daunorubicin <i>Daunorubicin hydrochloride</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	30/12/2022	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
L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i>			
Hetero Europe S.L.	Marketing authorisation application	26/02/2025	3

Applicant	Nature of the application	Application receipt date	Number of applications
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
L01EF01 palbociclib <i>Palbociclib</i>			
Synthon B.V.	Marketing authorisation application	12/11/2024	3
STADA Arzneimittel AG	Marketing authorisation application	30/04/2025	3
Teva GmbH	Marketing authorisation application	30/05/2025	3
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
L01EJ01 ruxolitinib <i>Ruxolitinib hydrochloride</i>			
Orion Corporation	Marketing authorisation application	27/06/2024	4
Vivanta Generics s.r.o.	Marketing authorisation application	01/08/2024	4
Sandoz A/S	Marketing authorisation application	03/02/2025	4
L01EX02 sorafenib <i>Sorafenib tosilate</i>			
Devatis GmbH	Marketing authorisation application	31/07/2025	1
L01EX08 lenvatinib <i>Lenvatinib besilate</i>			
Synthon B.V.	Marketing authorisation application	30/11/2023	2
Accord Healthcare B.V.	Marketing authorisation application	29/03/2024	2
Sandoz B.V.	Marketing authorisation application	29/03/2024	4
Teva GmbH	Marketing authorisation application	25/11/2024	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
L01EX09 nintedanib <i>Nintedanib esylate</i>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	18/12/2023	2
ratiopharm GmbH	Marketing authorisation application	26/09/2024	2
PGF Pharma International d.o.o.	Marketing authorisation application	02/06/2025	2

Applicant	Nature of the application	Application receipt date	Number of applications
L01XA01 cisplatin <i>Cisplatin</i>			
Amarox Pharma B.V.	Marketing authorisation application	30/05/2025	1
L01XA03 oxaliplatin <i>Oxaliplatin</i>			
Amarox Pharma B.V.	Marketing authorisation application	29/07/2025	1
L01XX27 arsenic trioxide <i>Arsenic trioxide</i>			
Tillomed Malta Limited	Marketing authorisation application	02/04/2024	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
L02BB04 enzalutamide <i>Enzalutamide</i>			
Teva Nederland B.V.	Marketing authorisation application	27/03/2024	2
Day Zero ehf	Marketing authorisation application	23/04/2025	2
Amarox Pharma B.V.	Marketing authorisation application	02/07/2025	2
Qilu Pharma Spain S.L.	Marketing authorisation application	31/07/2025	2
L02BG04 letrozole <i>Letrozole</i>			
Sandoz B.V.	Marketing authorisation application	22/03/2024	1
Tarbis Farma S.L.	Marketing authorisation application	02/12/2024	1
L02BX03 abiraterone <i>Abiraterone acetate</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/08/2023	2
Devatis GmbH	Marketing authorisation application	08/05/2025	1
L03AX03 BCG vaccine <i>Mycobacterium bovis BCG (Danish strain 1331), live attenuated</i>			
AJ Vaccines A/S	Marketing authorisation application	10/06/2025	1
L04AA06 mycophenolic acid <i>Mycophenolate mofetil</i>			
Amarox Pharma B.V.	Marketing authorisation application	23/06/2025	1
L04AA31 teriflunomide <i>Teriflunomide</i>			
Heaton k.s.	Marketing authorisation application	20/12/2023	1
L04AA32 apremilast <i>Apremilast</i>			
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
Sandoz s.r.o.	Marketing authorisation application	07/04/2025	2

Applicant	Nature of the application	Application receipt date	Number of applications
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
L04AD02 tacrolimus <i>Tacrolimus monohydrate</i>			
Orifarm Healthcare A/S	Marketing authorisation application	29/11/2023	4
L04AE01 fingolimod <i>Fingolimod hydrochloride</i>			
Pharmaselect International Beteiligungs GmbH	Marketing authorisation application	06/10/2021	1
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
L04AK02 teriflunomide <i>Teriflunomide</i>			
STADA Nordic ApS	Marketing authorisation application	13/12/2024	2
L04AX03 methotrexate <i>Methotrexate disodium</i>			
STADA Arzneimittel AG	Marketing authorisation application	25/01/2024	10
L04AX05 pirfenidone <i>Pirfenidone</i>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	03/03/2025	2
L04AX06 pomalidomide <i>Pomalidomide</i>			
Olpha AS	Marketing authorisation application	29/09/2023	4
Amarox Pharma B.V.	Marketing authorisation application	03/10/2024	4
L04AX07 dimethyl fumarate <i>Dimethyl fumarate</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	30/09/2024	2
Amarox Pharma B.V.	Marketing authorisation application	22/10/2024	2
M01AE01 ibuprofen <i>Ibuprofen</i>			
Strides Nordic ApS	Marketing authorisation application	02/04/2024	3
Fairmed Healthcare GmbH	Marketing authorisation application	03/05/2024	3
Sandoz A/S	Marketing authorisation application	13/12/2024	2
Sandoz A/S	Marketing authorisation application	13/12/2024	4
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

Applicant	Nature of the application	Application receipt date	Number of applications
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
M02AA15 diclofenac <i>Diclofenac diethylamine</i>			
Fysioline Oy	Marketing authorisation application	18/07/2025	1
M02AA15 diclofenac <i>Diclofenac sodium</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	26/09/2024	1
Haleon Denmark ApS	Marketing authorisation application	03/06/2025	1
M03AC09 rocuronium bromide <i>Rocuronium bromide</i>			
Accord Healthcare B.V.	Marketing authorisation application	31/05/2021	1
Noridem Enterprises Limited	Marketing authorisation application	07/06/2024	1
Amarox Pharma B.V.	Marketing authorisation application	02/06/2025	1
M03AC11 cisatracurium <i>Cisatracurium besilate</i>			
Noridem Enterprises Limited	Marketing authorisation application	24/02/2025	1
M03BX01 baclofen <i>Baclofen</i>			
2Care4 Generics ApS	Marketing authorisation application	31/01/2025	1
M04AA01 allopurinol <i>Allopurinol</i>			
Renantos Pharmavertriebsgesellschaft mbH	Marketing authorisation application	02/05/2024	3
M04AC01 colchicine <i>Colchicine</i>			
Indoco Remedies Czech s.r.o.	Marketing authorisation application	26/01/2022	1
M05BB04 risedronic acid, calcium and colecalciferol, sequential <i>Calcium carbonate, Cholecalciferol concentrate (powder form), Risedronate sodium</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	27/12/2024	1
N01AH06 remifentanil <i>Remifentanil hydrochloride</i>			
Kalceks AS	Marketing authorisation application	30/04/2025	3
Noridem Enterprises Limited	Marketing authorisation application	01/07/2025	3
N01BB02 lidocaine <i>Lidocaine hydrochloride monohydrate</i>			
Noridem Enterprises Limited	Marketing authorisation application	21/03/2024	2

Applicant	Nature of the application	Application receipt date	Number of applications
N01BB02 lidocaine <i>Lidocaine</i>			
Orion Corporation	Marketing authorisation application	31/01/2025	1
N01BB09 ropivacaine <i>Ropivacaine hydrochloride monohydrate</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	12/12/2024	4
Noridem Enterprises Limited	Marketing authorisation application	20/01/2025	5
N01BB51 bupivacaine, combinations <i>Bupivacaine hydrochloride monohydrate, Adrenaline tartrate</i>			
Macure Pharma ApS	Marketing authorisation application	11/04/2025	2
N01BB58 articaine, combinations <i>Articaine hydrochloride, Epinephrine</i>			
Laboratorios Normon S.A.	Marketing authorisation application	25/03/2025	2
N02AA05 oxycodone <i>Oxycodone hydrochloride</i>			
G.L. Pharma GmbH	Marketing authorisation application	22/05/2025	2
N02BE01 paracetamol <i>Paracetamol</i>			
ratiopharm GmbH	Marketing authorisation application	15/07/2024	2
Noridem Enterprises Limited	Marketing authorisation application	24/03/2025	1
Fresenius Kabi Deutschland GmbH	Marketing authorisation application	08/04/2025	1
N02BE51 paracetamol, combinations excl. psycholeptics <i>Ibuprofen, Paracetamol</i>			
Vale Pharmaceuticals Limited	Marketing authorisation application	09/10/2023	1
Fysioline Oy	Marketing authorisation application	10/04/2025	1
N02BE51 paracetamol, combinations excl. psycholeptics <i>Paracetamol, Caffeine</i>			
Haleon Denmark ApS	Marketing authorisation application	17/12/2024	1
N02BF02 pregabalin <i>Pregabalin</i>			
Grindeks AS	Marketing authorisation application	01/08/2024	6
N02CC01 sumatriptan <i>Sumatriptan succinate</i>			
Orion Corporation	Marketing authorisation application	30/08/2024	1
Orion Corporation	Marketing authorisation application	30/08/2024	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	05/08/2024	2
N02CC05 almotriptan <i>Almotriptan D,L-hydrogen malate</i>			
Abacus Medicine A/S	Parallel import	03/12/2024	1
N02CX02 clonidine <i>Clonidine hydrochloride</i>			
Macure Pharma ApS	Marketing authorisation application	28/08/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
N03AA03 primidone <i>Primidone</i>			
2Care4 Generics ApS	Marketing authorisation application	01/10/2024	3
N03AB02 phenytoin <i>Phenytoin sodium</i>			
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	03/03/2025	1
N03AD01 ethosuximide <i>Ethosuximide</i>			
Neuraxpharm Arzneimittel GmbH	Marketing authorisation application	23/05/2025	1
N03AF02 oxcarbazepine <i>Oxcarbazepine</i>			
Amarox Pharma GmbH	Marketing authorisation application	11/03/2025	3
N03AG01 valproic acid <i>Sodium valproate, Valproic acid</i>			
Orifarm Oy	Parallel import	13/01/2025	1
N03AG01 valproic acid <i>Sodium valproate</i>			
Desitin Arzneimittel GmbH	Marketing authorisation application	30/04/2025	4
N03AX09 lamotrigine <i>Lamotrigine</i>			
Syri Pharma Limited	Marketing authorisation application	31/08/2023	1
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	08/01/2024	5
N03AX14 levetiracetam <i>Levetiracetam</i>			
C4 health GmbH	Marketing authorisation application	22/12/2023	4
Fresenius Kabi Austria GmbH	Marketing authorisation application	28/08/2024	1
Kalceks AS	Marketing authorisation application	31/01/2025	1
Orifarm Oy	Parallel import	28/07/2025	1
Grindeks AS	Marketing authorisation application	01/08/2025	4
N03AX18 lacosamide <i>Lacosamide</i>			
As Grindex	Marketing authorisation application	22/12/2023	4
Tillomed Malta Limited	Marketing authorisation application	09/07/2024	1
Amarox Pharma GmbH	Marketing authorisation application	08/05/2025	1
N03AX22 perampanel <i>Perampanel hydrate (4:3)</i>			
Orion Corporation	Marketing authorisation application	31/05/2024	6
N03AX23 brivaracetam <i>Brivaracetam</i>			
Medical Valley Invest AB	Marketing authorisation application	02/05/2024	5
Desitin Arzneimittel GmbH	Marketing authorisation application	28/06/2024	5
Desitin Arzneimittel GmbH	Marketing authorisation application	31/07/2024	1
Orion Corporation	Marketing authorisation application	30/08/2024	5
Glenmark Arzneimittel GmbH	Marketing authorisation application	18/10/2024	5
Orion Corporation	Marketing authorisation application	02/06/2025	5

Applicant	Nature of the application	Application receipt date	Number of applications
N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor <i>Levodopa, Carbidopa monohydrate, Entacapone</i>			
Neuraxpharm Sweden AB	Marketing authorisation application	29/05/2023	7
N04BB01 amantadine <i>Amantadine hydrochloride</i>			
Macure Pharma ApS	Marketing authorisation application	28/11/2024	1
N04BC09 rotigotine <i>Rotigotine</i>			
Orion Corporation	Marketing authorisation application	30/09/2024	6
N04BD03 safinamide <i>Safinamide methanesulfonate</i>			
Vivanta Generics s.r.o.	Marketing authorisation application	19/09/2023	2
N05AA02 levomepromazine <i>Levomepromazine maleate</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	29/03/2024	2
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
N05AH04 quetiapine <i>Quetiapine fumarate</i>			
Grindeks AS	Marketing authorisation application	07/10/2022	4
Grindeks AS	Marketing authorisation application	10/10/2022	5
N05AX Other antipsychotics <i>Sodium valproate</i>			
Desitin Arzneimittel GmbH	Marketing authorisation application	30/04/2025	4
N05AX12 aripiprazole <i>Aripiprazole monohydrate</i>			
STADA Arzneimittel AG	Marketing authorisation application	28/03/2024	1
Sandoz A/S	Marketing authorisation application	02/04/2024	2
N05AX12 aripiprazole <i>Aripiprazole</i>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	22/04/2024	4
N05AX13 paliperidone <i>Paliperidone palmitate</i>			
Universal Farma S.L.	Marketing authorisation application	31/10/2022	6
Viatriis Limited	Marketing authorisation application	01/12/2023	12
Viatriis 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

Applicant	Nature of the application	Application receipt date	Number of applications
N05BA01 diazepam <i>Diazepam</i>			
Macure Pharma ApS	Marketing authorisation application	01/11/2024	1
N05BA06 lorazepam <i>Lorazepam</i>			
Orion Corporation	Marketing authorisation application	26/04/2024	1
N05BB01 hydroxyzine <i>Hydroxyzine hydrochloride</i>			
Abacus Medicine A/S	Parallel import	02/08/2024	1
N05CD08 midazolam <i>Midazolam maleate</i>			
SERB S.A.	Marketing authorisation application	27/02/2025	1
N05CD08 midazolam <i>Midazolam</i>			
Laboratoire Aguettant	Marketing authorisation application	31/07/2024	2
N05CH01 melatonin <i>Melatonin</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	01/03/2024	1
Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. z o.o.	Marketing authorisation application	12/07/2024	1
Orion Corporation	Marketing authorisation application	29/11/2024	2
N05CM18 dexmedetomidine <i>Dexmedetomidine hydrochloride</i>			
Hameln Pharma GmbH	Marketing authorisation application	31/08/2023	1
Noridem Enterprises Limited	Marketing authorisation application	21/10/2024	1
N06AA09 amitriptyline <i>Amitriptyline hydrochloride</i>			
Neuraxpharm Sweden AB	Marketing authorisation application	03/04/2024	1
N06AB06 sertraline <i>Sertraline hydrochloride</i>			
RIA Generics Limited	Marketing authorisation application	22/05/2023	2
N06AX11 mirtazapine <i>Mirtazapine</i>			
Grindeks AS	Marketing authorisation application	12/10/2023	3
Devatis GmbH	Marketing authorisation application	08/04/2025	3
N06AX12 bupropion <i>Bupropion hydrochloride</i>			
Aliud Pharma GmbH&Co. KG	Marketing authorisation application	12/03/2024	2
Amarox Pharma B.V.	Marketing authorisation application	30/01/2025	2
N06AX16 venlafaxine <i>Venlafaxine hydrochloride</i>			
IPCA Produtos Farmacêuticos Unipessoal Lda.	Marketing authorisation application	02/05/2024	3

Applicant	Nature of the application	Application receipt date	Number of applications
N06AX26 vortioxetine <i>Vortioxetine hydrobromide</i>			
KRKA d.d. Novo mesto	Marketing authorisation application	24/09/2024	4
Orion Corporation	Marketing authorisation application	16/01/2025	4
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
Teva GmbH	Marketing authorisation application	01/09/2025	4
N06BA02 dexamfetamine <i>Dexamphetamine sulphate</i>			
2Care4 Generics ApS	Marketing authorisation application	03/03/2025	3
ACE Pharmaceuticals BV	Marketing authorisation application	26/03/2025	1
N06BA04 methylphenidate <i>Methylphenidate hydrochloride</i>			
Laboratorios Liconsa S.A.	Marketing authorisation application	02/04/2025	5
N06BA09 atomoxetine <i>Atomoxetine hydrochloride</i>			
Amarox Pharma GmbH	Marketing authorisation application	30/04/2025	7
2Care4 Generics ApS	Marketing authorisation application	31/07/2025	1
N06BA12 lisdexamfetamine <i>Lisdexamfetamine dimesylate</i>			
Aspire Pharma (Malta) Limited	Marketing authorisation application	21/01/2025	6
Sandoz A/S	Marketing authorisation application	21/01/2025	6
N06DA03 rivastigmine <i>Rivastigmine</i>			
Sandoz A/S	Marketing authorisation application	01/07/2024	3
Strides Nordic ApS	Marketing authorisation application	02/09/2024	3
N06DX01 memantine <i>Memantine hydrochloride</i>			
UAB Baltijos Bite	Marketing authorisation application	01/12/2023	2
N07BA03 varenicline <i>Varenicline citrate</i>			
Alfred E. Tiefenbacher (GmbH & Co. KG)	Marketing authorisation application	29/08/2024	3
N07BA03 varenicline <i>Varenicline tartrate</i>			
Viatris Limited	Marketing authorisation application	29/02/2024	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
P03AX Other ectoparasiticides, incl. scabicides <i>Benzyl benzoate</i>			
Sun-Farm Sp. z o.o.	Marketing authorisation application	28/06/2024	2

Applicant	Nature of the application	Application receipt date	Number of applications
QA03FA01 metoclopramide <i>Metoclopramide hydrochloride monohydrate</i>			
ADOH B.V.	Marketing authorisation application	11/04/2024	1
QA06AD11 lactulose <i>Lactulose</i>			
Alfasan Nederland B.V.	Marketing authorisation application	03/02/2025	1
QC09AA07 benazepril <i>Benazepril hydrochloride</i>			
Virbac	Marketing authorisation application	26/02/2024	1
QC09CA07 telmisartan <i>Telmisartan</i>			
Alfasan Nederland B.V.	Marketing authorisation application	07/03/2022	1
QD08AG03 iodine <i>Iodine</i>			
Delaval	Marketing authorisation application	11/12/2024	2
QG04BX91 phenylpropanolamine <i>Phenylpropanolamine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	21/03/2022	1
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
QH03BB02 thiamazole <i>Thiamazole</i>			
Virbac	Marketing authorisation application	28/08/2024	1
QI01AD09 Avian infectious bursal disease virus vaccine (Gumboro disease) <i>Infectious bursal disease virus, strain LC 75, Live</i>			
Elanco GmbH	Marketing authorisation application	02/06/2025	1
QI02AB17 Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia <i>Escherichia coli, strain 5117 J5, inactivated, Staphylococcus aureus, strain DSM 4910, inactivated</i>			
Boehringer Ingelheim Vetmedica GmbH	Marketing authorisation application	03/12/2024	1
QI02AE05 mycoplasma <i>Mycoplasma bovis, strain N2805-1, live</i>			
Zoetis Animal Health ApS	Marketing authorisation application	09/07/2025	1
QI02AP01 Trichophyton vaccine <i>Trichophyton verrucosum, live, attenuated</i>			
Salfarm Danmark A/S	Marketing authorisation application	08/03/2024	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, 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

Applicant	Nature of the application	Application receipt date	Number of applications
QJ01AA06 oxytetracycline <i>Oxytetracycline hydrochloride</i>			
Fatro S.p.A.	Marketing authorisation application	14/05/2025	1
QJ01BA90 florfenicol <i>Florfenicol</i>			
Interchemie Werken De Adelaar Eesti AS	Marketing authorisation application	18/06/2025	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>Sulfadiazine, Trimethoprim</i>			
Dopharma Research B.V.	Marketing authorisation application	22/01/2025	1
QJ01EW10 sulfadiazine and trimethoprim, incl. derivatives <i>Trimethoprim, Sulfadiazine</i>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	28/05/2025	2
QM01AC06 meloxicam <i>Meloxicam</i>			
Alfasan Nederland B.V.	Marketing authorisation application	13/09/2021	1
Alfasan Nederland B.V.	Marketing authorisation application	21/09/2021	1
Alfasan Nederland B.V.	Marketing authorisation application	08/10/2021	1
Alfasan Nederland B.V.	Marketing authorisation application	11/11/2021	1
Alfasan Nederland B.V.	Marketing authorisation application	03/11/2022	2
Cyton AH Biosciences GmbH	Marketing authorisation application	22/10/2024	1
QM01AE03 ketoprofen <i>Ketoprofen</i>			
VetViva Richter GmbH	Marketing authorisation application	20/03/2025	1
QM01AE91 carprofen <i>Carprofen</i>			
Alfasan Nederland B.V.	Marketing authorisation application	07/12/2022	2
Alfasan Nederland B.V.	Marketing authorisation application	09/09/2024	7
Norbrook Laboratories (Ireland) Limited	Marketing authorisation application	25/09/2024	1
QM01AG02 tolfenamic acid <i>Tolfenamic acid</i>			
HuVepharma	Marketing authorisation application	08/10/2024	1
QM01AH91 robenacoxib <i>Robenacoxib</i>			
Fatro S.p.A.	Marketing authorisation application	28/11/2023	3
KRKA d.d. Novo mesto	Marketing authorisation application	09/09/2024	1
KRKA d.d. Novo mesto	Marketing authorisation application	25/04/2025	1
KRKA d.d. Novo mesto	Marketing authorisation application	28/04/2025	1
QM01AX90 pentosan polysulphate <i>Pentosan polysulfate sodium</i>			
Forte Healthcare Licencing Limited	Marketing authorisation application	05/03/2025	1
QN01AX99 other general anesthetics, combinations <i>Tiletamine hydrochloride, Zolazepam hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	18/06/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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>			
Laboratoire TVM	Marketing authorisation application	12/10/2020	1
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
Alfasan Nederland B.V.	Marketing authorisation application	19/09/2023	4
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
QN05CM18 Dexmedetomidine <i>Dexmedetomidine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	15/09/2022	1
QN05CM90 detomidine <i>Detomidine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	14/04/2022	1
QN05CM91 medetomidine <i>Medetomidine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	15/09/2022	1
QN05CM92 xylazine <i>Xylazine hydrochloride</i>			
Forte Healthcare Licencing Limited	Marketing authorisation application	01/04/2025	1
QN51AA01 pentobarbital <i>Pentobarbital sodium</i>			
Wirtschaftsgenossenschaft deutscher Tierärzte eG	Marketing authorisation application	21/08/2025	1
QP51BC03 diclazuril <i>Diclazuril</i>			
HuVepharm	Marketing authorisation application	22/01/2024	1
QP52AA51 praziquantel, combinations <i>Praziquantel, Pyrantel embonate, Febantel</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	08/06/2023	2
QP53AC55 flumethrin, combinations <i>Flumethrin, Imidacloprid, Titanium dioxide</i>			
Beaphar B.V.	Marketing authorisation application	16/09/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
QP53AC55 flumethrin, combinations <i>Flumethrin, Imidacloprid</i>			
Beaphar B.V.	Marketing authorisation application	16/09/2024	2
QP53AC55 flumethrin, combinations <i>Imidacloprid, Flumethrin</i>			
Virbac	Marketing authorisation application	03/07/2024	3
QP54AA01 ivermectin <i>Ivermectin</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	17/10/2023	1
QP54AA51 ivermectin, combinations <i>Ivermectin, Praziquantel</i>			
Bioveta a.s.	Marketing authorisation application	10/01/2025	1
QP54AB51 milbemycin oxime, combinations <i>Milbemycin oxime, Praziquantel</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	27/10/2017	1
Alfasan Nederland B.V.	Marketing authorisation application	09/02/2021	6
ALFAMED	Marketing authorisation application	14/09/2023	4
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	23/01/2024	1
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	29/01/2024	2
QR03CC13 clenbuterol <i>Clenbuterol hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	05/03/2024	1
QS01AA01 chloramphenicol <i>Chloramphenicol</i>			
Domes Pharma	Marketing authorisation application	24/06/2025	1
R01AA07 xylometazoline <i>Xylometazoline hydrochloride</i>			
Vianex S.A.	Marketing authorisation application	01/11/2024	2
R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Fluticasone propionate</i>			
Adalvo Limited	Marketing authorisation application	02/06/2025	2
R01BA52 pseudoephedrine, combinations <i>Pseudoephedrine hydrochloride, Chlorphenamine maleate</i>			
UAB Baltijos Bite	Marketing authorisation application	28/06/2024	1
R02AA06 cetylpyridinium <i>Cetylpyridinium chloride, Lidocaine hydrochloride monohydrate</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	22/04/2025	1
R02AX01 flurbiprofen <i>Flurbiprofen</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	03/11/2023	1
Naiax Pharma S.L.	Marketing authorisation application	28/08/2024	1
Naiax Pharma S.L.	Marketing authorisation application	29/08/2024	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

Applicant	Nature of the application	Application receipt date	Number of applications
R03AL04 indacaterol and glycopyrronium bromide <i>Indacaterol maleate, Glycopyrronium bromide</i>			
Genetic S.p.A.	Marketing authorisation application	24/07/2024	1
R05X OTHER COLD PREPARATIONS <i>Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide, Chlorphenamine maleate</i>			
UAB Baltijos Bite	Marketing authorisation application	28/06/2024	1
R06AA04 clemastine <i>Clemastine fumarate</i>			
Macure Healthcare Limited	Marketing authorisation application	17/01/2025	1
R06AE03 cyclizine <i>Cyclizine lactate</i>			
2Care4 Generics ApS	Marketing authorisation application	28/02/2025	1
R06AE07 cetirizine <i>Cetirizine dihydrochloride</i>			
Haleon Ireland Limited	Marketing authorisation application	30/04/2024	2
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
Orion Corporation	Marketing authorisation application	27/09/2024	1
ratiopharm GmbH	Marketing authorisation application	20/08/2025	1
R06AX29 bilastine <i>Bilastine monohydrate</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	30/08/2024	1
R07AX02 ivacaftor <i>Ivacaftor</i>			
Accord Healthcare B.V.	Marketing authorisation application	02/05/2024	1
STADA Arzneimittel AG	Marketing authorisation application	30/09/2024	1
Lupin Europe GmbH	Marketing authorisation application	31/01/2025	2
Sandoz B.V.	Marketing authorisation application	02/05/2025	1
Genepharm S.A.	Marketing authorisation application	12/05/2025	2
S01AX15 propamidine <i>Propamidine isetionate</i>			
Horus Pharma	Marketing authorisation application	01/06/2023	1
S01BA Corticosteroids, plain <i>Clobetasol propionate</i>			
Laboratorios Salvat S.A.	Marketing authorisation application	23/02/2024	1
S01BA01 dexamethasone <i>Dexamethasone sodium phosphate</i>			
Laboratoires Théa	Marketing authorisation application	01/07/2024	1
Pharmathen S.A.	Marketing authorisation application	20/05/2025	1
S01BC04 flurbiprofen <i>Flurbiprofen sodium dihydrate</i>			
Horus Pharma	Marketing authorisation application	28/08/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
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
S01EC04 brinzolamide <i>Brinzolamide</i>			
Hexal A/S	Marketing authorisation application	31/07/2024	1
S01EC54 brinzolamide, combinations <i>Brinzolamide, Brimonidine tartrate</i>			
Pharmaselect International Beteiligungs GmbH	Marketing authorisation application	01/04/2025	1
S01ED51 timolol, combinations <i>Bimatoprost, Timolol</i>			
Laboratoires Thea	Marketing authorisation application	12/02/2024	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 maleate</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	30/05/2024	1
Laboratorios Salvat S.A.	Marketing authorisation application	09/07/2024	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>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	26/06/2024	1
Pharmathen S.A.	Marketing authorisation application	07/03/2025	1
Bausch + Lomb Ireland Limited	Marketing authorisation application	21/03/2025	1
Genetic S.p.A.	Marketing authorisation application	21/03/2025	2
Laboratorios Salvat S.A.	Marketing authorisation application	09/05/2025	1
S01EE03 bimatoprost <i>Bimatoprost</i>			
GHN Pharma Nordic AB	Marketing authorisation application	24/02/2025	1
S01EE04 travoprost <i>Travoprost</i>			
Blumont Ofta Trading Limited	Marketing authorisation application	30/09/2024	1
S01XA12 dexpanthenol <i>Dexpanthenol</i>			
Dr. Gerhard Mann Chem.-Pharm. fabrik GmbH	Marketing authorisation application	25/06/2024	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>Sodium chloride</i>			
Noridem Enterprises Limited	Marketing authorisation application	18/02/2025	1

Applicant	Nature of the application	Application receipt date	Number of applications
V07AB Solvents and diluting agents, incl. irrigating solutions <i>Water for injection</i>			
Noridem Enterprises Limited	Marketing authorisation application	29/11/2024	1
V09AA01 technetium (99mTc) exametazime <i>Exametazime</i>			
Radiopharmacy Laboratorium Kft.	Marketing authorisation application	28/08/2025	1
V09DB01 technetium (99mTc) nanocolloid <i>Human albumin microcolloidal particles</i>			
Radiopharmacy Laboratorium Kft.	Marketing authorisation application	19/12/2024	1
V09HA02 technetium (99mTc) exametazime labelled cells <i>Exametazime</i>			
Radiopharmacy Laboratorium Kft.	Marketing authorisation application	28/08/2025	1