

Applicant	Nature of the application	Application receipt date	Number of applications
<b>A02AH Antacids with sodium bicarbonate</b> <i>Sodium hydrogen carbonate</i>			
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	28/02/2024	1
<b>A02BC01 omeprazole</b> <i>Omeprazole</i>			
Inn - Farm Družba Za Trgovino In Storitve d.o.o.	Marketing authorisation application	30/06/2022	2
<b>A02BC02 pantoprazole</b> <i>Pantoprazole sodium sesquihydrate</i>			
STADA Arzneimittel AG	Marketing authorisation application	01/06/2022	1
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	30/10/2023	1
<b>A02BC05 esomeprazole</b> <i>Esomeprazole magnesium trihydrate</i>			
Hexal A/S	Marketing authorisation application	29/09/2023	2
<b>A02BC05 esomeprazole</b> <i>Esomeprazole sodium</i>			
Oresund Pharma ApS	Marketing authorisation application	28/02/2023	1
<b>A02BX Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)</b> <i>Sodium alginate, Sodium hydrogen carbonate, Calcium carbonate</i>			
RB Health Nordic A/S	Marketing authorisation application	05/08/2022	2
RB Health Nordic A/S	Marketing authorisation application	08/08/2022	1
<b>A03AX Other drugs for functional gastrointestinal disorders</b> <i>Peppermint oil</i>			
Sana Pharma Medical AS	Marketing authorisation application	31/01/2023	1
<b>A03AX13 silicones</b> <i>Simethicone</i>			
CLINRES FARMACIJA raziskave d.o.o.	Marketing authorisation application	26/06/2023	1
<b>A03FA01 metoclopramide</b> <i>Metoclopramide hydrochloride monohydrate</i>			
G.L. Pharma GmbH	Marketing authorisation application	03/05/2023	1
<b>A04AA01 ondansetron</b> <i>Ondansetron</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	16/02/2023	2
<b>A06AB08 sodium picosulfate</b> <i>Sodium picosulfate monohydrate</i>			
Paranova Oy	Parallel import	16/02/2024	1
<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>A07AA02 nystatin</b> <i>Nystatin</i>			
Orifarm Oy	Parallel import	09/04/2024	1
<b>A07EC02 mesalazine</b> <i>Mesalazine</i>			
Dr. Falk Pharma GmbH	Marketing authorisation application	01/02/2024	1
<b>A07FA02 saccharomyces boulardii</b> <i>Saccharomyces boulardii</i>			
Paranova Oy	Parallel import	12/10/2023	1

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<b>A09AA02 multienzymes (lipase, protease etc.) Pancreas powder</b>			
AVVA Pharmaceuticals Ltd.	Marketing authorisation application	14/07/2020	2
<b>A10BA02 metformin Metformin hydrochloride</b>			
Accord Healthcare B.V.	Marketing authorisation application	22/07/2019	2
Strides Nordic ApS	Marketing authorisation application	01/12/2023	3
Activase Pharmaceuticals Ltd.	Marketing authorisation application	29/02/2024	3
<b>A10BD07 metformin and sitagliptin Sitagliptin hydrochloride monohydrate, Metformin hydrochloride</b>			
Pharmathen S.A.	Marketing authorisation application	01/08/2022	2
<b>A10BD07 metformin and sitagliptin Sitagliptin hydrochloride, Metformin hydrochloride</b>			
UAB Sanoswiss	Marketing authorisation application	15/12/2021	2
Vivanta Generics s.r.o.	Marketing authorisation application	22/06/2022	2
<b>A10BD07 metformin and sitagliptin Sitagliptin monohydrate phosphate, Metformin hydrochloride</b>			
Zentiva k.s.	Marketing authorisation application	23/12/2022	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>			
Sandoz Hungaria Kft.	Marketing authorisation application	03/07/2023	2
<b>A10BH01 sitagliptin Sitagliptin hydrochloride</b>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/09/2021	3
UAB Sanoswiss	Marketing authorisation application	15/12/2021	2
<b>A10BH01 sitagliptin Sitagliptin monohydrate phosphate</b>			
Zentiva, k.s.	Marketing authorisation application	01/03/2022	3
Morningside Healthcare (Malta) Limited	Marketing authorisation application	22/11/2023	3
<b>A10BH05 linagliptin Linagliptin</b>			
Galenicum Health S.L.U	Marketing authorisation application	21/10/2022	1
Viatrix Limited	Marketing authorisation application	16/12/2022	1
Sandoz Hungaria Kft.	Marketing authorisation application	28/04/2023	1
Orion Corporation	Marketing authorisation application	01/09/2023	1
Accord Healthcare B.V.	Marketing authorisation application	02/04/2024	1
<b>A10BJ02 liraglutide Liraglutide</b>			
Sandoz A/S	Marketing authorisation application	01/11/2021	1
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	29/12/2022	1
Adalvo Limited	Marketing authorisation application	31/01/2023	1
Cipla Europe NV	Marketing authorisation application	09/03/2023	1
Cipla Europe NV	Marketing authorisation application	03/04/2023	1

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<b>A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i></b>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	31/01/2024	2
STADA Arzneimittel AG	Marketing authorisation application	01/03/2024	2
Orion Corporation	Marketing authorisation application	25/04/2024	2
<b>A10BK03 empagliflozin <i>Empagliflozin</i></b>			
Devatis GmbH	Marketing authorisation application	11/04/2024	2
<b>A11CC06 calcifediol <i>Calcifediol monohydrate</i></b>			
FAES FARMA, S.A.	Marketing authorisation application	20/04/2023	1
<b>A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i></b>			
Fresenius Kabi AB	Marketing authorisation application	19/10/2023	1
<b>A11EB Vitamin B-complex with vitamin C <i>Ascorbic acid, Thiamine hydrochloride, Nicotinamide, Riboflavin sodium fosfate, Glucose monohydrate, Pyridoxine hydrochloride</i></b>			
Macure Healthcare Limited	Marketing authorisation application	27/12/2023	1
<b>A12AA03 calcium gluconate <i>Calcium gluconate</i></b>			
Macure Healthcare Limited	Marketing authorisation application	25/05/2022	1
<b>A12BA02 potassium citrate <i>Potassium citrate</i></b>			
Vital Pharma Nordic ApS	Marketing authorisation application	05/04/2024	1
<b>A16AA05 carglumic acid <i>Carglumic acid</i></b>			
Waymade B.V.	Marketing authorisation application	02/02/2023	1
<b>A16AX04 nitisinone <i>Nitisinone</i></b>			
Dipharma Arzneimittel GmbH	Marketing authorisation application	25/10/2023	4
<b>B01AC21 treprostinil <i>Treprostinil sodium</i></b>			
Orifarm Oy	Parallel import	09/11/2022	2
<b>B01AC24 ticagrelor <i>Ticagrelor</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/07/2021	2
Accord Healthcare B.V.	Marketing authorisation application	22/02/2023	2
Holsten Pharma GmbH	Marketing authorisation application	13/04/2023	2
<b>B01AE07 dabigatran etexilate <i>Dabigatran etexilate mesilate</i></b>			
Laboratorios Liconsa S.A.	Marketing authorisation application	01/11/2021	3

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<b>B01AF01 rivaroxaban <i>Rivaroxaban</i></b>			
Grindeks AS	Marketing authorisation application	31/12/2021	3
Acino AG	Marketing authorisation application	27/01/2023	6
Tillomed Pharma GmbH	Marketing authorisation application	30/01/2023	5
Sandoz A/S	Marketing authorisation application	01/02/2023	3
Bausch Health Ireland Limited	Marketing authorisation application	31/03/2023	4
Indoco Remedies Czech s.r.o.	Marketing authorisation application	03/08/2023	5
ADOH B.V.	Marketing authorisation application	25/08/2023	4
<b>B01AF02 apixaban <i>Apixaban</i></b>			
Adalvo Limited	Marketing authorisation application	01/07/2022	8
Demo S.A.	Marketing authorisation application	01/07/2022	2
G.L. Pharma GmbH	Marketing authorisation application	01/07/2022	2
Indoco Remedies Czech s.r.o.	Marketing authorisation application	15/08/2022	2
Cipla Europe NV	Marketing authorisation application	31/01/2023	2
Adalvo Limited	Marketing authorisation application	10/02/2023	4
Biogaran	Marketing authorisation application	10/02/2023	2
Doc Generici S.r.l.	Marketing authorisation application	10/02/2023	2
Grindeks AS	Marketing authorisation application	27/07/2023	2
Arriello s.r.o.	Marketing authorisation application	30/08/2023	2
Taw Pharma (Ireland) Limited	Marketing authorisation application	30/08/2023	2
<b>B01AF03 edoxaban <i>Edoxaban tosilate</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	30/06/2023	3
<b>B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i></b>			
Sandoz A/S	Marketing authorisation application	28/07/2023	3
Zentiva k.s.	Marketing authorisation application	02/10/2023	3
Teva GmbH	Marketing authorisation application	29/12/2023	3
Synthon B.V.	Marketing authorisation application	21/03/2024	3
<b>B02AA02 tranexamic acid <i>Tranexamic acid</i></b>			
Tillomed Pharma GmbH	Marketing authorisation application	14/02/2023	1
<b>B02BX05 eltrombopag <i>Eltrombopag olamine</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	15/02/2023	3
KRKA d.d. Novo mesto	Marketing authorisation application	06/03/2023	3
STADA Arzneimittel AG	Marketing authorisation application	30/06/2023	3
Synthon B.V.	Marketing authorisation application	04/04/2024	3
<b>B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i></b>			
Viatriis Limited	Marketing authorisation application	20/12/2022	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>B03BA03 hydroxocobalamin</b> <i>Hydroxocobalamin acetate</i>			
Orion Corporation	Marketing authorisation application	16/06/2022	1
<b>B03BB01 folic acid</b> <i>Folic acid</i>			
Viatriis Oy	Marketing authorisation application	11/07/2022	1
<b>B05BA02 fat emulsions</b> <i>Olive oil, refined, Fish oil, rich in omega-3-acids, Triglycerides, medium-chain, Soya-bean oil, refined</i>			
Noridem Enterprises Limited	Marketing authorisation application	06/02/2024	1
<b>B05BA10 combinations</b> <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
<b>B05BA10 combinations</b> <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
<b>B05BA10 combinations</b> <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
<b>B05BB01 electrolytes</b> <i>Calcium gluconate</i>			
FrostPharma AB	Marketing authorisation application	19/06/2023	1
<b>B05DA Isotonic solutions</b> <i>ICODEXTRIN, Sodium chloride, Sodium (S)-lactate solution, Calcium chloride dihydrate, Magnesium chloride hexahydrate</i>			
Noridem Enterprises Limited	Marketing authorisation application	02/02/2024	1
<b>B05XA07 calcium chloride</b> <i>Calcium chloride dihydrate</i>			
Baxter Holding B.V.	Marketing authorisation application	20/07/2023	1
<b>B05XA16 cardioplegia solutions</b> <i>Procaine hydrochloride, Magnesium sulfate heptahydrate, Potassium chloride, Xylitol</i>			
MIT Gesundheit GmbH	Marketing authorisation application	20/04/2016	1
<b>B05XA31 electrolytes in combination with other drugs</b> <i>Ferric chloride hexahydrate, Zinc chloride, Manganese chloride tetrahydrate, Copper chloride dihydrate, Chromium chloride hexahydrate, Sodium selenite pentahydrate, Sodium molybdate dihydrate, Potassium iodide, Sodium fluoride</i>			
B. Braun Melsungen AG	Marketing authorisation application	10/04/2024	1
<b>C01BB01 lidocaine</b> <i>Lidocaine hydrochloride monohydrate</i>			
Noridem Enterprises Limited	Marketing authorisation application	21/03/2024	1
<b>C01CA02 isoprenaline</b> <i>Isoprenaline</i>			
Laboratorios Tillomed Spain S.L.U	Marketing authorisation application	13/10/2023	2
<b>C01CA03 norepinephrine</b> <i>Noradrenaline tartrate, Norepinephrine</i>			
Noridem Enterprises Limited	Marketing authorisation application	02/02/2022	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>C01CA03 norepinephrine</b> <i>Norepinephrine bitartrate</i>			
Laboratoire Aguettant	Marketing authorisation application	30/01/2024	1
<b>C01CA07 dobutamine</b> <i>Dobutamine hydrochloride</i>			
PANPHARMA	Marketing authorisation application	29/12/2023	1
<b>C01CE02 milrinone</b> <i>Milrinone</i>			
Stragen Nordic A/S	Marketing authorisation application	01/12/2023	1
<b>C01CX08 levosimendan</b> <i>Levosimendan</i>			
Waymade B.V.	Marketing authorisation application	25/01/2022	1
<b>C01EB10 adenosine</b> <i>Adenosine</i>			
Orifarm Oy	Parallel import	10/03/2023	1
<b>C02AC01 clonidine</b> <i>Clonidine hydrochloride</i>			
Macure Pharma ApS	Marketing authorisation application	01/11/2021	1
<b>C02KX01 bosentan</b> <i>Bosentan monohydrate</i>			
Accord Healthcare B.V.	Marketing authorisation application	27/12/2023	1
<b>C02KX04 macitentan</b> <i>Macitentan</i>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	21/12/2023	1
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
Devatis GmbH	Marketing authorisation application	14/03/2024	1
<b>C02KX05 riociguat</b> <i>Riociguat</i>			
Adalvo Limited	Marketing authorisation application	01/11/2023	5
<b>C03XA01 tolvaptan</b> <i>Tolvaptan</i>			
STADA Arzneimittel AG	Marketing authorisation application	30/06/2023	5
<b>C05AE01 glyceryl trinitrate</b> <i>Glycerol trinitrate</i>			
Paranova Oy	Parallel import	25/03/2024	1
<b>C05CX03 hippocastani semen</b> <i>Aesculus hippocastani extractum siccum (lat.), Ethanol</i>			
Sana Pharma Medical AS	Marketing authorisation application	30/08/2023	1
<b>C07AB07 bisoprolol</b> <i>Bisoprolol</i>			
Kappler Pharma Consult GmbH	Marketing authorisation application	28/12/2023	6
<b>C09AA02 enalapril</b> <i>Enalapril maleate</i>			
RIA Generics Limited	Marketing authorisation application	28/04/2023	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>C09CA06 candesartan <i>Candesartan cilexetil</i></b>			
Laboratorios Liconsa S.A.	Marketing authorisation application	28/10/2022	4
<b>C09DA03 valsartan and diuretics <i>Indapamide, Valsartan</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	22/12/2023	1
<b>C09DA06 candesartan and diuretics <i>Indapamide, Candesartan cilexetil</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	28/07/2023	4
<b>C09DA07 telmisartan and diuretics <i>Telmisartan, Indapamide</i></b>			
Pro.Med.Cs Praha a.s.	Marketing authorisation application	14/12/2023	1
<b>C09DA08 olmesartan medoxomil and diuretics <i>Hydrochlorothiazide, Olmesartan medoxomil</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	26/06/2023	4
<b>C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan disodium</i></b>			
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
Devatis GmbH	Marketing authorisation application	27/11/2023	3
Teva GmbH	Marketing authorisation application	04/12/2023	3
<b>C09DX04 valsartan and sacubitril <i>Sacubitril, Valsartan</i></b>			
Viatri Limited	Marketing authorisation application	30/01/2024	3
<b>C10AA05 atorvastatin <i>Atorvastatin calcium</i></b>			
Teva B.V.	Marketing authorisation application	01/06/2022	4
<b>C10AA07 rosuvastatin <i>Rosuvastatin calcium</i></b>			
Sigillata Limited	Marketing authorisation application	30/03/2023	6
Sigillata Limited	Marketing authorisation application	14/12/2023	6
<b>C10AX09 ezetimibe <i>Ezetimibe</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	31/01/2023	1
<b>C10BA05 atorvastatin and ezetimibe <i>Ezetimibe, Atorvastatin calcium trihydrate</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	10/11/2023	1
<b>C10BA05 atorvastatin and ezetimibe <i>Ezetimibe, Atorvastatin calcium</i></b>			
KRKA d.d. Novo mesto	Marketing authorisation application	10/11/2023	3
<b>D01AC01 clotrimazole <i>Clotrimazole</i></b>			
Laboratorios Salvat S.A.	Marketing authorisation application	03/03/2023	1
<b>D06AX01 fusidic acid <i>Fusidic acid</i></b>			
Strides Nordic ApS	Marketing authorisation application	01/12/2023	1

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<b>D07AC13 mometasone</b> <i>Mometasone furoate</i>			
Grindeks AS	Marketing authorisation application	21/10/2022	2
<b>D07CC01 betamethasone and antibiotics</b> <i>Fusidic acid, Betamethasone valerate</i>			
Strides Nordic ApS	Marketing authorisation application	01/12/2023	1
<b>D08AC02 chlorhexidine</b> <i>Chlorhexidine digluconate solution 20 %</i>			
Laboratorios Salvat S.A.	Marketing authorisation application	06/05/2022	1
<b>D08AG02 povidone-iodine</b> <i>Polyvidone-iodine</i>			
Drehm Pharma GmbH	Marketing authorisation application	02/07/2019	1
Mundipharma Oy	Marketing authorisation application	18/07/2019	1
<b>D10AD53 adapalene, combinations</b> <i>Adapalene, Benzoyl peroxide</i>			
STADA Arzneimittel AG	Marketing authorisation application	27/03/2024	2
<b>D11AX01 minoxidil</b> <i>Minoxidil</i>			
Auxilia Pharma OÜ	Marketing authorisation application	31/08/2023	1
<b>G01AX14 lactobacillus</b> <i>Lactobacillus gasseri DSM 14869, Lactobacillus rhamnosus DSM 14870</i>			
Diapharm GmbH & Co. KG	Marketing authorisation application	06/03/2024	1
<b>G02AD06 misoprostol</b> <i>Misoprostol</i>			
Inphena A/S	Marketing authorisation application	06/03/2024	1
<b>G02C OTHER GYNECOLOGICALS</b> <i>Rhapontic rhubarb root dry extract DER (16-26:1)</i>			
Dr. Loges + Co. GmbH	Marketing authorisation application	23/05/2023	1
<b>G03AA16 dienogest and ethinylestradiol</b> <i>Dienogest, Ethinylestradiol</i>			
Exeltis Healthcare S.L.	Marketing authorisation application	14/02/2023	1
<b>G03AD02 ulipristal</b> <i>Ulipristal acetate</i>			
Orifarm Oy	Parallel import	09/04/2024	1
<b>G03BA03 testosterone</b> <i>Testosterone undecanoate</i>			
LOGENEX Pharm GmbH	Marketing authorisation application	11/04/2023	1
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	28/07/2023	1
<b>G03BA03 testosterone</b> <i>Testosterone</i>			
The Simple Pharma Company Limited	Marketing authorisation application	19/12/2023	1
<b>G03CA03 estradiol</b> <i>Estradiol hemihydrate</i>			
Orion Corporation	Marketing authorisation application	17/01/2023	4
Laboratorios Cinfa S.A.	Marketing authorisation application	30/10/2023	2



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<b>G03GA02 human menopausal gonadotrophin <i>Menotropine</i></b>			
Paranova Oy	Parallel import	27/04/2022	2
IBSA Farmaceutici Italia S.r.l	Marketing authorisation application	21/04/2023	2
<b>G04BD12 mirabegron <i>Mirabegron</i></b>			
Sandoz A/S	Marketing authorisation application	25/01/2021	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	03/07/2023	1
Zentiva k.s.	Marketing authorisation application	03/07/2023	1
Avansor Pharma Oy	Marketing authorisation application	22/12/2023	1
Adalvo Limited	Marketing authorisation application	27/12/2023	2
<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>			
Devatis GmbH	Marketing authorisation application	16/02/2024	4
<b>H01BA02 desmopressin <i>Desmopressin acetate trihydrate</i></b>			
Owlpharma Consulting LDA	Marketing authorisation application	06/06/2023	3
<b>H01BA02 desmopressin <i>Desmopressin acetate</i></b>			
Orion Corporation	Marketing authorisation application	29/04/2022	3
<b>H01CB03 lanreotide <i>Lanreotide acetate</i></b>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	01/11/2022	3
Viartis Limited	Marketing authorisation application	17/10/2023	3
Zentiva Pharma GmbH	Marketing authorisation application	17/10/2023	3
<b>H02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	24/03/2022	1
PANPHARMA	Marketing authorisation application	24/01/2024	1
<b>H02AB02 dexamethasone <i>Dexamethasone</i></b>			
2Care4 Generics ApS	Marketing authorisation application	22/08/2023	2
<b>H02AB04 methylprednisolone <i>Methylprednisolone</i></b>			
Orion Corporation	Marketing authorisation application	28/12/2021	2
<b>H02AB09 hydrocortisone <i>Hydrocortisone</i></b>			
Tiofarma B.V.	Marketing authorisation application	21/03/2023	5
Morningside Healthcare (Malta) Limited	Marketing authorisation application	01/03/2024	2
Hualan Pharmaceuticals Limited	Marketing authorisation application	02/04/2024	5
<b>H03AA01 levothyroxine sodium <i>Levothyroxine sodium</i></b>			
Strides Nordic ApS	Marketing authorisation application	23/10/2023	8
SERB	Marketing authorisation application	05/01/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>J01AA02 doxycycline <i>Doxycycline hyclate</i></b>			
Macure Healthcare Limited	Marketing authorisation application	27/03/2024	1
<b>J01AA12 tigecycline <i>Tigecycline</i></b>			
UAB Norameda	Marketing authorisation application	28/11/2023	1
<b>J01CA01 ampicillin <i>Ampicillin sodium</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	28/04/2023	2
Demo S.A.	Marketing authorisation application	30/11/2023	3
<b>J01CE01 benzylpenicillin <i>Benzylpenicillin sodium</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	30/06/2023	4
<b>J01CF02 cloxacillin <i>Cloxacillin sodium</i></b>			
Stragen Nordic A/S	Marketing authorisation application	08/04/2024	1
<b>J01CR01 ampicillin and beta-lactamase inhibitor <i>Ampicillin sodium, Sulbactam sodium</i></b>			
Apta Medica Internacional d.o.o.	Marketing authorisation application	29/09/2023	2
<b>J01DD01 cefotaxime <i>Cefotaxime sodium</i></b>			
Farmaprojects, S.A.U.	Marketing authorisation application	22/09/2023	2
<b>J01DD02 ceftazidime <i>Ceftazidime pentahydrate</i></b>			
Farmaprojects, S.A.U.	Marketing authorisation application	25/03/2024	3
<b>J01DD04 ceftriaxone <i>Ceftriaxone sodium</i></b>			
Farmaprojects, S.A.U.	Marketing authorisation application	26/01/2024	2
<b>J01DH02 meropenem <i>Meropenem trihydrate</i></b>			
Navamedic ASA	Marketing authorisation application	05/04/2023	2
Apta Medica Internacional d.o.o.	Marketing authorisation application	27/03/2024	3
<b>J01DH03 ertapenem <i>Ertapenem sodium</i></b>			
Steriscience B.V.	Marketing authorisation application	25/07/2022	1
Qilu Pharma Spain S.L.	Marketing authorisation application	23/12/2022	1
Apta Medica Internacional d.o.o.	Marketing authorisation application	11/03/2024	1
<b>J01DH51 imipenem and cilastatin <i>Imipenem monohydrate, Cilastatin sodium</i></b>			
Orifarm Oy	Parallel import	10/08/2023	1
<b>J01FA10 azithromycin <i>Azithromycin dihydrate</i></b>			
Orifarm Oy	Parallel import	26/10/2023	1
<b>J01FF01 clindamycin <i>Clindamycin phosphate</i></b>			
AS Kalceks	Marketing authorisation application	21/12/2021	1
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	02/01/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>J01GB03 gentamicin <i>Gentamicin sulfate</i></b>			
Macure Healthcare Limited	Marketing authorisation application	01/11/2023	4
<b>J01MA12 levofloxacin <i>Levofloxacin hemihydrate</i></b>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	08/12/2023	1
<b>J01XA01 vancomycin <i>Vancomycin hydrochloride</i></b>			
Hameln Pharma GmbH	Marketing authorisation application	31/01/2023	2
STADA Arzneimittel AG	Marketing authorisation application	31/10/2023	2
Laboratorio Reig Jofré, S.A.	Marketing authorisation application	22/04/2024	2
<b>J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i></b>			
Adalvo Limited	Marketing authorisation application	24/02/2023	1
Adalvo Limited	Marketing authorisation application	23/11/2023	1
<b>J01XB01 colistin <i>Colistimethate sodium</i></b>			
Noridem Enterprises Limited	Marketing authorisation application	25/01/2024	4
<b>J01XE01 nitrofurantoin <i>Nitrofurantoin</i></b>			
PharmSol Europe Limited	Marketing authorisation application	01/02/2022	2
<b>J01XX09 daptomycin <i>Daptomycin</i></b>			
MIP Pharma GmbH	Marketing authorisation application	26/04/2023	2
<b>J02AA01 amphotericin <i>Amphotericin b</i></b>			
TLC Biopharmaceuticals B.V.	Marketing authorisation application	24/10/2022	1
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	16/11/2022	1
Tillomed Pharma GmbH	Marketing authorisation application	25/05/2023	1
<b>J02AC03 voriconazole <i>Voriconazole</i></b>			
Accord Healthcare Polska Sp. z.o.o.	Marketing authorisation application	18/09/2023	1
<b>J02AC04 posaconazole <i>Posaconazole</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	03/07/2023	1
<b>J02AX05 micafungin <i>Micafungin sodium</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	31/03/2022	2
<b>J05AJ01 raltegravir <i>Raltegravir potassium</i></b>			
LUPIN EUROPE GMBH	Marketing authorisation application	13/02/2023	1
Medical Valley Invest AB	Marketing authorisation application	20/10/2023	1
Viatris Limited	Marketing authorisation application	20/10/2023	1
Vale Pharmaceuticals Limited	Marketing authorisation application	22/12/2023	1
<b>J07BB02 influenza, purified antigen <i>Influenza A virus H1N1, split virion, inactivated, Influenza A virus H3N2, split virion, inactivated, Influenza B virus, split virion, inactivated</i></b>			
Sanofi Winthrop Industrie	Marketing authorisation application	22/03/2024	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>J07BB02 influenza, purified antigen <i>Influenza A virus H1N1, surface antigen, inactivated, Influenza A virus H3N2, surface antigen, inactivated, Influenza B virus, surface antigen, inactivated</i></b>			
Abbott Biologicals B.V.	Marketing authorisation application	02/02/2024	1
<b>J07BB02 influenza, purified antigen <i>Influenza A virus H3N2, split virion, inactivated, Influenza A virus H1N1, split virion, inactivated, Influenza B virus, split virion, inactivated</i></b>			
Sanofi Winthrop Industrie	Marketing authorisation application	01/03/2024	1
<b>L01AA01 cyclophosphamide <i>Cyclophosphamide monohydrate</i></b>			
Atnahs Pharma Netherlands B.V.	Marketing authorisation application	31/08/2021	2
Accord Healthcare S.L.U.	Marketing authorisation application	30/01/2023	1
<b>L01AA03 melphalan <i>Melphalan hydrochloride</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	30/03/2021	1
SPT Healthcare Limited	Marketing authorisation application	29/02/2024	1
<b>L01AD01 carmustine <i>Carmustine</i></b>			
Tillomed Pharma GmbH	Marketing authorisation application	21/08/2023	1
<b>L01BA01 methotrexate <i>Methotrexate</i></b>			
2Care4 Generics ApS	Marketing authorisation application	24/10/2023	2
<b>L01BA04 pemetrexed <i>Pemetrexed disodium heptahydrate</i></b>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	27/05/2022	10
Glenmark Arzneimittel GmbH	Marketing authorisation application	11/07/2022	2
<b>L01BB04 cladribine <i>Cladribine</i></b>			
Atnahs Pharma Netherlands B.V.	Marketing authorisation application	31/08/2023	1
<b>L01BC02 fluorouracil <i>Fluorouracil</i></b>			
Paranova Oy	Parallel import	10/11/2023	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
Hikma Farmacêutica (Portugal) S.A.	Marketing authorisation application	19/04/2024	1
<b>L01CD01 paclitaxel <i>Paclitaxel</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	30/09/2021	1
Panacea Biotec Germany GmbH	Marketing authorisation application	01/08/2023	1
Qilu Pharma Spain S.L.	Marketing authorisation application	16/10/2023	1
<b>L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i></b>			
Reddy Holding GmbH	Marketing authorisation application	01/12/2021	1
<b>L01DB02 daunorubicin <i>Daunorubicin hydrochloride</i></b>			
Hikma Farmaceutica (Portugal), S.A.	Marketing authorisation application	30/12/2022	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L01EA01 imatinib <i>Imatinib</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	01/08/2023	2
<b>L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i></b>			
PharOS - Pharmaceutical Oriented Services Ltd	Marketing authorisation application	26/04/2023	3
<b>L01EA03 nilotinib <i>Nilotinib</i></b>			
Koanaa Healthcare Spain S.L.	Marketing authorisation application	03/07/2023	3
<b>L01EX03 pazopanib <i>Pazopanib hydrochloride</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	01/07/2022	2
Glenmark Pharmaceuticals s.r.o.	Marketing authorisation application	01/09/2023	2
<b>L01EX07 cabozantinib <i>Cabozantinib S-malate</i></b>			
Teva B.V.	Marketing authorisation application	31/03/2023	3
<b>L01EX08 lenvatinib <i>Lenvatinib besilate</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	29/03/2024	2
Sandoz B.V.	Marketing authorisation application	29/03/2024	4
<b>L01EX08 lenvatinib <i>Lenvatinib</i></b>			
Synthon B.V.	Marketing authorisation application	30/11/2023	2
<b>L01EX09 nintedanib <i>Nintedanib esylate</i></b>			
Sandoz A/S	Marketing authorisation application	01/12/2022	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	18/12/2023	2
<b>L01XG01 bortezomib <i>Bortezomib</i></b>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	09/10/2023	1
<b>L01XX27 arsenic trioxide <i>Arsenic trioxide</i></b>			
Tillomed Malta Limited	Marketing authorisation application	02/04/2024	1
<b>L01XX41 eribulin <i>Eribulin mesylate</i></b>			
EVER Valinject GmbH	Marketing authorisation application	21/12/2022	1
Seacross Pharma (Europe) Limited	Marketing authorisation application	03/07/2023	1
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>			
STADA Arzneimittel AG	Marketing authorisation application	15/05/2023	1
Orion Corporation	Marketing authorisation application	03/11/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L02BB04 enzalutamide <i>Enzalutamide</i></b>			
Sandoz A/S	Marketing authorisation application	03/04/2023	2
PharOS - Pharmaceutical Oriented Services Ltd	Marketing authorisation application	01/06/2023	2
PharOS - Pharmaceutical Oriented Services Ltd	Marketing authorisation application	02/06/2023	2
1A Farma A/S	Marketing authorisation application	10/11/2023	1
Teva Nederland B.V.	Marketing authorisation application	27/03/2024	2
<b>L02BG04 letrozole <i>Letrozole</i></b>			
Sandoz B.V.	Marketing authorisation application	22/03/2024	1
<b>L02BX03 abiraterone <i>Abiraterone acetate</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	01/08/2023	2
<b>L04AA27 fingolimod <i>Fingolimod hydrochloride</i></b>			
Devatis GmbH	Marketing authorisation application	20/02/2024	2
<b>L04AA31 teriflunomide <i>Teriflunomide</i></b>			
Heaton k.s.	Marketing authorisation application	20/12/2023	1
Desitin Arzneimittel GmbH	Marketing authorisation application	15/03/2024	1
<b>L04AA32 apremilast <i>Apremilast</i></b>			
Avansor Pharma Oy	Marketing authorisation application	17/01/2023	1
STADA Arzneimittel AG	Marketing authorisation application	30/01/2023	2
Teva B.V.	Marketing authorisation application	31/01/2023	1
Sandoz A/S	Marketing authorisation application	02/02/2023	2
KRKA d.d. Novo mesto	Marketing authorisation application	30/03/2023	2
<b>L04AD02 tacrolimus <i>Tacrolimus monohydrate</i></b>			
Orifarm Healthcare A/S	Marketing authorisation application	29/11/2023	4
<b>L04AE01 fingolimod <i>Fingolimod hydrochloride</i></b>			
Pharmaselect International Beteiligungs GmbH	Marketing authorisation application	06/10/2021	1
<b>L04AK02 teriflunomide <i>Teriflunomide</i></b>			
Olainfarm AS	Marketing authorisation application	25/10/2023	1
<b>L04AX03 methotrexate <i>Methotrexate disodium</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	25/01/2024	10
<b>L04AX03 methotrexate <i>Methotrexate</i></b>			
2Care4 Generics ApS	Marketing authorisation application	24/10/2023	2
<b>L04AX05 pifenedione <i>Pifenedione</i></b>			
Cipla Europe NV	Marketing authorisation application	29/11/2022	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>L04AX06 pomalidomide Pomalidomide</b>			
Avansor Pharma Oy	Marketing authorisation application	09/08/2023	4
Devatis GmbH	Marketing authorisation application	09/08/2023	4
Glenmark Arzneimittel GmbH	Marketing authorisation application	09/08/2023	4
STADA Arzneimittel AG	Marketing authorisation application	09/08/2023	4
Sandoz A/S	Marketing authorisation application	09/08/2023	4
Grindeks AS	Marketing authorisation application	10/08/2023	4
Olainfarm AS	Marketing authorisation application	29/09/2023	4
Bioglan Ab	Marketing authorisation application	27/02/2024	3
<b>L04AX07 dimethyl fumarate Dimethyl fumarate</b>			
Bausch Health Ireland Limited	Marketing authorisation application	28/10/2022	2
Orion Corporation	Marketing authorisation application	29/11/2022	2
ratiopharm GmbH	Marketing authorisation application	30/11/2022	2
1A Farma A/S	Marketing authorisation application	30/12/2022	2
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	04/09/2023	2
Teva GmbH	Marketing authorisation application	27/12/2023	2
STADA Nordic ApS	Marketing authorisation application	01/03/2024	2
Adalvo Limited	Marketing authorisation application	13/03/2024	1
<b>M01AB05 diclofenac Diclofenac epolamine</b>			
ADOH B.V.	Marketing authorisation application	14/02/2024	1
<b>M01AE01 ibuprofen Ibuprofen</b>			
Strides Pharma (Cyprus) Limited	Marketing authorisation application	06/05/2020	3
Fairmed Healthcare GmbH	Marketing authorisation application	07/05/2020	3
Pharmaclan s.r.o.	Marketing authorisation application	03/05/2021	2
Pharmaclan s.r.o.	Marketing authorisation application	24/08/2021	1
Orion Corporation	Marketing authorisation application	26/08/2022	2
Fysioline Oy	Marketing authorisation application	07/08/2023	1
Strides Nordic ApS	Marketing authorisation application	02/04/2024	3
<b>M01AE02 naproxen Naproxen</b>			
Accord Healthcare B.V.	Marketing authorisation application	01/10/2020	2
<b>M01AE51 ibuprofen, combinations Ibuprofen, Paracetamol</b>			
ratiopharm GmbH	Marketing authorisation application	19/04/2024	1
<b>M01AE52 naproxen and esomeprazole Naproxen, Esomeprazole magnesium trihydrate, Esomeprazole magnesium</b>			
Sandoz A/S	Marketing authorisation application	17/10/2022	1
<b>M01AH04 parecoxib Parecoxib sodium</b>			
Macure Healthcare Limited	Marketing authorisation application	30/11/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>M01AH05 etoricoxib</b> <i>Etoricoxib</i>			
Strides Nordic ApS	Marketing authorisation application	20/11/2023	4
<b>M01AX25 chondroitin sulfate</b> <i>Chondroitin sulphate sodium</i>			
mediReg Doradztwo Farmaceutyczne Przemysław Chudy	Marketing authorisation application	29/04/2022	1
<b>M02AA15 diclofenac</b> <i>Diclofenac diethylamine</i>			
STADA Arzneimittel AG	Marketing authorisation application	05/04/2024	1
<b>M03AB01 suxamethonium</b> <i>Suxamethonium chloride</i>			
Abboxia AB	Marketing authorisation application	25/08/2023	1
<b>M03AC09 rocuronium bromide</b> <i>Rocuronium bromide</i>			
Accord Healthcare B.V.	Marketing authorisation application	31/05/2021	1
<b>M03AX01 botulinum toxin</b> <i>Botulinum toxin type A</i>			
Galderma International	Marketing authorisation application	24/07/2023	1
<b>M04AC01 colchicine</b> <i>Colchicine</i>			
Indoco Remedies Czech s.r.o.	Marketing authorisation application	26/01/2022	1
<b>M05BA07 risedronic acid</b> <i>Risedronate sodium hemipentahydrate</i>			
Orifarm Oy	Parallel import	18/04/2024	1
<b>M05BA08 zoledronic acid</b> <i>Zoledronic acid monohydrate</i>			
Seacross Pharma (Europe) Limited	Marketing authorisation application	02/01/2023	1
<b>N01BB01 bupivacaine</b> <i>Bupivacaine hydrochloride monohydrate</i>			
Dextreg	Marketing authorisation application	20/11/2023	1
<b>N01BB02 lidocaine</b> <i>Lidocaine hydrochloride monohydrate</i>			
UAB Baltijos Bite	Marketing authorisation application	23/12/2021	2
Noridem Enterprises Limited	Marketing authorisation application	21/03/2024	2
<b>N01BB52 lidocaine, combinations</b> <i>Lidocaine hydrochloride monohydrate, Adrenaline tartrate</i>			
Dextreg	Marketing authorisation application	30/01/2024	2
<b>N02AE01 buprenorphine</b> <i>Buprenorphine hydrochloride</i>			
G.L. Pharma GmbH	Marketing authorisation application	30/08/2023	2
<b>N02BA51 acetylsalicylic acid, combinations excl. psycholeptics</b> <i>Acetylsalicylic acid, Caffeine, Ascorbic acid</i>			
Orifarm Healthcare A/S	Marketing authorisation application	22/03/2024	1
<b>N02BE51 paracetamol, combinations excl. psycholeptics</b> <i>Ibuprofen, Paracetamol</i>			
Vale Pharmaceuticals Limited	Marketing authorisation application	09/10/2023	1



Applicant	Nature of the application	Application receipt date	Number of applications
<b>N02BF01 gabapentin <i>Gabapentin</i></b>			
Orifarm Oy	Parallel import	03/07/2023	1
ratiopharm GmbH	Marketing authorisation application	25/09/2023	2
Oresund Pharma ApS	Marketing authorisation application	01/12/2023	1
<b>N02CC05 almotriptan <i>Almotriptan D,L-hydrogen malate</i></b>			
Paranova Oy	Parallel import	09/02/2024	1
<b>N03AX09 lamotrigine <i>Lamotrigine</i></b>			
Syri Pharma Limited	Marketing authorisation application	31/08/2023	1
Ptr Pharma Consulting Unipessoal Lda.	Marketing authorisation application	08/01/2024	5
<b>N03AX14 levetiracetam <i>Levetiracetam</i></b>			
C4 health GmbH	Marketing authorisation application	22/12/2023	4
Noridem Enterprises Limited	Marketing authorisation application	12/03/2024	1
<b>N03AX15 zonisamide <i>Zonisamide</i></b>			
Desitin Arzneimittel GmbH	Marketing authorisation application	28/03/2024	1
<b>N03AX17 stiripentol <i>Stiripentol</i></b>			
Billev Pharma ApS	Marketing authorisation application	12/12/2022	4
<b>N03AX18 lacosamide <i>Lacosamide</i></b>			
Strides Pharma (Cyprus) Limited	Marketing authorisation application	22/03/2023	1
As Grindex	Marketing authorisation application	22/12/2023	4
<b>N03AX23 brivaracetam <i>Brivaracetam</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	19/01/2024	5
Holsten Pharma GmbH	Marketing authorisation application	22/01/2024	5
Teva B.V.	Marketing authorisation application	22/01/2024	5
Glenmark Arzneimittel GmbH	Marketing authorisation application	25/01/2024	5
Accord Healthcare B.V.	Marketing authorisation application	30/01/2024	5
Exeltis Healthcare S.L.	Marketing authorisation application	02/05/2024	4
<b>N04BA02 levodopa and decarboxylase inhibitor <i>Levodopa, Carbidopa monohydrate</i></b>			
Orion Corporation	Marketing authorisation application	28/02/2023	1
<b>N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor <i>Levodopa, Carbidopa monohydrate, Entacapone</i></b>			
Neuraxpharm Sweden AB	Marketing authorisation application	29/05/2023	7
<b>N04BC09 rotigotine <i>Rotigotine</i></b>			
Luye Pharma AG	Marketing authorisation application	11/04/2024	6
<b>N04BD03 safinamide <i>Safinamide methanesulfonate</i></b>			
Vivanta Generics s.r.o.	Marketing authorisation application	19/09/2023	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N05AA02 levomepromazine <i>Levomepromazine maleate</i></b>			
Morningside Healthcare (Malta) Limited	Marketing authorisation application	29/03/2024	2
<b>N05AD08 droperidol <i>Droperidol</i></b>			
Dextreg	Marketing authorisation application	27/02/2023	2
<b>N05AE05 lurasidone <i>Lurasidone hydrochloride</i></b>			
Accord Healthcare B.V.	Marketing authorisation application	21/12/2022	3
<b>N05AH02 clozapine <i>Clozapine</i></b>			
Drehm Pharma GmbH	Marketing authorisation application	01/08/2022	2
Viatrix Oy	Marketing authorisation application	29/06/2023	1
Grindeks AS	Marketing authorisation application	27/09/2023	2
Viatrix Healthcare GmbH	Marketing authorisation application	18/12/2023	4
<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
<b>N05AX12 aripiprazole <i>Aripiprazole monohydrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	28/03/2024	1
Sandoz A/S	Marketing authorisation application	02/04/2024	2
<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>			
Exeltis Healthcare S.L.	Marketing authorisation application	31/10/2022	5
Sandoz A/S	Marketing authorisation application	01/02/2023	5
Viatrix Limited	Marketing authorisation application	01/12/2023	12
<b>N05BA06 lorazepam <i>Lorazepam</i></b>			
Macure Pharma ApS	Marketing authorisation application	17/01/2024	1
Orion Corporation	Marketing authorisation application	26/04/2024	1
<b>N05BA12 alprazolam <i>Alprazolam</i></b>			
Grindeks AS	Marketing authorisation application	28/10/2021	3
<b>N05BB01 hydroxyzine <i>Hydroxyzine hydrochloride</i></b>			
Orifarm Oy	Parallel import	10/04/2024	1
<b>N05CD08 midazolam <i>Midazolam</i></b>			
Laboratoire Aguettant	Marketing authorisation application	01/03/2023	1
<b>N05CF01 zopiclone <i>Zopiclone</i></b>			
Grindeks AS	Marketing authorisation application	25/07/2022	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N05CH01 melatonin <i>Melatonin</i></b>			
Glenmark Arzneimittel GmbH	Marketing authorisation application	08/11/2023	1
Pierpaoli Exelyas S.r.l.	Marketing authorisation application	30/11/2023	2
Newbury Pharmaceuticals AB	Marketing authorisation application	20/12/2023	1
Pharma Nord ApS	Marketing authorisation application	21/12/2023	1
Morningside Healthcare (Malta) Limited	Marketing authorisation application	01/03/2024	1
<b>N05CM18 dexmedetomidine <i>Dexmedetomidine hydrochloride</i></b>			
B. Braun Melsungen AG	Marketing authorisation application	27/04/2023	2
Hameln Pharma GmbH	Marketing authorisation application	31/08/2023	1
<b>N06AA09 amitriptyline <i>Amitriptyline hydrochloride</i></b>			
Neuraxpharm Sweden AB	Marketing authorisation application	03/04/2024	1
<b>N06AA10 nortriptyline <i>Nortriptyline hydrochloride</i></b>			
Double-E Pharma Ltd	Marketing authorisation application	17/04/2024	2
<b>N06AB06 sertraline <i>Sertraline hydrochloride</i></b>			
RIA Generics Limited	Marketing authorisation application	22/05/2023	2
<b>N06AF04 tranylcypromine <i>Tranylcypromine sulphate</i></b>			
Abboxia AB	Marketing authorisation application	25/09/2023	1
<b>N06AX11 mirtazapine <i>Mirtazapine</i></b>			
Grindeks AS	Marketing authorisation application	12/10/2023	3
<b>N06AX12 bupropion <i>Bupropion hydrochloride</i></b>			
Paranova Oy	Parallel import	15/01/2019	1
Omet Pharma AB	Marketing authorisation application	07/03/2022	1
Aliud Pharma GmbH&Co. KG	Marketing authorisation application	12/03/2024	2
<b>N06AX16 venlafaxine <i>Venlafaxine hydrochloride</i></b>			
Cipla Europe NV	Marketing authorisation application	02/05/2023	4
<b>N06AX26 vortioxetine <i>Vortioxetine hydrobromide</i></b>			
Adalvo Limited	Marketing authorisation application	08/07/2022	4
Viatriis Limited	Marketing authorisation application	01/12/2023	4
<b>N06BA02 dexamfetamine <i>Dexamphetamine sulphate</i></b>			
Sea Pharma AB	Marketing authorisation application	21/02/2024	3
<b>N06BA12 lisdexamfetamine <i>Lisdexamfetamine dimesylate</i></b>			
Orion Corporation	Marketing authorisation application	30/11/2022	6
<b>N06DX01 memantine <i>Memantine hydrochloride</i></b>			
UAB Baltijos Bite	Marketing authorisation application	01/12/2023	2

Applicant	Nature of the application	Application receipt date	Number of applications
<b>N07AA Anticholinesterases <i>Ipidacrine hydrochloride monohydrate</i></b>			
Grindeks AS	Marketing authorisation application	13/10/2022	3
<b>N07BA01 nicotine <i>Nicotine resinate</i></b>			
Haleon Denmark ApS	Marketing authorisation application	30/06/2023	8
<b>N07BA03 varenicline <i>Varenicline tartrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	29/05/2020	3
Brancaster Pharma Ireland Ltd.	Marketing authorisation application	14/08/2023	3
Medichem S.A.	Marketing authorisation application	29/01/2024	2
Viartis Limited	Marketing authorisation application	29/02/2024	3
Orion Corporation	Marketing authorisation application	28/03/2024	3
<b>N07CA01 betahistine <i>Betahistine dihydrochloride</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	30/03/2023	3
<b>P01AB01 metronidazole <i>Metronidazole</i></b>			
DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH	Marketing authorisation application	26/07/2021	2
<b>P01CX01 pentamidine isethionate <i>Pentamidine diisetonate</i></b>			
Tillomed Pharma GmbH	Marketing authorisation application	30/12/2022	1
<b>P02CF01 ivermectin <i>Ivermectin</i></b>			
Orifarm Healthcare A/S	Marketing authorisation application	26/06/2023	1
Glenmark Arzneimittel GmbH	Marketing authorisation application	30/06/2023	1
<b>P03AA54 disulfiram, combinations <i>Disulfiram, Benzyl benzoate</i></b>			
Bioglan AB	Marketing authorisation application	28/03/2024	1
<b>QA03FA01 metoclopramide <i>Metoclopramide hydrochloride monohydrate</i></b>			
ADOH B.V.	Marketing authorisation application	11/04/2024	1
<b>QA12AX Calcium, combinations with vitamin D and/or other drugs <i>Calcium gluconate, Magnesium chloride hexahydrate</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	29/10/2020	2
<b>QC01CE90 pimobendane <i>Pimobendan</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	18/10/2021	5
Boehringer Ingelheim Vetmedica GmbH	Marketing authorisation application	15/04/2024	1
<b>QC09AA07 benazepril <i>Benazepril hydrochloride</i></b>			
Virbac	Marketing authorisation application	26/02/2024	1
<b>QC09CA07 telmisartan <i>Telmisartan</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	07/03/2022	1
<b>QG04BX91 phenylpropanolamine <i>Phenylpropanolamine hydrochloride</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	21/03/2022	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>QH02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i></b>			
Curados B.V.	Marketing authorisation application	20/07/2020	1
<b>QH02CA01 trilostane <i>Trilostane</i></b>			
Dechra Regulatory B.V.	Marketing authorisation application	30/06/2023	4
Dechra Regulatory B.V.	Marketing authorisation application	21/02/2024	1
<b>QH03AA01 levothyroxine sodium <i>Levothyroxine sodium</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	04/11/2022	8
<b>QH03BB02 thiamazole <i>Thiamazole</i></b>			
Dechra Regulatory B.V.	Marketing authorisation application	24/10/2022	1
<b>QI01AD07 Avian infectious bronchitis virus vaccine <i>Avian infectious bronchitis virus, live, attenuated</i></b>			
Ceva Sante Animale	Marketing authorisation application	05/07/2023	1
<b>QI02AP01 Trichophyton vaccine <i>Trichophyton verrucosum, live, attenuated</i></b>			
Salfarm Danmark A/S	Marketing authorisation application	08/03/2024	1
<b>QI09AB08 Escherichia vaccine + Clostridium vaccine <i>Rotavirus suis OSU 6, group A, Escherichia coli O 149:K88 ac (F4), Escherichia coli O 101:K99 (F5;F41), Escherichia coli K85:987P (F6), Clostridium perfringens toxoid β</i></b>			
Bioveta a.s.	Marketing authorisation application	20/03/2023	1
<b>QJ01CA04 amoxicillin <i>Amoxicillin trihydrate</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	15/06/2022	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	13/03/2024	1
<b>QJ01FA90 tylosin <i>Tylosin</i></b>			
Dopharma Research B.V.	Marketing authorisation application	18/04/2023	1
<b>QJ02AC02 itraconazole <i>Itraconazole</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	12/11/2021	1
<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
HuVepharma	Marketing authorisation application	09/05/2022	1
Alfasan Nederland B.V.	Marketing authorisation application	03/11/2022	2
HuVepharma	Marketing authorisation application	31/01/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>QM01AE91 carprofen</b> <i>Carprofen</i>			
Alfasan Nederland B.V.	Marketing authorisation application	07/12/2022	2
<b>QM01AH91 robenacoxib</b> <i>Robenacoxib</i>			
Fatro S.p.A.	Marketing authorisation application	28/11/2023	3
<b>QN01AX03 ketamine</b> <i>Ketamine hydrochloride</i>			
Alfasan Nederland B.V.	Marketing authorisation application	14/01/2021	1
<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>QN02AF01 butorphanol</b> <i>Butorphanol Tartrate</i>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	17/10/2023	1
<b>QN02AX02 tramadol</b> <i>Tramadol hydrochloride</i>			
Laboratoire TVM	Marketing authorisation application	12/10/2020	1
Alfasan Nederland B.V.	Marketing authorisation application	05/12/2022	6
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	18/01/2023	4
<b>QN03AA02 phenobarbital</b> <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
<b>QN04BC02 Pergolide</b> <i>Pergolide mesilate</i>			
Alfasan Nederland B.V.	Marketing authorisation application	12/04/2023	3
<b>QN05CD08 midazolam</b> <i>Midazolam</i>			
Dechra Regulatory B.V.	Marketing authorisation application	23/10/2023	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</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>			
Alfasan Nederland B.V.	Marketing authorisation application	07/06/2021	1
<b>QP51BC03 diclazuril</b> <i>Diclazuril</i>			
HuVepharma	Marketing authorisation application	22/01/2024	1
<b>QP52AA51 praziquantel, combinations</b> <i>Praziquantel, Emodepside</i>			
KRKA, d.d., Novo mesto	Marketing authorisation application	04/04/2024	3

Applicant	Nature of the application	Application receipt date	Number of applications
<b>QP52AA51 praziquantel, combinations <i>Praziquantel, Pyrantel embonate, Febantel</i></b>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	08/06/2023	2
<b>QP52AA51 praziquantel, combinations <i>Praziquantel, Pyrantel embonate</i></b>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	06/04/2023	1
<b>QP54AA01 ivermectin <i>Ivermectin</i></b>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	17/10/2023	1
<b>QP54AA04 eprinomectin <i>Eprinomectin</i></b>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	07/07/2015	1
<b>QP54AB51 milbemycin oxime, combinations <i>Milbemycin oxime, Praziquantel</i></b>			
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	27/10/2017	1
Alfasan Nederland B.V.	Marketing authorisation application	09/02/2021	6
Ceva Sante Animale	Marketing authorisation application	01/07/2022	5
Virbac	Marketing authorisation application	21/06/2023	3
ALFAMED	Marketing authorisation application	14/09/2023	4
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	26/10/2023	2
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	23/01/2024	1
Chanelle Pharmaceuticals Manufacturing Limited	Marketing authorisation application	29/01/2024	2
<b>QR03CC13 clenbuterol <i>Clenbuterol hydrochloride</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	05/03/2024	1
<b>QS01AA01 chloramphenicol <i>Chloramphenicol</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	22/03/2024	1
<b>QS01AA11 gentamicin <i>Gentamicin sulfate</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	06/04/2023	1
<b>QS01CA01 dexamethasone and antiinfectives <i>Chloramphenicol, Dexamethasone sodium phosphate</i></b>			
CP-Pharma Handelsgesellschaft mbH	Marketing authorisation application	22/03/2024	1
<b>QV03AB90 atipamezole <i>Atipamezole hydrochloride</i></b>			
Alfasan Nederland B.V.	Marketing authorisation application	02/06/2022	1
<b>R01AA09 tramazoline <i>Tramazoline hydrochloride monohydrate</i></b>			
PharOS - Pharmaceutical Oriented Services Ltd	Marketing authorisation application	03/05/2023	1
<b>R01AC02 levocabastine <i>Levocabastine</i></b>			
Paranova Oy	Parallel import	03/10/2023	1
<b>R01AD11 triamcinolone <i>Triamcinolone acetoneide</i></b>			
Medipha Sante	Marketing authorisation application	01/04/2022	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>R01AD12 fluticasone furoate <i>Fluticasone furoate</i></b>			
Substipharm	Marketing authorisation application	30/11/2021	1
Teva B.V.	Marketing authorisation application	16/12/2022	1
<b>R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Azelastine, Fluticasone propionate, Fluticasone</i></b>			
Adalvo Limited	Marketing authorisation application	26/02/2024	1
<b>R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Fluticasone propionate</i></b>			
Adalvo Limited	Marketing authorisation application	31/07/2023	2
Especialidades Farmaceuticas Centrum S.A.	Marketing authorisation application	31/07/2023	1
<b>R02AA20 various <i>Lidocaine hydrochloride monohydrate, Amylmetacresol, 2,4-Dichlorobenzylalcohol</i></b>			
Mundipharma Oy	Marketing authorisation application	04/10/2022	1
<b>R02AX01 flurbiprofen <i>Flurbiprofen</i></b>			
Kappler Pharma Consult GmbH	Marketing authorisation application	03/11/2023	1
<b>R02AX03 benzydamine <i>Benzydamine hydrochloride, Cetylpyridinium chloride</i></b>			
KRKA, d.d., Novo mesto	Marketing authorisation application	29/02/2024	1
<b>R03AK08 formoterol and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	12/09/2022	2
Glenmark Arzneimittel GmbH	Marketing authorisation application	03/04/2023	2
Viartis Limited	Marketing authorisation application	14/09/2023	1
Orifarm Healthcare A/S	Marketing authorisation application	02/04/2024	2
Teva B.V.	Marketing authorisation application	02/04/2024	2
<b>R03BA08 ciclesonide <i>Ciclesonide</i></b>			
Orifarm Healthcare A/S	Marketing authorisation application	01/12/2022	3
Glenmark Arzneimittel GmbH	Marketing authorisation application	09/03/2023	2
<b>R03BB04 tiotropium bromide <i>Tiotropium bromide monohydrate</i></b>			
STADA Arzneimittel AG	Marketing authorisation application	22/12/2021	1
<b>R06AE07 cetirizine <i>Cetirizine dihydrochloride</i></b>			
Orifarm Oy	Parallel import	16/04/2024	1
<b>R06AX27 desloratadine <i>Desloratadine</i></b>			
Pharmacons ApS	Marketing authorisation application	29/08/2022	1
Kappler Pharma Consult GmbH	Marketing authorisation application	31/08/2023	1
<b>S01AX15 propamidine <i>Propamidine isethionate</i></b>			
Horus Pharma	Marketing authorisation application	01/06/2023	1
<b>S01BA Corticosteroids, plain <i>Clobetasol propionate</i></b>			
Laboratorios Salvat S.A.	Marketing authorisation application	23/02/2024	1



Applicant	Nature of the application	Application receipt date	Number of applications
<b>S01CA01 dexamethasone and antiinfectives</b> <i>Dexamethasone sodium phosphate, Levofloxacin hemihydrate</i>			
Paranova Oy	Parallel import	06/02/2024	1
<b>S01EA05 brimonidine</b> <i>Brimonidine tartrate</i>			
Pharmathen S.A.	Marketing authorisation application	29/04/2022	1
<b>S01EC03 dorzolamide</b> <i>Dorzolamide hydrochloride</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	10/07/2023	1
<b>S01ED51 timolol, combinations</b> <i>Bimatoprost, Timolol</i>			
Laboratoires Thea	Marketing authorisation application	12/02/2024	1
<b>S01ED51 timolol, combinations</b> <i>Dorzolamide hydrochloride, Timolol maleate</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	12/06/2023	1
<b>S01ED51 timolol, combinations</b> <i>Tafuprost, Timolol maleate</i>			
Santen Oy	Marketing authorisation application	14/06/2023	1
<b>S01ED51 timolol, combinations</b> <i>Travoprost, Timolol maleate</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	11/04/2023	1
<b>S01EE01 latanoprost</b> <i>Latanoprost</i>			
Pharmabide Ltd	Marketing authorisation application	03/03/2023	1
Pharmabide Ltd	Marketing authorisation application	12/12/2023	1
<b>S01EE04 travoprost</b> <i>Travoprost</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	20/01/2023	1
<b>S01GA07 brimonidine</b> <i>Brimonidine tartrate</i>			
Bausch + Lomb Ireland Limited	Marketing authorisation application	25/09/2023	1
<b>S01GX02 levocabastine</b> <i>Levocabastine</i>			
Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Marketing authorisation application	23/11/2023	1
<b>S01HA02 oxybuprocaine</b> <i>Oxybuprocaine hydrochloride</i>			
AGEPHA Pharma s.r.o	Marketing authorisation application	13/01/2022	1
<b>S01XA18 ciclosporin</b> <i>Ciclosporin</i>			
Sun Pharmaceutical Industries Europe B.V.	Marketing authorisation application	12/10/2022	1
<b>S02CA05 fluocinolone acetonide and antiinfectives</b> <i>Ciprofloxacin hydrochloride, Fluocinolone acetonide</i>			
Paranova Oy	Parallel import	18/03/2024	1
<b>V01AA07 insects</b> <i>Vespula venom</i>			
ALK-Abello A/S	Marketing authorisation application	12/03/2024	2
<b>V03AB23 acetylcysteine</b> <i>Acetylcysteine</i>			
Macure Healthcare Limited	Marketing authorisation application	19/05/2023	1

Applicant	Nature of the application	Application receipt date	Number of applications
<b>V03AB35 sugammadex</b> <i>Sugammadex sodium</i> Accord Healthcare B.V.	Marketing authorisation application	30/01/2023	2
<b>V04CH02 indigo carmine</b> <i>Indigo carmine</i> SERB S.A.	Marketing authorisation application	28/04/2023	1
<b>V08AD01 ethyl esters of iodised fatty acids</b> <i>Ethiodized oil</i> Guerbet	Marketing authorisation application	22/02/2021	1
<b>V09GA01 technetium (99mTc) sestamibi</b> <i>Stannous chloride dihydrate, Tetrakis (2-methoxy isobutyl isonitrile) copper (I) tetrafluoroborate</i> Radiopharmacy Laboratorium Kft.	Marketing authorisation application	28/06/2023	1
<b>V09IX14 gallium (68Ga) gozetotide</b> <i>Gallium (68Ga) gozetotide</i> Telix Innovations	Marketing authorisation application	28/04/2023	1
<b>V10XA01 sodium iodide (131I)</b> <i>Sodium iodide</i> Narodowe Centrum Badán Jadrowych	Marketing authorisation application	31/01/2024	1