

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| A02AH Antacids with sodium bicarbonate <i>Sodium hydrogen carbonate</i> | | | |
| Ptr Pharma Consulting Unipessoal Lda. | Marketing authorisation application | 28/02/2024 | 1 |
| A02BC01 omeprazole <i>Omeprazole</i> | | | |
| Inn - Farm Družba Za Trgovino In Storitve d.o.o. | Marketing authorisation application | 30/06/2022 | 2 |
| A02BC02 pantoprazole <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 |
| A02BC05 esomeprazole <i>Esomeprazole magnesium trihydrate</i> | | | |
| Hexal A/S | Marketing authorisation application | 29/09/2023 | 2 |
| A02BC05 esomeprazole <i>Esomeprazole sodium</i> | | | |
| Oresund Pharma ApS | Marketing authorisation application | 28/02/2023 | 1 |
| A02BX Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) <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 |
| A03AX Other drugs for functional gastrointestinal disorders <i>Peppermint oil</i> | | | |
| Sana Pharma Medical AS | Marketing authorisation application | 31/01/2023 | 1 |
| A03AX13 silicones <i>Simethicone</i> | | | |
| CLINRES FARMACIJA raziskave d.o.o. | Marketing authorisation application | 26/06/2023 | 1 |
| A03FA01 metoclopramide <i>Metoclopramide hydrochloride monohydrate</i> | | | |
| G.L. Pharma GmbH | Marketing authorisation application | 03/05/2023 | 1 |
| A04AA01 ondansetron <i>Ondansetron</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 16/02/2023 | 2 |
| A06AB08 sodium picosulfate <i>Sodium picosulfate monohydrate</i> | | | |
| Paranova Oy | Parallel import | 16/02/2024 | 1 |
| A06AG11 laurilsulfate, incl. combinations <i>Sodium lauryl sulfoacetate, Sorbitol, liquid (crystallising)</i> | | | |
| Laboratorios Liconsa S.A. | Marketing authorisation application | 22/01/2024 | 1 |
| A07AA02 nystatin <i>Nystatin</i> | | | |
| Orifarm Oy | Parallel import | 09/04/2024 | 1 |
| A07EC02 mesalazine <i>Mesalazine</i> | | | |
| Dr. Falk Pharma GmbH | Marketing authorisation application | 01/02/2024 | 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.) Pancreas powder | | | |
| AVVA Pharmaceuticals Ltd. | Marketing authorisation application | 14/07/2020 | 2 |
| A10BA02 metformin Metformin hydrochloride | | | |
| 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 |
| A10BD07 metformin and sitagliptin Sitagliptin hydrochloride monohydrate, Metformin hydrochloride | | | |
| Pharmathen S.A. | Marketing authorisation application | 01/08/2022 | 2 |
| A10BD07 metformin and sitagliptin Sitagliptin hydrochloride, Metformin hydrochloride | | | |
| UAB Sanoswiss | Marketing authorisation application | 15/12/2021 | 2 |
| Vivanta Generics s.r.o. | Marketing authorisation application | 22/06/2022 | 2 |
| A10BD07 metformin and sitagliptin Sitagliptin monohydrate phosphate, Metformin hydrochloride | | | |
| Zentiva k.s. | Marketing authorisation application | 23/12/2022 | 2 |
| A10BD08 metformin and vildagliptin Vildagliptin, Metformin hydrochloride | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 02/08/2021 | 2 |
| A10BD11 metformin and linagliptin Linagliptin, Metformin hydrochloride | | | |
| Sandoz Hungaria Kft. | Marketing authorisation application | 03/07/2023 | 2 |
| A10BH01 sitagliptin Sitagliptin hydrochloride | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 01/09/2021 | 3 |
| UAB Sanoswiss | Marketing authorisation application | 15/12/2021 | 2 |
| A10BH01 sitagliptin Sitagliptin monohydrate phosphate | | | |
| Zentiva, k.s. | Marketing authorisation application | 01/03/2022 | 3 |
| Morningside Healthcare (Malta) Limited | Marketing authorisation application | 22/11/2023 | 3 |
| A10BH05 linagliptin Linagliptin | | | |
| Galenicum Health S.L.U | Marketing authorisation application | 21/10/2022 | 1 |
| Viatriis 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 |
| A10BJ02 liraglutide Liraglutide | | | |
| 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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|--|-------------------------------------|--------------------------|------------------------|
| A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i> | | | |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 31/01/2024 | 2 |
| STADA Arzneimittel AG | Marketing authorisation application | 01/03/2024 | 2 |
| A10BK02 canagliflozin <i>Canagliflozin</i> | | | |
| Teva B.V. | Marketing authorisation application | 23/11/2021 | 2 |
| A11CC06 calcifediol <i>Calcifediol monohydrate</i> | | | |
| FAES FARMA, S.A. | Marketing authorisation application | 20/04/2023 | 1 |
| A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i> | | | |
| Fresenius Kabi AB | Marketing authorisation application | 19/10/2023 | 1 |
| A11EB Vitamin B-complex with vitamin C <i>Ascorbic acid, Thiamine hydrochloride, Nicotinamide, Riboflavin sodium fosfate, Glucose monohydrate, Pyridoxine hydrochloride</i> | | | |
| Macure Healthcare Limited | Marketing authorisation application | 27/12/2023 | 1 |
| A12AA03 calcium gluconate <i>Calcium gluconate</i> | | | |
| Macure Healthcare Limited | Marketing authorisation application | 25/05/2022 | 1 |
| A12BA02 potassium citrate <i>Potassium citrate</i> | | | |
| Vital Pharma Nordic ApS | Marketing authorisation application | 05/04/2024 | 1 |
| A16AA05 carglumic acid <i>Carglumic acid</i> | | | |
| Waymade B.V. | Marketing authorisation application | 02/02/2023 | 1 |
| A16AX04 nitisinone <i>Nitisinone</i> | | | |
| Dipharma Arzneimittel GmbH | Marketing authorisation application | 25/10/2023 | 4 |
| B01AC06 acetylsalicylic acid <i>Acetylsalicylic acid</i> | | | |
| Asamedic AS | Marketing authorisation application | 28/09/2023 | 1 |
| B01AC21 treprostinil <i>Treprostinil sodium</i> | | | |
| Orifarm Oy | Parallel import | 09/11/2022 | 2 |
| B01AC24 ticagrelor <i>Ticagrelor</i> | | | |
| 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 |
| B01AE07 dabigatran etexilate <i>Dabigatran etexilate mesilate</i> | | | |
| Laboratorios Liconsa S.A. | Marketing authorisation application | 01/11/2021 | 3 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| B01AF01 rivaroxaban <i>Rivaroxaban</i> | | | |
| 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 |
| B01AF02 apixaban <i>Apixaban</i> | | | |
| 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 |
| B01AF03 edoxaban <i>Edoxaban tosilate</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 30/06/2023 | 3 |
| B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i> | | | |
| 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 |
| B02AA02 tranexamic acid <i>Tranexamic acid</i> | | | |
| Tillomed Pharma GmbH | Marketing authorisation application | 14/02/2023 | 1 |
| B02BD03 factor VIII inhibitor bypassing activity <i>Factor VIII inhibitor bypassing activity</i> | | | |
| Baxalta Innovations GmbH | Marketing authorisation application | 15/03/2023 | 1 |
| B02BX05 eltrombopag <i>Eltrombopag olamine</i> | | | |
| 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 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i> | | | |
| Viatris Limited | Marketing authorisation application | 20/12/2022 | 1 |
| B03BA03 hydroxocobalamin <i>Hydroxocobalamin acetate</i> | | | |
| Orion Corporation | Marketing authorisation application | 16/06/2022 | 1 |
| B03BB01 folic acid <i>Folic acid</i> | | | |
| Viatris Oy | Marketing authorisation application | 11/07/2022 | 1 |
| B05BA02 fat emulsions <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 |
| 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>Calcium gluconate</i> | | | |
| FrostPharma AB | Marketing authorisation application | 19/06/2023 | 1 |
| B05DA Isotonic solutions <i>ICODEXTRIN, Sodium chloride, Sodium (S)-lactate solution, Calcium chloride dihydrate, Magnesium chloride hexahydrate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 02/02/2024 | 1 |
| B05XA07 calcium chloride <i>Calcium chloride dihydrate</i> | | | |
| Baxter Holding B.V. | Marketing authorisation application | 20/07/2023 | 1 |
| B05XA16 cardioplegia solutions <i>Procaine hydrochloride, Magnesium sulfate heptahydrate, Potassium chloride, Xylitol</i> | | | |
| MIT Gesundheit GmbH | Marketing authorisation application | 20/04/2016 | 1 |
| C01BB01 lidocaine <i>Lidocaine hydrochloride monohydrate</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 21/03/2024 | 1 |
| C01CA02 isoprenaline <i>Isoprenalin</i> | | | |
| Laboratorios Tillomed Spain S.L.U | Marketing authorisation application | 13/10/2023 | 2 |
| C01CA03 norepinephrine <i>Noradrenaline tartrate, Norepinephrine</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 02/02/2022 | 1 |
| C01CA03 norepinephrine <i>Norepinephrine bitartrate</i> | | | |
| Laboratoire Aguettant | Marketing authorisation application | 30/01/2024 | 1 |

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|---|-------------------------------------|--------------------------|------------------------|
| C01CA07 dobutamine <i>Dobutamine hydrochloride</i> | | | |
| PANPHARMA | Marketing authorisation application | 29/12/2023 | 1 |
| C01CE02 milrinone <i>Milrinone</i> | | | |
| Stragen Nordic A/S | Marketing authorisation application | 01/12/2023 | 1 |
| C01CX08 levosimendan <i>Levosimendan</i> | | | |
| Waymade B.V. | Marketing authorisation application | 25/01/2022 | 1 |
| C01EB10 adenosine <i>Adenosine</i> | | | |
| Orifarm Oy | Parallel import | 10/03/2023 | 1 |
| C02AC01 clonidine <i>Clonidine hydrochloride</i> | | | |
| Macure Pharma ApS | Marketing authorisation application | 01/11/2021 | 1 |
| C02KX01 bosentan <i>Bosentan monohydrate</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 27/12/2023 | 1 |
| C02KX04 macitentan <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 |
| C02KX05 riociguat <i>Riociguat</i> | | | |
| Adalvo Limited | Marketing authorisation application | 01/11/2023 | 5 |
| C03CA01 furosemide <i>Furosemide</i> | | | |
| Laboratórios Basi Indústria Farmacêutica S.A. | Marketing authorisation application | 09/08/2021 | 1 |
| C03XA01 tolvaptan <i>Tolvaptan</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 30/06/2023 | 5 |
| C05AE01 glyceryl trinitrate <i>Glycerol trinitrate</i> | | | |
| Paranova Oy | Parallel import | 25/03/2024 | 1 |
| C05CX03 hippocastani semen <i>Aesculus hippocastani extractum siccum (lat.), Ethanol</i> | | | |
| Sana Pharma Medical AS | Marketing authorisation application | 30/08/2023 | 1 |
| C07AB07 bisoprolol <i>Bisoprolol</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 28/12/2023 | 6 |
| C08CA13 lercanidipine <i>Lercanidipine hydrochloride</i> | | | |
| Omet Pharma AB | Marketing authorisation application | 31/05/2022 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| C09AA02 enalapril <i>Enalapril maleate</i> | | | |
| RIA Generics Limited | Marketing authorisation application | 28/04/2023 | 3 |
| C09CA06 candesartan <i>Candesartan cilexetil</i> | | | |
| Laboratorios Liconsa S.A. | Marketing authorisation application | 28/10/2022 | 4 |
| C09DA03 valsartan and diuretics <i>Indapamide, Valsartan</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 22/12/2023 | 1 |
| C09DA06 candesartan and diuretics <i>Indapamide, Candesartan cilexetil</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 28/07/2023 | 4 |
| C09DA07 telmisartan and diuretics <i>Telmisartan, Indapamide</i> | | | |
| Pro.Med.Cs Praha a.s. | Marketing authorisation application | 14/12/2023 | 1 |
| C09DA08 olmesartan medoxomil and diuretics <i>Hydrochlorothiazide, Olmesartan medoxomil</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 26/06/2023 | 4 |
| 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 |
| Devatis GmbH | Marketing authorisation application | 27/11/2023 | 3 |
| Teva GmbH | Marketing authorisation application | 04/12/2023 | 3 |
| C09DX04 valsartan and sacubitril <i>Sacubitril, Valsartan</i> | | | |
| Viartis Limited | Marketing authorisation application | 30/01/2024 | 3 |
| C10AA05 atorvastatin <i>Atorvastatin calcium</i> | | | |
| Teva B.V. | Marketing authorisation application | 01/06/2022 | 4 |
| C10AA07 rosuvastatin <i>Rosuvastatin calcium</i> | | | |
| Sigillata Limited | Marketing authorisation application | 30/03/2023 | 6 |
| Sigillata Limited | Marketing authorisation application | 14/12/2023 | 6 |
| C10AX09 ezetimibe <i>Ezetimibe</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 31/01/2023 | 1 |
| C10BA05 atorvastatin and ezetimibe <i>Ezetimibe, Atorvastatin calcium trihydrate</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 10/11/2023 | 1 |
| C10BA05 atorvastatin and ezetimibe <i>Ezetimibe, Atorvastatin calcium</i> | | | |
| KRKA d.d. Novo mesto | Marketing authorisation application | 10/11/2023 | 3 |
| D01AC01 clotrimazole <i>Clotrimazole</i> | | | |
| Laboratorios Salvat S.A. | Marketing authorisation application | 03/03/2023 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| D06AX01 fusidic acid <i>Fusidic acid</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 01/12/2023 | 1 |
| D07AC13 mometasone <i>Mometasone furoate</i> | | | |
| Grindeks AS | Marketing authorisation application | 21/10/2022 | 2 |
| D07CC01 betamethasone and antibiotics <i>Fusidic acid, Betamethasone valerate</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 01/12/2023 | 1 |
| D08AC02 chlorhexidine <i>Chlorhexidine digluconate solution 20 %</i> | | | |
| Laboratorios Salvat S.A. | Marketing authorisation application | 06/05/2022 | 1 |
| D08AG02 povidone-iodine <i>Polyvidone-iodine</i> | | | |
| Drehm Pharma GmbH | Marketing authorisation application | 02/07/2019 | 1 |
| 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 |
| D11AX01 minoxidil <i>Minoxidil</i> | | | |
| Auxilia Pharma OÜ | Marketing authorisation application | 31/08/2023 | 1 |
| G01AX14 lactobacillus <i>Lactobacillus gasseri DSM 14869, Lactobacillus rhamnosus DSM 14870</i> | | | |
| Diapharm GmbH & Co. KG | Marketing authorisation application | 06/03/2024 | 1 |
| G02AD06 misoprostol <i>Misoprostol</i> | | | |
| Inphena A/S | Marketing authorisation application | 06/03/2024 | 1 |
| G02C OTHER GYNECOLOGICALS <i>Rhapontic rhubarb root dry extract DER (16-26:1)</i> | | | |
| Dr. Loges + Co. GmbH | Marketing authorisation application | 23/05/2023 | 1 |
| G03AA16 dienogest and ethinylestradiol <i>Dienogest, Ethinylestradiol</i> | | | |
| Exeltis Healthcare S.L. | Marketing authorisation application | 14/02/2023 | 1 |
| G03BA03 testosterone <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 |
| G03BA03 testosterone <i>Testosterone</i> | | | |
| The Simple Pharma Company Limited | Marketing authorisation application | 19/12/2023 | 1 |
| G03CA03 estradiol <i>Estradiol hemihydrate</i> | | | |
| Orion Corporation | Marketing authorisation application | 17/01/2023 | 4 |
| Laboratorios Cinfa S.A. | Marketing authorisation application | 30/10/2023 | 2 |
| G03CA04 estriol <i>Estriol</i> | | | |
| DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH | Marketing authorisation application | 14/03/2022 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| G03GA02 human menopausal gonadotrophin <i>Menotropine</i> | | | |
| Paranova Oy | Parallel import | 27/04/2022 | 2 |
| IBSA Farmaceutici Italia S.r.l | Marketing authorisation application | 21/04/2023 | 2 |
| G04BD12 mirabegron <i>Mirabegron</i> | | | |
| 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 |
| G04BE03 sildenafil <i>Sildenafil citrate</i> | | | |
| ADOH B.V. | Marketing authorisation application | 01/12/2023 | 4 |
| G04BE08 tadalafil <i>Tadalafil</i> | | | |
| Devatis GmbH | Marketing authorisation application | 16/02/2024 | 4 |
| H01BA02 desmopressin <i>Desmopressin acetate trihydrate</i> | | | |
| Owlpharma Consulting LDA | Marketing authorisation application | 06/06/2023 | 3 |
| H01BA02 desmopressin <i>Desmopressin acetate</i> | | | |
| Orion Corporation | Marketing authorisation application | 29/04/2022 | 3 |
| H01CB03 lanreotide <i>Lanreotide acetate</i> | | | |
| 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 |
| H02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 24/03/2022 | 1 |
| PANPHARMA | Marketing authorisation application | 24/01/2024 | 1 |
| H02AB02 dexamethasone <i>Dexamethasone</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 22/08/2023 | 2 |
| H02AB04 methylprednisolone <i>Methylprednisolone</i> | | | |
| Orion Corporation | Marketing authorisation application | 28/12/2021 | 2 |
| H02AB09 hydrocortisone <i>Hydrocortisone</i> | | | |
| 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 |
| H03AA01 levothyroxine sodium <i>Levothyroxine sodium</i> | | | |
| 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 |
|--|-------------------------------------|--------------------------|------------------------|
| J01AA02 doxycycline Doxycycline hyclate | | | |
| Macure Healthcare Limited | Marketing authorisation application | 27/03/2024 | 1 |
| J01AA12 tigecycline Tigecycline | | | |
| UAB Noramed | Marketing authorisation application | 28/11/2023 | 1 |
| J01CA01 ampicillin Ampicillin sodium | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 28/04/2023 | 2 |
| Demo S.A. | Marketing authorisation application | 30/11/2023 | 3 |
| J01CE01 benzylpenicillin Benzylpenicillin sodium | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 30/06/2023 | 4 |
| J01CR01 ampicillin and beta-lactamase inhibitor Ampicillin sodium, Sulbactam sodium | | | |
| Apta Medica Internacional d.o.o. | Marketing authorisation application | 29/09/2023 | 2 |
| J01DD01 cefotaxime Cefotaxime sodium | | | |
| Farmaprojects, S.A.U. | Marketing authorisation application | 22/09/2023 | 2 |
| J01DD02 ceftazidime Ceftazidime pentahydrate | | | |
| Farmaprojects, S.A.U. | Marketing authorisation application | 25/03/2024 | 3 |
| J01DD04 ceftriaxone Ceftriaxone sodium | | | |
| Farmaprojects, S.A.U. | Marketing authorisation application | 26/01/2024 | 2 |
| J01DH02 meropenem Meropenem trihydrate | | | |
| Navamedic ASA | Marketing authorisation application | 05/04/2023 | 2 |
| Apta Medica Internacional d.o.o. | Marketing authorisation application | 27/03/2024 | 3 |
| J01DH03 ertapenem Ertapenem sodium | | | |
| 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 |
| J01DH51 imipenem and cilastatin Imipenem monohydrate, Cilastatin sodium | | | |
| Orifarm Oy | Parallel import | 10/08/2023 | 1 |
| J01FA10 azithromycin Azithromycin dihydrate | | | |
| Orifarm Oy | Parallel import | 26/10/2023 | 1 |
| J01FF01 clindamycin Clindamycin phosphate | | | |
| AS Kalceks | Marketing authorisation application | 21/12/2021 | 1 |
| Hikma Farmacêutica (Portugal) S.A. | Marketing authorisation application | 02/01/2023 | 1 |
| J01GB03 gentamicin Gentamicin sulfate | | | |
| Macure Healthcare Limited | Marketing authorisation application | 01/11/2023 | 4 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| J01MA12 levofloxacin <i>Levofloxacin hemihydrate</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 08/12/2023 | 1 |
| J01XA01 vancomycin <i>Vancomycin hydrochloride</i> | | | |
| Orion Corporation | Marketing authorisation application | 31/10/2022 | 2 |
| Hameln Pharma GmbH | Marketing authorisation application | 31/01/2023 | 2 |
| STADA Arzneimittel AG | Marketing authorisation application | 31/10/2023 | 2 |
| J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i> | | | |
| Adalvo Limited | Marketing authorisation application | 24/02/2023 | 1 |
| Adalvo Limited | Marketing authorisation application | 23/11/2023 | 1 |
| J01XB01 colistin <i>Colistimethate sodium</i> | | | |
| Noridem Enterprises Limited | Marketing authorisation application | 25/01/2024 | 4 |
| J01XE01 nitrofurantoin <i>Nitrofurantoin</i> | | | |
| PharmSol Europe Limited | Marketing authorisation application | 01/02/2022 | 2 |
| J01XX09 daptomycin <i>Daptomycin</i> | | | |
| MIP Pharma GmbH | Marketing authorisation application | 26/04/2023 | 2 |
| J02AA01 amphotericin <i>Amphotericin b</i> | | | |
| 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 |
| J02AC03 voriconazole <i>Voriconazole</i> | | | |
| Accord Healthcare Polska Sp. z.o.o. | Marketing authorisation application | 18/09/2023 | 1 |
| J02AC04 posaconazole <i>Posaconazole</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 03/07/2023 | 1 |
| J02AX05 micafungin <i>Micafungin sodium</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 31/03/2022 | 2 |
| J05AJ01 raltegravir <i>Raltegravir potassium</i> | | | |
| LUPIN EUROPE GMBH | Marketing authorisation application | 13/02/2023 | 1 |
| Medical Valley Invest AB | Marketing authorisation application | 20/10/2023 | 1 |
| Viatrix Limited | Marketing authorisation application | 20/10/2023 | 1 |
| Vale Pharmaceuticals Limited | Marketing authorisation application | 22/12/2023 | 1 |
| 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> | | | |
| Sanofi Winthrop Industrie | Marketing authorisation application | 22/03/2024 | 1 |
| 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> | | | |
| Abbott Biologicals B.V. | Marketing authorisation application | 02/02/2024 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| 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> | | | |
| Sanofi Winthrop Industrie | Marketing authorisation application | 01/03/2024 | 1 |
| L01AA01 cyclophosphamide <i>Cyclophosphamide monohydrate</i> | | | |
| Atnahs Pharma Netherlands B.V. | Marketing authorisation application | 31/08/2021 | 2 |
| Accord Healthcare S.L.U. | Marketing authorisation application | 30/01/2023 | 1 |
| L01AA03 melphalan <i>Melphalan hydrochloride</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 30/03/2021 | 1 |
| SPT Healthcare Limited | Marketing authorisation application | 29/02/2024 | 1 |
| L01AC01 thiotepa <i>Thiotepa</i> | | | |
| SPT Healthcare Limited | Marketing authorisation application | 01/02/2024 | 2 |
| L01AD01 carmustine <i>Carmustine</i> | | | |
| Tillomed Pharma GmbH | Marketing authorisation application | 21/08/2023 | 1 |
| L01BA01 methotrexate <i>Methotrexate</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 24/10/2023 | 2 |
| L01BA04 pemetrexed <i>Pemetrexed disodium heptahydrate</i> | | | |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 27/05/2022 | 10 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 11/07/2022 | 2 |
| L01BB04 cladribine <i>Cladribine</i> | | | |
| Atnahs Pharma Netherlands B.V. | Marketing authorisation application | 31/08/2023 | 1 |
| L01BC02 fluorouracil <i>Fluorouracil</i> | | | |
| Paranova Oy | Parallel import | 10/11/2023 | 1 |
| L01BC07 azacitidine <i>Azacitidine</i> | | | |
| Tarchomińskie Zakłady Farmaceutyczne, Polfa S.A. | Marketing authorisation application | 26/11/2021 | 1 |
| DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH | Marketing authorisation application | 09/01/2023 | 1 |
| ELC GROUP S.R.O. | Marketing authorisation application | 28/06/2023 | 1 |
| L01CD01 paclitaxel <i>Paclitaxel</i> | | | |
| 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 |
| L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i> | | | |
| Reddy Holding GmbH | Marketing authorisation application | 01/12/2021 | 1 |
| L01DB02 daunorubicin <i>Daunorubicin hydrochloride</i> | | | |
| Hikma Farmaceutica (Portugal), S.A. | Marketing authorisation application | 30/12/2022 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| L01EA01 imatinib <i>Imatinib</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 01/08/2023 | 2 |
| L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i> | | | |
| PharOS - Pharmaceutical Oriented Services Ltd | Marketing authorisation application | 26/04/2023 | 3 |
| L01EA03 nilotinib <i>Nilotinib</i> | | | |
| Koanaa Healthcare Spain S.L. | Marketing authorisation application | 03/07/2023 | 3 |
| L01EX03 pazopanib <i>Pazopanib hydrochloride</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 01/07/2022 | 2 |
| Glenmark Pharmaceuticals s.r.o. | Marketing authorisation application | 01/09/2023 | 2 |
| L01EX07 cabozantinib <i>Cabozantinib S-malate</i> | | | |
| Teva B.V. | Marketing authorisation application | 31/03/2023 | 3 |
| L01EX08 lenvatinib <i>Lenvatinib besilate</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 29/03/2024 | 2 |
| Sandoz B.V. | Marketing authorisation application | 29/03/2024 | 4 |
| L01EX08 lenvatinib <i>Lenvatinib</i> | | | |
| Synthon B.V. | Marketing authorisation application | 30/11/2023 | 2 |
| L01EX09 nintedanib <i>Nintedanib esylate</i> | | | |
| Sandoz A/S | Marketing authorisation application | 01/12/2022 | 2 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 18/12/2023 | 2 |
| L01XG01 bortezomib <i>Bortezomib</i> | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 09/10/2023 | 1 |
| L01XX27 arsenic trioxide <i>Arsenic trioxide</i> | | | |
| Tillomed Malta Limited | Marketing authorisation application | 02/04/2024 | 1 |
| L01XX41 eribulin <i>Eribulin mesylate</i> | | | |
| 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 |
| L02BA03 fulvestrant <i>Fulvestrant</i> | | | |
| 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 |
|---|-------------------------------------|--------------------------|------------------------|
| L02BB04 enzalutamide <i>Enzalutamide</i> | | | |
| 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 | 27/02/2024 | 2 |
| L02BG04 letrozole <i>Letrozole</i> | | | |
| Sandoz B.V. | Marketing authorisation application | 22/03/2024 | 1 |
| L02BX03 abiraterone <i>Abiraterone acetate</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 01/08/2023 | 2 |
| L04AA27 fingolimod <i>Fingolimod hydrochloride</i> | | | |
| Devatis GmbH | Marketing authorisation application | 20/02/2024 | 2 |
| L04AA31 teriflunomide <i>Teriflunomide</i> | | | |
| Heaton k.s. | Marketing authorisation application | 20/12/2023 | 1 |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 15/03/2024 | 1 |
| L04AA32 apremilast <i>Apremilast, Apremilast, Apremilast</i> | | | |
| Sandoz A/S | Marketing authorisation application | 02/02/2023 | 1 |
| L04AA32 apremilast <i>Apremilast</i> | | | |
| 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 | 1 |
| KRKA d.d. Novo mesto | Marketing authorisation application | 30/03/2023 | 2 |
| 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 |
| L04AK02 teriflunomide <i>Teriflunomide</i> | | | |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 11/09/2023 | 1 |
| Olainfarm AS | Marketing authorisation application | 25/10/2023 | 1 |
| L04AX03 methotrexate <i>Methotrexate disodium</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 25/01/2024 | 10 |
| L04AX03 methotrexate <i>Methotrexate</i> | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 24/10/2023 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| L04AX05 pirfenidone <i>Pirfenidone</i> | | | |
| Cipla Europe NV | Marketing authorisation application | 29/11/2022 | 2 |
| L04AX06 pomalidomide <i>Pomalidomide</i> | | | |
| 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 |
| L04AX07 dimethyl fumarate <i>Dimethyl fumarate</i> | | | |
| 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 |
| M01AB05 diclofenac <i>Diclofenac epolamine</i> | | | |
| ADOH B.V. | Marketing authorisation application | 14/02/2024 | 1 |
| M01AE01 ibuprofen <i>Ibuprofen</i> | | | |
| 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 |
| M01AE02 naproxen <i>Naproxen</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 01/10/2020 | 2 |
| M01AE52 naproxen and esomeprazole <i>Naproxen, Esomeprazole magnesium trihydrate, Esomeprazole magnesium</i> | | | |
| Sandoz A/S | Marketing authorisation application | 17/10/2022 | 1 |
| M01AH04 parecoxib <i>Parecoxib sodium</i> | | | |
| Macure Healthcare Limited | Marketing authorisation application | 30/11/2023 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| M01AH05 etoricoxib <i>Etoricoxib</i> | | | |
| Strides Nordic ApS | Marketing authorisation application | 20/11/2023 | 4 |
| M01AX25 chondroitin sulfate <i>Chondroitin sulphate sodium</i> | | | |
| mediReg Doradztwo Farmaceutyczne Przemysław Chudy | Marketing authorisation application | 29/04/2022 | 1 |
| M03AB01 suxamethonium <i>Suxamethonium chloride</i> | | | |
| Abboxia AB | Marketing authorisation application | 25/08/2023 | 1 |
| M03AC09 rocuronium bromide <i>Rocuronium bromide</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 31/05/2021 | 1 |
| M03AX01 botulinum toxin <i>Botulinum toxin type A</i> | | | |
| Galderma International | Marketing authorisation application | 24/07/2023 | 1 |
| M04AC01 colchicine <i>Colchicine</i> | | | |
| Indoco Remedies Czech s.r.o. | Marketing authorisation application | 26/01/2022 | 1 |
| M05BA08 zoledronic acid <i>Zoledronic acid monohydrate</i> | | | |
| Seacross Pharma (Europe) Limited | Marketing authorisation application | 02/01/2023 | 1 |
| N01BB01 bupivacaine <i>Bupivacaine hydrochloride monohydrate</i> | | | |
| Dextreg | Marketing authorisation application | 20/11/2023 | 1 |
| N01BB02 lidocaine <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 |
| N01BB52 lidocaine, combinations <i>Lidocaine hydrochloride monohydrate, Adrenaline tartrate</i> | | | |
| Dextreg | Marketing authorisation application | 30/01/2024 | 2 |
| N02AA55 oxycodone and naloxone <i>Oxycodone hydrochloride, Naloxone hydrochloride dihydrate</i> | | | |
| Neuraxpharm Arzneimittel GmbH | Marketing authorisation application | 18/07/2023 | 5 |
| N02AE01 buprenorphine <i>Buprenorphine hydrochloride</i> | | | |
| G.L. Pharma GmbH | Marketing authorisation application | 30/08/2023 | 2 |
| N02BA51 acetylsalicylic acid, combinations excl. psycholeptics <i>Acetylsalicylic acid, Caffeine, Ascorbic acid</i> | | | |
| Orifarm Healthcare A/S | Marketing authorisation application | 22/03/2024 | 1 |
| N02BE51 paracetamol, combinations excl. psycholeptics <i>Ibuprofen, Paracetamol</i> | | | |
| Vale Pharmaceuticals Limited | Marketing authorisation application | 09/10/2023 | 1 |
| N02BF01 gabapentin <i>Gabapentin</i> | | | |
| 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 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| N02CC04 rizatriptan <i>Rizatriptan benzoate</i> | | | |
| Orifarm Oy | Parallel import | 23/09/2022 | 1 |
| N02CC05 almotriptan <i>Almotriptan D,L-hydrogen malate</i> | | | |
| Paranova Oy | Parallel import | 09/02/2024 | 1 |
| N03AX03 sultiame <i>Sultiame</i> | | | |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 31/05/2023 | 1 |
| 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 |
| Noridem Enterprises Limited | Marketing authorisation application | 12/03/2024 | 1 |
| N03AX15 zonisamide <i>Zonisamide</i> | | | |
| Desitin Arzneimittel GmbH | Marketing authorisation application | 28/03/2024 | 1 |
| N03AX17 stiripentol <i>Stiripentol</i> | | | |
| Billev Pharma ApS | Marketing authorisation application | 12/12/2022 | 4 |
| N03AX18 lacosamide <i>Lacosamide</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 02/05/2022 | 1 |
| Strides Pharma (Cyprus) Limited | Marketing authorisation application | 22/03/2023 | 1 |
| As Grindex | Marketing authorisation application | 22/12/2023 | 4 |
| N03AX23 brivaracetam <i>Brivaracetam</i> | | | |
| 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 |
| N04BA02 levodopa and decarboxylase inhibitor <i>Levodopa, Carbidopa monohydrate</i> | | | |
| Orion Corporation | Marketing authorisation application | 28/02/2023 | 1 |
| N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor <i>Levodopa, Carbidopa monohydrate, Entacapone</i> | | | |
| Neuraxpharm Sweden AB | Marketing authorisation application | 29/05/2023 | 7 |
| N04BD03 safinamide <i>Safinamide methanesulfonate</i> | | | |
| Vivanta Generics s.r.o. | Marketing authorisation application | 19/09/2023 | 2 |
| N05AA02 levomepromazine <i>Levomepromazine maleate</i> | | | |
| Morningside Healthcare (Malta) Limited | Marketing authorisation application | 29/03/2024 | 2 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| N05AD08 droperidol Droperidol | | | |
| Dextreg | Marketing authorisation application | 27/02/2023 | 2 |
| N05AE05 lurasidone Lurasidone hydrochloride | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 21/12/2022 | 3 |
| N05AH02 clozapine Clozapine | | | |
| Drehm Pharma GmbH | Marketing authorisation application | 01/08/2022 | 2 |
| Viartis Oy | Marketing authorisation application | 29/06/2023 | 1 |
| Grindeks AS | Marketing authorisation application | 27/09/2023 | 2 |
| Viartis Healthcare GmbH | Marketing authorisation application | 18/12/2023 | 4 |
| N05AH04 quetiapine Quetiapine fumarate | | | |
| Grindeks AS | Marketing authorisation application | 07/10/2022 | 4 |
| Grindeks AS | Marketing authorisation application | 10/10/2022 | 5 |
| N05AX12 aripiprazole Aripiprazole monohydrate | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 28/03/2024 | 1 |
| Sandoz A/S | Marketing authorisation application | 02/04/2024 | 2 |
| N05AX13 paliperidone Paliperidone palmitate | | | |
| Exeltis Healthcare S.L. | Marketing authorisation application | 31/10/2022 | 5 |
| STADA Arzneimittel AG | Marketing authorisation application | 21/12/2022 | 5 |
| Sandoz A/S | Marketing authorisation application | 01/02/2023 | 5 |
| Viartis Limited | Marketing authorisation application | 01/12/2023 | 12 |
| N05BA06 lorazepam Lorazepam | | | |
| Macure Pharma ApS | Marketing authorisation application | 17/01/2024 | 1 |
| N05BA12 alprazolam Alprazolam | | | |
| Grindeks AS | Marketing authorisation application | 28/10/2021 | 3 |
| N05CD08 midazolam Midazolam | | | |
| Laboratoire Aguettant | Marketing authorisation application | 01/03/2023 | 1 |
| N05CF01 zopiclone Zopiclone | | | |
| Grindeks AS | Marketing authorisation application | 25/07/2022 | 3 |
| N05CH01 melatonin Melatonin | | | |
| 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 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| N05CM18 dexmedetomidine <i>Dexmedetomidine hydrochloride</i> | | | |
| B. Braun Melsungen AG | Marketing authorisation application | 27/04/2023 | 2 |
| Hameln Pharma GmbH | Marketing authorisation application | 31/08/2023 | 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 |
| N06AF04 tranlycypromine <i>Tranlycypromine sulphate</i> | | | |
| Abboxia AB | Marketing authorisation application | 25/09/2023 | 1 |
| N06AX11 mirtazapine <i>Mirtazapine</i> | | | |
| Grindeks AS | Marketing authorisation application | 12/10/2023 | 3 |
| N06AX12 bupropion <i>Bupropion hydrochloride</i> | | | |
| 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 |
| N06AX16 venlafaxine <i>Venlafaxine hydrochloride</i> | | | |
| Cipla Europe NV | Marketing authorisation application | 02/05/2023 | 4 |
| Orifarm Oy | Parallel import | 28/12/2023 | 1 |
| N06AX26 vortioxetine <i>Vortioxetine hydrobromide</i> | | | |
| Adalvo Limited | Marketing authorisation application | 08/07/2022 | 4 |
| Viartis Limited | Marketing authorisation application | 01/12/2023 | 4 |
| N06BA02 dexamfetamine <i>Dexamphetamine sulphate</i> | | | |
| Orifarm Healthcare A/S | Marketing authorisation application | 01/02/2023 | 3 |
| Sea Pharma AB | Marketing authorisation application | 21/02/2024 | 3 |
| N06BA12 lisdexamfetamine <i>Lisdexamfetamine dimesylate</i> | | | |
| Orion Corporation | Marketing authorisation application | 30/11/2022 | 6 |
| N06DX01 memantine <i>Memantine hydrochloride</i> | | | |
| UAB Baltijos Bite | Marketing authorisation application | 01/12/2023 | 2 |
| N07AA Anticholinesterases <i>Ipidacrine hydrochloride monohydrate</i> | | | |
| Grindeks AS | Marketing authorisation application | 13/10/2022 | 3 |
| N07BA01 nicotine <i>Nicotine resinate</i> | | | |
| Haleon Denmark ApS | Marketing authorisation application | 30/06/2023 | 8 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| N07BA03 varenicline Varenicline tartrate | | | |
| 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 |
| N07CA01 betahistine Betahistine dihydrochloride | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 30/03/2023 | 3 |
| P01AB01 metronidazole Metronidazole | | | |
| DiaMed Beratungsgesellschaft für pharmaz. Unternehmen mbH | Marketing authorisation application | 26/07/2021 | 2 |
| P01CX01 pentamidine isethionate Pentamidine diisetionate | | | |
| Tillomed Pharma GmbH | Marketing authorisation application | 30/12/2022 | 1 |
| P02CA03 albendazole Albendazole | | | |
| 2Care4 Generics ApS | Marketing authorisation application | 30/03/2023 | 1 |
| P02CF01 ivermectin Ivermectin | | | |
| Orifarm Healthcare A/S | Marketing authorisation application | 26/06/2023 | 1 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 30/06/2023 | 1 |
| P03AA54 disulfiram, combinations Disulfiram, Benzyl benzoate | | | |
| Bioglan AB | Marketing authorisation application | 28/03/2024 | 1 |
| QA03FA01 metoclopramide Metoclopramide hydrochloride monohydrate | | | |
| ADOH B.V. | Marketing authorisation application | 11/04/2024 | 1 |
| QA12AX Calcium, combinations with vitamin D and/or other drugs Calcium gluconate, Magnesium chloride hexahydrate | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 29/10/2020 | 2 |
| QA12CX99 Other mineral products, combinations Butafosfan, Cyanocobalamin | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 11/03/2021 | 1 |
| QC01CE90 pimobendane Pimobendan | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 18/10/2021 | 5 |
| QC09AA07 benazepril Benazepril hydrochloride | | | |
| Virbac | Marketing authorisation application | 26/02/2024 | 1 |
| QC09CA07 telmisartan Telmisartan | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/03/2022 | 1 |
| QG04BX91 phenylpropanolamine Phenylpropanolamine hydrochloride | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 21/03/2022 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| QH02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i> | | | |
| Curados B.V. | Marketing authorisation application | 20/07/2020 | 1 |
| QH02CA01 trilostane <i>Trilostane</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 28/01/2022 | 5 |
| Dechra Regulatory B.V. | Marketing authorisation application | 30/06/2023 | 4 |
| Dechra Regulatory B.V. | Marketing authorisation application | 21/02/2024 | 1 |
| QH03AA01 levothyroxine sodium <i>Levothyroxine sodium</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 04/11/2022 | 8 |
| QH03BB02 thiamazole <i>Thiamazole</i> | | | |
| Dechra Regulatory B.V. | Marketing authorisation application | 24/10/2022 | 1 |
| QI01AD07 Avian infectious bronchitis virus vaccine <i>Avian infectious bronchitis virus, live, attenuated</i> | | | |
| Ceva Sante Animale | Marketing authorisation application | 05/07/2023 | 1 |
| QI02AP01 Trichophyton vaccine <i>Trichophyton verrucosum, live, attenuated</i> | | | |
| Salfarm Danmark A/S | Marketing authorisation application | 08/03/2024 | 1 |
| 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> | | | |
| Bioveta a.s. | Marketing authorisation application | 20/03/2023 | 1 |
| QJ01CA04 amoxicillin <i>Amoxicillin trihydrate</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 15/06/2022 | 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> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 13/12/2022 | 1 |
| QJ01EW10 sulfadiazine and trimethoprim, incl. derivatives <i>Trimethoprim, Sulfadiazine</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 13/03/2024 | 1 |
| QJ01FA90 tylosin <i>Tylosin</i> | | | |
| Dopharma Research B.V. | Marketing authorisation application | 18/04/2023 | 1 |
| QJ02AC02 itraconazole <i>Itraconazole</i> | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 12/11/2021 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| 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 |
| 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 |
| QM01AE91 carprofen <i>Carprofen</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/12/2022 | 2 |
| QM01AH91 robenacoxib <i>Robenacoxib</i> | | | |
| Fatro S.p.A. | Marketing authorisation application | 28/11/2023 | 3 |
| QN01AX03 ketamine <i>Ketamine hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 14/01/2021 | 1 |
| QN02AC52 methadone, combinations excl. psycholeptics <i>Levomethadone hydrochloride, Fempipramide hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 28/02/2022 | 2 |
| QN02AF01 butorphanol <i>Butorphanol Tartrate</i> | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 17/10/2023 | 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 |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 18/01/2023 | 4 |
| 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 |
| QN05CD08 midazolam <i>Midazolam</i> | | | |
| Dechra Regulatory B.V. | Marketing authorisation application | 23/10/2023 | 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 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|--|-------------------------------------|--------------------------|------------------------|
| QN05CM91 medetomidine Medetomidine hydrochloride | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 15/09/2022 | 1 |
| QN05CM92 xylazine Xylazine hydrochloride | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 07/06/2021 | 1 |
| QP51BC03 diclazuril Diclazuril | | | |
| HuVepharma | Marketing authorisation application | 22/01/2024 | 1 |
| QP52AA51 praziquantel, combinations Praziquantel, Emodepside | | | |
| KRKA, d.d., Novo mesto | Marketing authorisation application | 04/04/2024 | 3 |
| QP52AA51 praziquantel, combinations Praziquantel, Pyrantel embonate, Febantel | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 08/06/2023 | 2 |
| QP52AA51 praziquantel, combinations Praziquantel, Pyrantel embonate | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 06/04/2023 | 1 |
| QP54AA01 ivermectin Ivermectin | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 17/10/2023 | 1 |
| QP54AA04 eprinomectin Eprinomectin | | | |
| Chanelle Pharmaceuticals Manufacturing Limited | Marketing authorisation application | 07/07/2015 | 1 |
| QP54AB51 milbemycin oxime, combinations Milbemycin oxime, Praziquantel | | | |
| 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 |
| QR03CC13 clenbuterol Clenbuterol hydrochloride | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 05/03/2024 | 1 |
| QS01AA01 chloramphenicol Chloramphenicol | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 22/03/2024 | 1 |
| QS01AA11 gentamicin Gentamicin sulfate | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 06/04/2023 | 1 |
| QS01CA01 dexamethasone and antiinfectives Chloramphenicol, Dexamethasone sodium phosphate | | | |
| CP-Pharma Handelsgesellschaft mbH | Marketing authorisation application | 22/03/2024 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| QV03AB90 atipamezole <i>Atipamezole hydrochloride</i> | | | |
| Alfasan Nederland B.V. | Marketing authorisation application | 02/06/2022 | 1 |
| R01AA09 tramazoline <i>Tramazoline hydrochloride monohydrate</i> | | | |
| PharOS - Pharmaceutical Oriented Services Ltd | Marketing authorisation application | 03/05/2023 | 1 |
| R01AC02 levocabastine <i>Levocabastine</i> | | | |
| Paranova Oy | Parallel import | 03/10/2023 | 1 |
| R01AD11 triamcinolone <i>Triamcinolone acetonide</i> | | | |
| Medipha Sante | Marketing authorisation application | 01/04/2022 | 1 |
| R01AD12 fluticasone furoate <i>Fluticasone furoate</i> | | | |
| Substipharm | Marketing authorisation application | 30/11/2021 | 1 |
| Teva B.V. | Marketing authorisation application | 16/12/2022 | 1 |
| R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Azelastine, Fluticasone propionate, Fluticasone</i> | | | |
| Adalvo Limited | Marketing authorisation application | 26/02/2024 | 1 |
| R01AD58 fluticasone, combinations <i>Azelastine hydrochloride, Fluticasone propionate</i> | | | |
| Adalvo Limited | Marketing authorisation application | 31/07/2023 | 2 |
| Especialidades Farmaceuticas Centrum S.A. | Marketing authorisation application | 31/07/2023 | 1 |
| R02AA20 various <i>Lidocaine hydrochloride monohydrate, Amylmetacresol, 2,4-Dichlorobenzylalcohol</i> | | | |
| Mundipharma Oy | Marketing authorisation application | 04/10/2022 | 1 |
| R02AX01 flurbiprofen <i>Flurbiprofen</i> | | | |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 03/11/2023 | 1 |
| R02AX03 benzydamine <i>Benzydamine hydrochloride, Cetylpyridinium chloride</i> | | | |
| KRKA, d.d., Novo mesto | Marketing authorisation application | 29/02/2024 | 1 |
| R03AK08 formoterol and beclometasone <i>Beclometasone dipropionate, Formoterol fumarate dihydrate</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 12/09/2022 | 2 |
| Sandoz A/S | Marketing authorisation application | 16/11/2022 | 2 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 03/04/2023 | 2 |
| Viatrix 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 |
| R03BA08 ciclesonide <i>Ciclesonide</i> | | | |
| Orifarm Healthcare A/S | Marketing authorisation application | 01/12/2022 | 3 |
| Glenmark Arzneimittel GmbH | Marketing authorisation application | 09/03/2023 | 2 |
| R03BB04 tiotropium bromide <i>Tiotropium bromide monohydrate</i> | | | |
| STADA Arzneimittel AG | Marketing authorisation application | 22/12/2021 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| R06AX27 desloratadine <i>Desloratadine</i> | | | |
| Pharmacons ApS | Marketing authorisation application | 29/08/2022 | 1 |
| Kappler Pharma Consult GmbH | Marketing authorisation application | 31/08/2023 | 1 |
| S01AE05 levofloxacin <i>Levofloxacin hemihydrate</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 07/10/2022 | 1 |
| S01AX15 propamidine <i>Propamidine isethionate</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 |
| S01CA01 dexamethasone and antiinfectives <i>Dexamethasone sodium phosphate, Levofloxacin hemihydrate</i> | | | |
| Paranova Oy | Parallel import | 06/02/2024 | 1 |
| S01EA05 brimonidine <i>Brimonidine tartrate</i> | | | |
| Pharmathen S.A. | Marketing authorisation application | 29/04/2022 | 1 |
| S01EC03 dorzolamide <i>Dorzolamide hydrochloride</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 10/07/2023 | 1 |
| Bausch + Lomb Ireland Limited | Marketing authorisation application | 19/09/2023 | 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> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 12/06/2023 | 1 |
| Bausch + Lomb Ireland Limited | Marketing authorisation application | 20/09/2023 | 1 |
| S01ED51 timolol, combinations <i>Tafluprost, Timolol maleate</i> | | | |
| Santen Oy | Marketing authorisation application | 14/06/2023 | 1 |
| S01ED51 timolol, combinations <i>Travoprost, Timolol maleate</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 11/04/2023 | 1 |
| S01EE01 latanoprost <i>Latanoprost</i> | | | |
| Pharmabide Ltd | Marketing authorisation application | 03/03/2023 | 1 |
| Pharmabide Ltd | Marketing authorisation application | 12/12/2023 | 1 |
| S01EE04 travoprost <i>Travoprost</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 20/01/2023 | 1 |
| S01GA07 brimonidine <i>Brimonidine tartrate</i> | | | |
| Bausch + Lomb Ireland Limited | Marketing authorisation application | 25/09/2023 | 1 |

| Applicant | Nature of the application | Application receipt date | Number of applications |
|---|-------------------------------------|--------------------------|------------------------|
| S01GX02 levocabastine <i>Levocabastine</i> | | | |
| Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. | Marketing authorisation application | 23/11/2023 | 1 |
| S01HA02 oxybuprocaine <i>Oxybuprocaine hydrochloride</i> | | | |
| AGEPHA Pharma s.r.o | Marketing authorisation application | 13/01/2022 | 1 |
| S01XA18 ciclosporin <i>Ciclosporin</i> | | | |
| Sun Pharmaceutical Industries Europe B.V. | Marketing authorisation application | 12/10/2022 | 1 |
| S02CA05 fluocinolone acetonide and antiinfectives <i>Ciprofloxacin hydrochloride, Fluocinolone acetonide</i> | | | |
| Paranova Oy | Parallel import | 18/03/2024 | 1 |
| V01AA07 insects <i>Vespula venom</i> | | | |
| ALK-Abello A/S | Marketing authorisation application | 12/03/2024 | 2 |
| V03AB23 acetylcysteine <i>Acetylcysteine</i> | | | |
| Macure Healthcare Limited | Marketing authorisation application | 19/05/2023 | 1 |
| V03AB35 sugammadex <i>Sugammadex sodium</i> | | | |
| Accord Healthcare B.V. | Marketing authorisation application | 30/01/2023 | 2 |
| V04CH02 indigo carmine <i>Indigo carmine</i> | | | |
| SERB S.A. | Marketing authorisation application | 28/04/2023 | 1 |
| V08AD01 ethyl esters of iodised fatty acids <i>Ethiodized oil</i> | | | |
| Guerbet | Marketing authorisation application | 22/02/2021 | 1 |
| V09GA01 technetium (99mTc) sestamibi <i>Stannous chloride dihydrate, Tetrakis (2-methoxy isobutyl isonitrile) copper (I) tetrafluoroborate</i> | | | |
| Radiopharmacy Laboratorium Kft. | Marketing authorisation application | 28/06/2023 | 1 |
| V09IX14 gallium (68Ga) gozetotide <i>Gallium (68Ga) gozetotide</i> | | | |
| Telix Innovations | Marketing authorisation application | 28/04/2023 | 1 |
| V10XA01 sodium iodide (131I) <i>Sodium iodide</i> | | | |
| Narodowe Centrum Badán Jadrowych | Marketing authorisation application | 31/01/2024 | 1 |