

| Applicant                                                                                                                                         | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>A02AC01 calcium carbonate</b> <i>Calcium carbonate</i>                                                                                         |                                     |                          |                        |
| Bayer Oy                                                                                                                                          | Marketing authorisation application | 22/01/2025               | 1                      |
| <b>A02AD04 hydrotalcite</b> <i>Hydrotalcite</i>                                                                                                   |                                     |                          |                        |
| Bayer Austria Ges.m.b.H.                                                                                                                          | Marketing authorisation application | 16/09/2024               | 1                      |
| <b>A02AH Antacids with sodium bicarbonate</b> <i>Sodium hydrogen carbonate</i>                                                                    |                                     |                          |                        |
| Ptr Pharma Consulting Unipessoal Lda.                                                                                                             | Marketing authorisation application | 28/02/2024               | 1                      |
| <b>A02BC02 pantoprazole</b> <i>Pantoprazole sodium</i>                                                                                            |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                                                                                       | Marketing authorisation application | 30/04/2025               | 2                      |
| <b>A02BC05 esomeprazole</b> <i>Esomeprazole magnesium trihydrate</i>                                                                              |                                     |                          |                        |
| Amarox Pharma GmbH                                                                                                                                | Marketing authorisation application | 20/02/2025               | 2                      |
| <b>A02BD08 bismuth subcitrate, metronidazole and tetracycline</b> <i>Bismuth subcitrate potassium, Metronidazole, Tetracycline hydrochloride</i>  |                                     |                          |                        |
| Laboratoires Juvise Pharmaceuticals                                                                                                               | Marketing authorisation application | 08/09/2025               | 1                      |
| <b>A03BA01 atropine</b> <i>Atropine sulfate</i>                                                                                                   |                                     |                          |                        |
| Dextreg                                                                                                                                           | Marketing authorisation application | 26/05/2025               | 2                      |
| <b>A04AA01 ondansetron</b> <i>Ondansetron hydrochloride dihydrate</i>                                                                             |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                       | Marketing authorisation application | 27/09/2024               | 1                      |
| Laboratoire Aguettant                                                                                                                             | Marketing authorisation application | 30/04/2025               | 1                      |
| <b>A04AA02 granisetron</b> <i>Granisetron hydrochloride</i>                                                                                       |                                     |                          |                        |
| STADA Arzneimittel AG                                                                                                                             | Marketing authorisation application | 29/05/2024               | 4                      |
| <b>A06AG11 laurilsulfate, incl. combinations</b> <i>Trisodium citrate dihydrate, Sodium lauryl sulfoacetate, Sorbitol, liquid (crystallising)</i> |                                     |                          |                        |
| Laboratorios Liconsa S.A.                                                                                                                         | Marketing authorisation application | 22/01/2024               | 1                      |
| <b>A07AA09 vancomycin</b> <i>Vancomycin hydrochloride</i>                                                                                         |                                     |                          |                        |
| Xeolas Pharmaceuticals Limited                                                                                                                    | Marketing authorisation application | 21/03/2025               | 2                      |
| <b>A07AA12 fidaxomicin</b> <i>Fidaxomicin</i>                                                                                                     |                                     |                          |                        |
| Adalvo Limited                                                                                                                                    | Marketing authorisation application | 07/07/2025               | 1                      |
| <b>A07EA06 budesonide</b> <i>Budesonide</i>                                                                                                       |                                     |                          |                        |
| Orion Corporation                                                                                                                                 | Marketing authorisation application | 11/04/2025               | 1                      |
| <b>A07EC02 mesalazine</b> <i>Mesalazine</i>                                                                                                       |                                     |                          |                        |
| Faes Farma S.A.                                                                                                                                   | Marketing authorisation application | 25/04/2025               | 1                      |
| <b>A09AA02 multienzymes (lipase, protease etc.)</b> <i>Pancreas powder (porcine)</i>                                                              |                                     |                          |                        |
| ADOH B.V.                                                                                                                                         | Marketing authorisation application | 11/06/2025               | 3                      |
| <b>A09AA02 multienzymes (lipase, protease etc.)</b> <i>Pancreas powder</i>                                                                        |                                     |                          |                        |
| AVVA Pharmaceuticals Ltd.                                                                                                                         | Marketing authorisation application | 14/07/2020               | 2                      |

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| <b>A10BA02 metformin</b> <i>Metformin hydrochloride</i>                                            |                                     |                          |                        |
| Activase Pharmaceuticals Ltd.                                                                      | Marketing authorisation application | 29/02/2024               | 3                      |
| <b>A10BD07 metformin and sitagliptin</b> <i>Sitagliptin hydrochloride, Metformin hydrochloride</i> |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                            | Marketing authorisation application | 22/06/2022               | 2                      |
| <b>A10BD08 metformin and vildagliptin</b> <i>Vildagliptin, Metformin hydrochloride</i>             |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                            | Marketing authorisation application | 02/08/2021               | 2                      |
| <b>A10BD11 metformin and linagliptin</b> <i>Linagliptin, Metformin hydrochloride</i>               |                                     |                          |                        |
| KRKA d.d. Novo mesto                                                                               | Marketing authorisation application | 23/12/2024               | 2                      |
| <b>A10BD15 metformin and dapagliflozin</b> <i>Dapagliflozin, Metformin hydrochloride</i>           |                                     |                          |                        |
| Adalvo Limited                                                                                     | Marketing authorisation application | 29/08/2025               | 2                      |
| <b>A10BD15 metformin and dapagliflozin</b> <i>Metformin hydrochloride, Dapagliflozin</i>           |                                     |                          |                        |
| ratiopharm Arzneimittel Vertriebs GmbH                                                             | Marketing authorisation application | 29/09/2025               | 2                      |
| <b>A10BD20 metformin and empagliflozin</b> <i>Empagliflozin, Metformin hydrochloride</i>           |                                     |                          |                        |
| KRKA d.d. Novo mesto                                                                               | Marketing authorisation application | 03/02/2025               | 4                      |
| <b>A10BH01 sitagliptin</b> <i>Sitagliptin hydrochloride</i>                                        |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                            | Marketing authorisation application | 01/09/2021               | 3                      |
| AshCure Pharma B.V.                                                                                | Marketing authorisation application | 20/05/2025               | 3                      |
| <b>A10BH01 sitagliptin</b> <i>Sitagliptin phosphate monohydrate</i>                                |                                     |                          |                        |
| Morningside Healthcare (Malta) Limited                                                             | Marketing authorisation application | 22/11/2023               | 3                      |
| Devatis GmbH                                                                                       | Marketing authorisation application | 30/08/2024               | 3                      |
| Pharmaceutical Innovation Services S.L.                                                            | Marketing authorisation application | 01/08/2025               | 3                      |
| <b>A10BH05 linagliptin</b> <i>Linagliptin</i>                                                      |                                     |                          |                        |
| Galenicum Health S.L.U                                                                             | Marketing authorisation application | 21/10/2022               | 1                      |
| Accord Healthcare B.V.                                                                             | Marketing authorisation application | 02/04/2024               | 1                      |
| Teva B.V.                                                                                          | Marketing authorisation application | 20/12/2024               | 1                      |
| Galenicum Health S.L.U                                                                             | Marketing authorisation application | 31/01/2025               | 1                      |
| Amarox Pharma GmbH                                                                                 | Marketing authorisation application | 01/07/2025               | 1                      |
| Glenmark Arzneimittel GmbH                                                                         | Marketing authorisation application | 31/07/2025               | 1                      |
| <b>A10BJ02 liraglutide</b> <i>Liraglutide</i>                                                      |                                     |                          |                        |
| Adalvo Limited                                                                                     | Marketing authorisation application | 31/01/2023               | 1                      |
| Cipla Europe NV                                                                                    | Marketing authorisation application | 09/03/2023               | 1                      |
| Medical Valley Invest AB                                                                           | Marketing authorisation application | 30/12/2024               | 1                      |

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| <b>A10BK01 dapagliflozin <i>Dapagliflozin propanediol monohydrate</i></b> |                                     |                          |                        |
| STADA Arzneimittel AG                                                     | Marketing authorisation application | 01/03/2024               | 2                      |
| Orion Corporation                                                         | Marketing authorisation application | 25/04/2024               | 2                      |
| G.L. Pharma GmbH                                                          | Marketing authorisation application | 18/08/2025               | 2                      |
| Zentiva k.s.                                                              | Marketing authorisation application | 18/08/2025               | 2                      |
| <b>A10BK01 dapagliflozin <i>Dapagliflozin</i></b>                         |                                     |                          |                        |
| Sandoz A/S                                                                | Marketing authorisation application | 24/06/2024               | 2                      |
| Genepharma S.A.                                                           | Marketing authorisation application | 01/08/2024               | 2                      |
| Accord Healthcare B.V.                                                    | Marketing authorisation application | 27/12/2024               | 2                      |
| Glenmark Pharmaceuticals s.r.o.                                           | Marketing authorisation application | 30/06/2025               | 2                      |
| <b>A10BK03 empagliflozin <i>Empagliflozin</i></b>                         |                                     |                          |                        |
| Avansor Pharma Oy                                                         | Marketing authorisation application | 29/07/2024               | 2                      |
| Reddy Holding GmbH                                                        | Marketing authorisation application | 11/04/2025               | 2                      |
| KRKA d.d. Novo mesto                                                      | Marketing authorisation application | 23/06/2025               | 2                      |
| Sun Pharmaceutical Industries Europe B.V.                                 | Marketing authorisation application | 01/08/2025               | 2                      |
| Sandoz Pharmaceuticals d.d                                                | Marketing authorisation application | 30/09/2025               | 2                      |
| <b>A11CC03 alfacalcidol <i>Alfacalcidol</i></b>                           |                                     |                          |                        |
| Strides Nordic ApS                                                        | Marketing authorisation application | 02/12/2024               | 3                      |
| <b>A11DA01 thiamine (vit B1) <i>Thiamine hydrochloride</i></b>            |                                     |                          |                        |
| Pemberton Laboratories Limited                                            | Marketing authorisation application | 21/11/2024               | 1                      |
| <b>A16AX06 miglustat <i>Miglustat</i></b>                                 |                                     |                          |                        |
| Waymade B.V.                                                              | Marketing authorisation application | 29/07/2024               | 1                      |
| <b>A16AX08 teduglutide <i>Teduglutide</i></b>                             |                                     |                          |                        |
| Adalvo Limited                                                            | Marketing authorisation application | 05/09/2024               | 1                      |
| <b>B01AB02 antithrombin <i>Antithrombine III humane</i></b>               |                                     |                          |                        |
| Octapharma AB                                                             | Marketing authorisation application | 21/08/2025               | 1                      |
| <b>B01AB05 enoxaparin <i>Enoxaparin sodium</i></b>                        |                                     |                          |                        |
| Changshan Europe S.r.l.                                                   | Marketing authorisation application | 03/03/2025               | 5                      |
| PGF Pharma International d.o.o.                                           | Marketing authorisation application | 03/03/2025               | 5                      |
| <b>B01AC16 eptifibatide <i>Eptifibatide</i></b>                           |                                     |                          |                        |
| Ctruz ApS                                                                 | Marketing authorisation application | 25/03/2025               | 2                      |
| <b>B01AC24 ticagrelor <i>Ticagrelor</i></b>                               |                                     |                          |                        |
| Devatis GmbH                                                              | Marketing authorisation application | 09/07/2024               | 2                      |
| <b>B01AC25 cangrelor <i>Cangrelor Tetrasodium</i></b>                     |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                   | Marketing authorisation application | 01/07/2025               | 1                      |

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| <b>B01AD02 alteplase <i>Alteplase</i></b>                                                        |                                     |                          |                        |
| 2care4 ApS                                                                                       | Parallel import                     | 18/06/2025               | 1                      |
| <b>B01AE07 dabigatran etexilate <i>Dabigatran etexilate mesilate</i></b>                         |                                     |                          |                        |
| Gedeon Richter Plc                                                                               | Marketing authorisation application | 02/05/2024               | 2                      |
| <b>B01AF01 rivaroxaban <i>Rivaroxaban</i></b>                                                    |                                     |                          |                        |
| Tillomed Pharma GmbH                                                                             | Marketing authorisation application | 30/01/2023               | 5                      |
| ratiopharm GmbH                                                                                  | Marketing authorisation application | 12/08/2024               | 5                      |
| Amarox Pharma B.V.                                                                               | Marketing authorisation application | 31/01/2025               | 4                      |
| <b>B01AF02 apixaban <i>Apixaban</i></b>                                                          |                                     |                          |                        |
| Indoco Remedies Czech s.r.o.                                                                     | Marketing authorisation application | 15/08/2022               | 2                      |
| Glenmark Arzneimittel GmbH                                                                       | Marketing authorisation application | 20/12/2024               | 2                      |
| PGF Pharma International d.o.o.                                                                  | Marketing authorisation application | 25/06/2025               | 2                      |
| <b>B01AF03 edoxaban <i>Edoxaban tosylate monohydrate</i></b>                                     |                                     |                          |                        |
| Synthon B.V.                                                                                     | Marketing authorisation application | 21/03/2024               | 3                      |
| Glenmark Arzneimittel GmbH                                                                       | Marketing authorisation application | 03/02/2025               | 3                      |
| Kappler Pharma Consult GmbH                                                                      | Marketing authorisation application | 02/05/2025               | 3                      |
| Amarox Pharma GmbH                                                                               | Marketing authorisation application | 23/09/2025               | 3                      |
| <b>B02AA02 tranexamic acid <i>Tranexamic acid</i></b>                                            |                                     |                          |                        |
| Tillomed Pharma GmbH                                                                             | Marketing authorisation application | 14/02/2023               | 1                      |
| <b>B02BB01 fibrinogen, human <i>Human fibrinogen</i></b>                                         |                                     |                          |                        |
| CSL Behring GmbH                                                                                 | Marketing authorisation application | 12/12/2024               | 1                      |
| Octapharma GmbH                                                                                  | Marketing authorisation application | 20/05/2025               | 1                      |
| <b>B02BX05 eltrombopag <i>Eltrombopag olamine</i></b>                                            |                                     |                          |                        |
| Coripharma ehf.                                                                                  | Marketing authorisation application | 20/12/2024               | 3                      |
| <b>B03AB05 ferric oxide polymaltose complexes <i>Iron(III)-hydroxide polymaltose complex</i></b> |                                     |                          |                        |
| Paranova Oy                                                                                      | Parallel import                     | 27/08/2024               | 2                      |
| Orifarm Oy                                                                                       | Parallel import                     | 11/09/2024               | 1                      |
| <b>B03AC Iron, parenteral preparations <i>Ferric carboxymaltose</i></b>                          |                                     |                          |                        |
| Orion Corporation                                                                                | Marketing authorisation application | 06/05/2024               | 1                      |
| Seacross Pharma (Europe) Limited                                                                 | Marketing authorisation application | 31/07/2024               | 1                      |
| Medical Valley Invest AB                                                                         | Marketing authorisation application | 27/12/2024               | 1                      |
| Devatis GmbH                                                                                     | Marketing authorisation application | 11/08/2025               | 1                      |
| <b>B03BA01 cyanocobalamin <i>Cyanocobalamin</i></b>                                              |                                     |                          |                        |
| Orion Corporation                                                                                | Marketing authorisation application | 25/10/2024               | 1                      |

| Applicant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Nature of the application           | Application receipt date | Number of applications |
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| <b>B05BA01 amino acids</b> <i>Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine</i>                                                                                                                                                                                                                                                                                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 31/07/2024               | 3                      |
| <b>B05BA02 fat emulsions</b> <i>Soya-bean oil, refined, Triglycerides, medium-chain, Olive oil, refined, Fish oil, rich in omega-3-acids</i>                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 06/02/2024               | 1                      |
| <b>B05BA03 carbohydrates</b> <i>Glucose monohydrate</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 30/08/2024               | 1                      |
| <b>B05BA10 combinations</b> <i>Alanine, Glucose monohydrate, Soya-bean oil, refined, Arginine, Triglycerides, medium-chain, Aspartic acid, Olive oil, refined, Cysteine, Fish oil, rich in omega-3-acids, Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine monohydrate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Calcium gluconate monohydrate, Sodium glycerophosphate hydrate, Magnesium sulfate heptahydrate, Potassium chloride, Sodium acetate trihydrate</i> |                                     |                          |                        |
| Fresenius Kabi AB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Marketing authorisation application | 16/11/2023               | 1                      |
| <b>B05BA10 combinations</b> <i>Alanine, Glucose monohydrate, Soya-bean oil, refined, Arginine, Triglycerides, medium-chain, Aspartic acid, Olive oil, refined, Cysteine, Fish oil, rich in omega-3-acids, Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine monohydrate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine, Calcium gluconate monohydrate, Sodium glycerophosphate hydrate, Magnesium sulfate heptahydrate, Potassium chloride</i>                            |                                     |                          |                        |
| Fresenius Kabi AB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Marketing authorisation application | 16/11/2023               | 1                      |
| <b>B05BA10 combinations</b> <i>Alanine, Glucose monohydrate, Soya-bean oil, refined, Arginine, Triglycerides, medium-chain, Aspartic acid, Olive oil, refined, Cysteine, Fish oil, rich in omega-3-acids, Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine monohydrate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine</i>                                                                                                                                                |                                     |                          |                        |
| Fresenius Kabi AB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Marketing authorisation application | 16/11/2023               | 1                      |
| <b>B05BB01 electrolytes</b> <i>Potassium chloride, Sodium chloride</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 09/05/2025               | 2                      |
| <b>B05BB01 electrolytes</b> <i>Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Sodium lactate solution</i>                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 02/10/2024               | 1                      |
| <b>B05BB01 electrolytes</b> <i>Sodium chloride</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 01/10/2024               | 1                      |
| <b>B05BC01 mannitol</b> <i>Mannitol</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 01/07/2025               | 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>B05XA01 potassium chloride</b> <i>Potassium chloride</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Marketing authorisation application | 18/03/2025               | 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>C01AA05 digoxin</b> <i>Digoxin</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                          |                        |
| Macure Pharma ApS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Marketing authorisation application | 30/09/2025               | 1                      |

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| <b>C01BB01 lidocaine</b> <i>Lidocaine hydrochloride monohydrate</i> |                                     |                          |                        |
| Noridem Enterprises Limited                                         | Marketing authorisation application | 21/03/2024               | 1                      |
| <b>C01CA07 dobutamine</b> <i>Dobutamine hydrochloride</i>           |                                     |                          |                        |
| PANPHARMA                                                           | Marketing authorisation application | 29/12/2023               | 1                      |
| <b>C01CA24 epinephrine</b> <i>Adrenaline tartrate</i>               |                                     |                          |                        |
| Viatriis AB                                                         | Marketing authorisation application | 02/05/2024               | 2                      |
| <b>C01EA01 alprostadil</b> <i>Alprostadil</i>                       |                                     |                          |                        |
| Oresund Pharma ApS (Øresund Pharma)                                 | Marketing authorisation application | 09/04/2025               | 1                      |
| <b>C01EB10 adenosine</b> <i>Adenosine</i>                           |                                     |                          |                        |
| Orifarm Oy                                                          | Parallel import                     | 10/03/2023               | 1                      |
| Macure Healthcare Limited                                           | Marketing authorisation application | 30/09/2024               | 1                      |
| <b>C02AB02 methyldopa (racemic)</b> <i>Methyldopa sesquihydrate</i> |                                     |                          |                        |
| Macure Pharma ApS                                                   | Marketing authorisation application | 01/04/2025               | 1                      |
| <b>C02AC02 guanfacine</b> <i>Guanfacine hydrochloride</i>           |                                     |                          |                        |
| Sandoz GmbH                                                         | Marketing authorisation application | 04/08/2025               | 4                      |
| <b>C02DD01 nitroprusside</b> <i>Sodium nitroprusside dihydrate</i>  |                                     |                          |                        |
| Macure Pharma ApS                                                   | Marketing authorisation application | 26/05/2025               | 1                      |
| <b>C02KX04 macitentan</b> <i>Macitentan</i>                         |                                     |                          |                        |
| Zentiva k.s.                                                        | Marketing authorisation application | 22/12/2023               | 1                      |
| Renata Pharmaceuticals (Ireland) Limited                            | Marketing authorisation application | 29/12/2023               | 1                      |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 04/01/2024               | 1                      |
| Vivanta Generics s.r.o.                                             | Marketing authorisation application | 30/04/2024               | 1                      |
| Sandoz A/S                                                          | Marketing authorisation application | 02/05/2024               | 1                      |
| Viatriis Limited                                                    | Marketing authorisation application | 09/08/2024               | 1                      |
| <b>C02KX05 riociguat</b> <i>Riociguat</i>                           |                                     |                          |                        |
| Olpha AS                                                            | Marketing authorisation application | 28/08/2025               | 5                      |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 30/09/2025               | 5                      |
| <b>C03CA01 furosemide</b> <i>Furosemide</i>                         |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                         | Marketing authorisation application | 30/08/2024               | 2                      |
| Noridem Enterprises Limited                                         | Marketing authorisation application | 04/12/2024               | 1                      |
| Kalceks AS                                                          | Marketing authorisation application | 20/12/2024               | 1                      |
| <b>C03DA01 spironolactone</b> <i>Spironolactone</i>                 |                                     |                          |                        |
| Amarox Pharma B.V.                                                  | Marketing authorisation application | 04/11/2024               | 3                      |

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| <b>C03XA01 tolvaptan <i>Tolvaptan</i></b>                                            |                                     |                          |                        |
| Accord Healthcare B.V.                                                               | Marketing authorisation application | 31/07/2024               | 3                      |
| <b>C05AE03 diltiazem <i>Diltiazem hydrochloride</i></b>                              |                                     |                          |                        |
| XGX Pharma ApS                                                                       | Marketing authorisation application | 27/01/2025               | 1                      |
| <b>C07AA05 propranolol <i>Propranolol hydrochloride</i></b>                          |                                     |                          |                        |
| 2Care4 Generics ApS                                                                  | Marketing authorisation application | 27/09/2024               | 2                      |
| Omet Pharma AB                                                                       | Marketing authorisation application | 14/04/2025               | 2                      |
| <b>C07AB02 metoprolol <i>Metoprolol succinate, Metoprolol</i></b>                    |                                     |                          |                        |
| Orion Corporation                                                                    | Marketing authorisation application | 04/04/2025               | 1                      |
| <b>C07AB02 metoprolol <i>Metoprolol succinate</i></b>                                |                                     |                          |                        |
| Orion Corporation                                                                    | Marketing authorisation application | 04/04/2025               | 3                      |
| <b>C07AB07 bisoprolol <i>Bisoprolol fumarate</i></b>                                 |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                          | Marketing authorisation application | 28/12/2023               | 6                      |
| <b>C08CA01 amlodipine <i>Amlodipine besylate</i></b>                                 |                                     |                          |                        |
| Teva B.V.                                                                            | Marketing authorisation application | 04/06/2024               | 2                      |
| <b>C09CA07 telmisartan <i>Telmisartan</i></b>                                        |                                     |                          |                        |
| Amarox Pharma B.V.                                                                   | Marketing authorisation application | 28/02/2025               | 3                      |
| <b>C09DA03 valsartan and diuretics <i>Indapamide, Valsartan</i></b>                  |                                     |                          |                        |
| KRKA d.d. Novo mesto                                                                 | Marketing authorisation application | 16/06/2025               | 1                      |
| <b>C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan disodium</i></b> |                                     |                          |                        |
| 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                      |
| Glenmark Arzneimittel GmbH                                                           | Marketing authorisation application | 07/02/2025               | 3                      |
| axunio Pharma GmbH                                                                   | Marketing authorisation application | 25/04/2025               | 3                      |
| Vale Pharmaceuticals Limited                                                         | Marketing authorisation application | 01/08/2025               | 3                      |
| Kappler Pharma Consult GmbH                                                          | Marketing authorisation application | 21/08/2025               | 3                      |
| <b>C09DX04 valsartan and sacubitril <i>Sacubitril sodium, Valsartan</i></b>          |                                     |                          |                        |
| Amarox Pharma B.V.                                                                   | Marketing authorisation application | 03/02/2025               | 3                      |
| <b>C09DX04 valsartan and sacubitril <i>Sacubitril valsartan sodium hydrate</i></b>   |                                     |                          |                        |
| Viartis Limited                                                                      | Marketing authorisation application | 30/01/2024               | 3                      |
| Reddy Holding GmbH                                                                   | Marketing authorisation application | 07/08/2025               | 3                      |
| <b>C10AA05 atorvastatin <i>Atorvastatin</i></b>                                      |                                     |                          |                        |
| Amarox Pharma B.V.                                                                   | Marketing authorisation application | 02/12/2024               | 4                      |

| Applicant                                                                                                 | Nature of the application           | Application receipt date | Number of applications |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>C10BA06 rosuvastatin and ezetimibe</b> <i>Ezetimibe, Rosuvastatin calcium</i>                          |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                                   | Marketing authorisation application | 17/06/2024               | 4                      |
| <b>C10BA06 rosuvastatin and ezetimibe</b> <i>Rosuvastatin calcium, Ezetimibe</i>                          |                                     |                          |                        |
| KRKA d.d. Novo mesto                                                                                      | Marketing authorisation application | 10/09/2024               | 2                      |
| <b>D05AX52 calcipotriol, combinations</b> <i>Betamethasone dipropionate, Calcipotriol hydrate</i>         |                                     |                          |                        |
| Glenmark Arzneimittel GmbH                                                                                | Marketing authorisation application | 01/08/2024               | 1                      |
| <b>D06BA01 silver sulfadiazine</b> <i>Silver sulfadiazine</i>                                             |                                     |                          |                        |
| Macure Pharma ApS                                                                                         | Marketing authorisation application | 15/07/2025               | 1                      |
| <b>D07AB02 hydrocortisone butyrate</b> <i>Hydrocortisone butyrate</i>                                     |                                     |                          |                        |
| Grindeks AS                                                                                               | Marketing authorisation application | 30/05/2025               | 1                      |
| <b>D07AC01 betamethasone</b> <i>Betamethasone valerate</i>                                                |                                     |                          |                        |
| Grindeks AS                                                                                               | Marketing authorisation application | 01/04/2025               | 1                      |
| Grindeks AS                                                                                               | Marketing authorisation application | 30/04/2025               | 1                      |
| <b>D07AC13 mometasone</b> <i>Mometasone furoate</i>                                                       |                                     |                          |                        |
| Grindeks AS                                                                                               | Marketing authorisation application | 21/10/2022               | 2                      |
| <b>D07AD01 clobetasol</b> <i>Clobetasol propionate</i>                                                    |                                     |                          |                        |
| Grindeks AS                                                                                               | Marketing authorisation application | 28/11/2024               | 1                      |
| Grindeks AS                                                                                               | Marketing authorisation application | 28/03/2025               | 1                      |
| <b>D07CC01 betamethasone and antibiotics</b> <i>Fusidic acid, Betamethasone valerate</i>                  |                                     |                          |                        |
| Strides Nordic ApS                                                                                        | Marketing authorisation application | 01/12/2023               | 1                      |
| <b>D08AG02 povidone-iodine</b> <i>Polyvidone-iodine</i>                                                   |                                     |                          |                        |
| Mundipharma Oy                                                                                            | Marketing authorisation application | 18/07/2019               | 1                      |
| <b>D10AD53 adapalene, combinations</b> <i>Clindamycin phosphate, Adapalene, Benzoyl peroxide, hydrous</i> |                                     |                          |                        |
| Bausch Health Ireland Limited                                                                             | Marketing authorisation application | 30/05/2024               | 1                      |
| <b>D10AE01 benzoyl peroxide</b> <i>Benzoyl peroxide, hydrous</i>                                          |                                     |                          |                        |
| Galenica AB                                                                                               | Marketing authorisation application | 07/03/2025               | 1                      |
| MagnaPharm Trading Slovakia s.r.o.                                                                        | Marketing authorisation application | 07/03/2025               | 1                      |
| Laboratoires MEDGEN                                                                                       | Marketing authorisation application | 10/03/2025               | 1                      |
| <b>D10BA01 isotretinoin</b> <i>Isotretinoin</i>                                                           |                                     |                          |                        |
| Strides Nordic ApS                                                                                        | Marketing authorisation application | 01/09/2025               | 2                      |
| <b>D11AH01 tacrolimus</b> <i>Tacrolimus monohydrate</i>                                                   |                                     |                          |                        |
| Adalvo Limited                                                                                            | Marketing authorisation application | 02/01/2025               | 2                      |
| Glenmark Arzneimittel GmbH                                                                                | Marketing authorisation application | 02/01/2025               | 2                      |

| Applicant                                                                                  | Nature of the application           | Application receipt date | Number of applications |
|--------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>G01AF01 metronidazole <i>Metronidazole</i></b>                                          |                                     |                          |                        |
| Abacus Medicine A/S                                                                        | Parallel import                     | 16/08/2024               | 1                      |
| <b>G01AF02 clotrimazole <i>Clotrimazole, Clotrimazole</i></b>                              |                                     |                          |                        |
| Bayer Oy                                                                                   | Marketing authorisation application | 30/01/2025               | 1                      |
| <b>G01AF02 clotrimazole <i>Clotrimazole</i></b>                                            |                                     |                          |                        |
| Bayer Oy                                                                                   | Marketing authorisation application | 03/04/2025               | 1                      |
| <b>G02AD06 misoprostol <i>Misoprostol</i></b>                                              |                                     |                          |                        |
| Inphena A/S                                                                                | Marketing authorisation application | 06/03/2024               | 1                      |
| <b>G02CX Other gynecologicals <i>Nifedipine</i></b>                                        |                                     |                          |                        |
| Laboratorio Reig Jofré S.A.                                                                | Marketing authorisation application | 24/09/2024               | 1                      |
| <b>G03AA14 nomegestrol and estradiol <i>Estradiol hemihydrate, Nomegestrol acetate</i></b> |                                     |                          |                        |
| Exeltis Healthcare S.L.                                                                    | Marketing authorisation application | 25/02/2025               | 1                      |
| <b>G03AC10 drospirenone <i>Drospirenone</i></b>                                            |                                     |                          |                        |
| Exeltis Healthcare S.L.                                                                    | Marketing authorisation application | 30/08/2024               | 1                      |
| <b>G03BA03 testosterone <i>Testosterone undecanoate</i></b>                                |                                     |                          |                        |
| Sun Pharmaceutical Industries Europe B.V.                                                  | Marketing authorisation application | 28/07/2023               | 1                      |
| Paranova Oy                                                                                | Parallel import                     | 02/09/2025               | 1                      |
| <b>G03BA03 testosterone <i>Testosterone</i></b>                                            |                                     |                          |                        |
| The Simple Pharma Company Limited                                                          | Marketing authorisation application | 19/12/2023               | 1                      |
| Exeltis Healthcare S.L.                                                                    | Marketing authorisation application | 10/02/2025               | 1                      |
| <b>G03CA03 estradiol <i>Estradiol hemihydrate</i></b>                                      |                                     |                          |                        |
| Paranova Oy                                                                                | Parallel import                     | 10/07/2025               | 1                      |
| <b>G03XB51 mifepristone, combinations <i>Mifepristone, Misoprostol</i></b>                 |                                     |                          |                        |
| ADOH B.V.                                                                                  | Marketing authorisation application | 29/11/2024               | 1                      |
| ADOH B.V.                                                                                  | Marketing authorisation application | 31/03/2025               | 1                      |
| <b>G04BD12 mirabegron <i>Mirabegron</i></b>                                                |                                     |                          |                        |
| Glenmark Arzneimittel GmbH                                                                 | Marketing authorisation application | 02/07/2024               | 1                      |
| STADA Arzneimittel AG                                                                      | Marketing authorisation application | 02/07/2024               | 1                      |
| Zentiva k.s.                                                                               | Marketing authorisation application | 02/07/2024               | 1                      |
| Sandoz B.V.                                                                                | Marketing authorisation application | 07/10/2025               | 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>                                                  |                                     |                          |                        |
| Amarox Pharma GmbH                                                                         | Marketing authorisation application | 30/10/2024               | 1                      |

| Applicant                                                                          | Nature of the application           | Application receipt date | Number of applications |
|------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>G04CA54 tamsulosin and tadalafil</b> <i>Tamsulosin hydrochloride, Tadalafil</i> |                                     |                          |                        |
| Midas Pharma GmbH                                                                  | Marketing authorisation application | 06/10/2025               | 1                      |
| <b>H01BB02 oxytocin</b> <i>Oxytocin</i>                                            |                                     |                          |                        |
| PANPHARMA                                                                          | Marketing authorisation application | 21/01/2025               | 1                      |
| Abacus Medicine A/S                                                                | Parallel import                     | 07/03/2025               | 1                      |
| <b>H01BB03 carbetocin</b> <i>Carbetocin</i>                                        |                                     |                          |                        |
| EVER Valinject GmbH                                                                | Marketing authorisation application | 30/09/2024               | 1                      |
| <b>H01CB02 octreotide</b> <i>Octreotide acetate</i>                                |                                     |                          |                        |
| Qilu Pharma Spain S.L.                                                             | Marketing authorisation application | 30/05/2025               | 3                      |
| STADA Arzneimittel AG                                                              | Marketing authorisation application | 12/08/2025               | 3                      |
| <b>H01CB03 lanreotide</b> <i>Lanreotide acetate</i>                                |                                     |                          |                        |
| Seacross Pharma (Europe) Limited                                                   | Marketing authorisation application | 31/01/2025               | 3                      |
| STADA Arzneimittel AG                                                              | Marketing authorisation application | 30/05/2025               | 3                      |
| <b>H01CC01 ganirelix</b> <i>Ganirelix acetate</i>                                  |                                     |                          |                        |
| Seacross Pharma (Europe) Limited                                                   | Marketing authorisation application | 15/04/2025               | 1                      |
| <b>H02AB02 dexamethasone</b> <i>Dexamethasone sodium phosphate</i>                 |                                     |                          |                        |
| PANPHARMA                                                                          | Marketing authorisation application | 24/01/2024               | 1                      |
| Noridem Enterprises Limited                                                        | Marketing authorisation application | 28/06/2024               | 1                      |
| <b>H02AB04 methylprednisolone</b> <i>Methylprednisolone sodium succinate</i>       |                                     |                          |                        |
| Abacus Medicine A/S                                                                | Parallel import                     | 05/03/2025               | 3                      |
| <b>H02AB09 hydrocortisone</b> <i>Hydrocortisone sodium succinate</i>               |                                     |                          |                        |
| Noridem Enterprises Limited                                                        | Marketing authorisation application | 02/05/2025               | 6                      |
| <b>H02AB09 hydrocortisone</b> <i>Hydrocortisone</i>                                |                                     |                          |                        |
| Morningside Healthcare (Malta) Limited                                             | Marketing authorisation application | 01/03/2024               | 2                      |
| <b>H03AA01 levothyroxine sodium</b> <i>Levothyroxine sodium</i>                    |                                     |                          |                        |
| Sandoz A/S                                                                         | Marketing authorisation application | 26/03/2025               | 2                      |
| <b>J01AA02 doxycycline</b> <i>Doxycycline hyclate</i>                              |                                     |                          |                        |
| Macure Healthcare Limited                                                          | Marketing authorisation application | 27/03/2024               | 1                      |
| <b>J01CA01 ampicillin</b> <i>Ampicillin sodium</i>                                 |                                     |                          |                        |
| Noridem Enterprises Limited                                                        | Marketing authorisation application | 30/11/2023               | 3                      |
| <b>J01CF02 cloxacillin</b> <i>Cloxacillin sodium</i>                               |                                     |                          |                        |
| Noridem Enterprises Limited                                                        | Marketing authorisation application | 31/07/2024               | 3                      |

| Applicant                                                                                                            | Nature of the application           | Application receipt date | Number of applications |
|----------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>J01CR02 amoxicillin and beta-lactamase inhibitor <i>Amoxicillin trihydrate, Potassium clavulanate diluted</i></b> |                                     |                          |                        |
| PGF Pharma International d.o.o.                                                                                      | Marketing authorisation application | 14/02/2025               | 4                      |
| <b>J01CR05 piperacillin and beta-lactamase inhibitor <i>Piperacillin monohydrate, Tazobactam</i></b>                 |                                     |                          |                        |
| B. Braun Melsungen AG                                                                                                | Marketing authorisation application | 13/12/2024               | 1                      |
| <b>J01DB04 cefazolin <i>Cefazoline sodium</i></b>                                                                    |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 03/02/2025               | 2                      |
| <b>J01DC02 cefuroxime <i>Cefuroxime sodium</i></b>                                                                   |                                     |                          |                        |
| Hameln Pharma GmbH                                                                                                   | Marketing authorisation application | 24/03/2025               | 1                      |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 10/09/2025               | 2                      |
| <b>J01DD02 ceftazidime <i>Ceftazidime pentahydrate</i></b>                                                           |                                     |                          |                        |
| Farmaprojects, S.A.U.                                                                                                | Marketing authorisation application | 25/03/2024               | 3                      |
| Navamedic ASA                                                                                                        | Marketing authorisation application | 01/10/2025               | 3                      |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 06/10/2025               | 2                      |
| <b>J01DD04 ceftriaxone <i>Ceftriaxone sodium</i></b>                                                                 |                                     |                          |                        |
| Apta Medica Internacional d.o.o.                                                                                     | Marketing authorisation application | 29/04/2025               | 2                      |
| <b>J01FA09 clarithromycin <i>Clarithromycin</i></b>                                                                  |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                                   | Marketing authorisation application | 14/11/2024               | 1                      |
| <b>J01FA10 azithromycin <i>Azithromycin dihydrate</i></b>                                                            |                                     |                          |                        |
| Gufic Ireland Limited                                                                                                | Marketing authorisation application | 31/12/2024               | 1                      |
| <b>J01FF01 clindamycin <i>Clindamycin phosphate</i></b>                                                              |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                                   | Marketing authorisation application | 02/01/2023               | 1                      |
| <b>J01GB03 gentamicin <i>Gentamicin sulfate</i></b>                                                                  |                                     |                          |                        |
| Macure Healthcare Limited                                                                                            | Marketing authorisation application | 01/11/2023               | 4                      |
| <b>J01GB06 amikacin <i>Amikacin sulfate</i></b>                                                                      |                                     |                          |                        |
| 2Care4 Generics ApS                                                                                                  | Marketing authorisation application | 28/06/2024               | 1                      |
| <b>J01MA02 ciprofloxacin <i>Ciprofloxacin lactate</i></b>                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 08/04/2025               | 1                      |
| <b>J01XA01 vancomycin <i>Vancomycin hydrochloride</i></b>                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 03/02/2025               | 2                      |
| <b>J01XA04 dalbavancin <i>Dalbavancin hydrochloride</i></b>                                                          |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                          | Marketing authorisation application | 27/12/2024               | 1                      |
| <b>J01XA04 dalbavancin <i>Dalbavancin</i></b>                                                                        |                                     |                          |                        |
| Welding GmbH & Co. KG                                                                                                | Marketing authorisation application | 25/06/2024               | 1                      |

| Applicant                                                                                                    | Nature of the application           | Application receipt date | Number of applications |
|--------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>J01XB01 colistin <i>Colistimethate sodium</i></b>                                                         |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                           | Marketing authorisation application | 28/05/2025               | 2                      |
| <b>J01XX05 methenamine <i>Methenamine hippurate</i></b>                                                      |                                     |                          |                        |
| Aspire Pharma (Malta) Limited                                                                                | Marketing authorisation application | 30/04/2025               | 1                      |
| <b>J01XX09 daptomycin <i>Daptomycin</i></b>                                                                  |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                           | Marketing authorisation application | 14/05/2025               | 2                      |
| <b>J02AA01 amphotericin <i>Amphotericin b</i></b>                                                            |                                     |                          |                        |
| TLC Biopharmaceuticals B.V.                                                                                  | Marketing authorisation application | 24/10/2022               | 1                      |
| Qilu Pharma Spain S.L.                                                                                       | Marketing authorisation application | 30/09/2024               | 1                      |
| Sun Pharmaceutical Industries Europe B.V.                                                                    | Marketing authorisation application | 11/02/2025               | 1                      |
| STADA Arzneimittel AG                                                                                        | Marketing authorisation application | 18/07/2025               | 1                      |
| Masuu Pharma Europe Limited                                                                                  | Marketing authorisation application | 01/10/2025               | 1                      |
| <b>J02AC04 posaconazole <i>Posaconazole</i></b>                                                              |                                     |                          |                        |
| PGF Pharma International d.o.o.                                                                              | Marketing authorisation application | 30/07/2025               | 1                      |
| <b>J02AX05 micafungin <i>Micafungin sodium</i></b>                                                           |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                           | Marketing authorisation application | 22/04/2025               | 2                      |
| Noridem Enterprises Limited                                                                                  | Marketing authorisation application | 30/05/2025               | 2                      |
| <b>J02AX06 anidulafungin <i>Anidulafungin</i></b>                                                            |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                           | Marketing authorisation application | 27/12/2024               | 1                      |
| <b>J05AB06 ganciclovir <i>Ganciclovir sodium</i></b>                                                         |                                     |                          |                        |
| Bioglan AB                                                                                                   | Marketing authorisation application | 02/10/2024               | 1                      |
| <b>J05AB14 valganciclovir <i>Valganciclovir hydrochloride</i></b>                                            |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                           | Marketing authorisation application | 02/10/2024               | 1                      |
| <b>J05AJ01 raltegravir <i>Raltegravir potassium</i></b>                                                      |                                     |                          |                        |
| Amarox Pharma GmbH                                                                                           | Marketing authorisation application | 13/11/2024               | 1                      |
| Viartis Limited                                                                                              | Marketing authorisation application | 13/05/2025               | 1                      |
| <b>J05AR03 tenofovir disoproxil and emtricitabine <i>Emtricitabine, Tenofovir disoproxil fumarate</i></b>    |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                           | Marketing authorisation application | 18/06/2025               | 1                      |
| <b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide fumarate</i></b>  |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                           | Marketing authorisation application | 16/12/2024               | 2                      |
| <b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide succinate</i></b> |                                     |                          |                        |
| Lupin Europe GmbH                                                                                            | Marketing authorisation application | 30/01/2025               | 2                      |
| <b>J05AR17 emtricitabine and tenofovir alafenamide <i>Emtricitabine, Tenofovir alafenamide</i></b>           |                                     |                          |                        |
| Medical Valley Invest AB                                                                                     | Marketing authorisation application | 03/02/2025               | 2                      |

| Applicant                                                                                                                                               | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>J05AR19 emtricitabine, tenofovir alafenamide and rilpivirine <i>Emtricitabine, Rilpivirine hydrochloride, Tenofovir alafenamide monofumarate</i></b> |                                     |                          |                        |
| Accord Healthcare S.L.U.                                                                                                                                | Marketing authorisation application | 02/06/2025               | 1                      |
| <b>L01AA01 cyclophosphamide <i>Cyclophosphamide monohydrate</i></b>                                                                                     |                                     |                          |                        |
| Baxter Oy                                                                                                                                               | Marketing authorisation application | 02/04/2025               | 2                      |
| <b>L01AA06 ifosfamide <i>Ifosfamide</i></b>                                                                                                             |                                     |                          |                        |
| Baxter Oy                                                                                                                                               | Marketing authorisation application | 14/02/2025               | 2                      |
| <b>L01AX03 temozolomide <i>Temozolomide</i></b>                                                                                                         |                                     |                          |                        |
| PGF Pharma International d.o.o.                                                                                                                         | Marketing authorisation application | 28/03/2025               | 6                      |
| <b>L01BC02 fluorouracil <i>Fluorouracil</i></b>                                                                                                         |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                                                                      | Marketing authorisation application | 11/09/2025               | 1                      |
| <b>L01BC07 azacitidine <i>Azacitidine</i></b>                                                                                                           |                                     |                          |                        |
| Tarchomińskie Zakłady Farmaceutyczne, Polfa S.A.                                                                                                        | Marketing authorisation application | 26/11/2021               | 1                      |
| ELC GROUP S.R.O.                                                                                                                                        | Marketing authorisation application | 28/06/2023               | 1                      |
| <b>L01BC08 decitabine <i>Decitabine</i></b>                                                                                                             |                                     |                          |                        |
| EVER Valinject GmbH                                                                                                                                     | Marketing authorisation application | 25/09/2024               | 1                      |
| <b>L01CD01 paclitaxel <i>Paclitaxel</i></b>                                                                                                             |                                     |                          |                        |
| Panacea Biotec Germany GmbH                                                                                                                             | Marketing authorisation application | 01/08/2023               | 1                      |
| Qilu Pharma Spain S.L.                                                                                                                                  | Marketing authorisation application | 16/10/2023               | 1                      |
| Hexal AG                                                                                                                                                | Marketing authorisation application | 02/12/2024               | 1                      |
| Orion Corporation                                                                                                                                       | Marketing authorisation application | 30/05/2025               | 1                      |
| Amarox Pharma B.V.                                                                                                                                      | Marketing authorisation application | 07/08/2025               | 1                      |
| <b>L01CD04 cabazitaxel <i>Cabazitaxel</i></b>                                                                                                           |                                     |                          |                        |
| Amarox Pharma B.V.                                                                                                                                      | Marketing authorisation application | 04/08/2025               | 1                      |
| <b>L01DB01 doxorubicin <i>Doxorubicin hydrochloride</i></b>                                                                                             |                                     |                          |                        |
| Sun Pharmaceutical Industries Europe B.V.                                                                                                               | Marketing authorisation application | 30/06/2025               | 1                      |
| <b>L01DB02 daunorubicin <i>Daunorubicin hydrochloride</i></b>                                                                                           |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                                                                      | Marketing authorisation application | 30/12/2022               | 1                      |
| <b>L01DC03 mitomycin <i>Mitomycin</i></b>                                                                                                               |                                     |                          |                        |
| Accord Healthcare S.L.U.                                                                                                                                | Marketing authorisation application | 22/09/2025               | 2                      |
| <b>L01EA01 imatinib <i>Imatinib mesylate</i></b>                                                                                                        |                                     |                          |                        |
| Grindeks AS                                                                                                                                             | Marketing authorisation application | 30/04/2024               | 2                      |
| Sandoz B.V.                                                                                                                                             | Marketing authorisation application | 03/05/2024               | 2                      |
| <b>L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate, Nilotinib dihydrochloride dihydrate</i></b>                                                |                                     |                          |                        |
| Devatis GmbH                                                                                                                                            | Marketing authorisation application | 27/11/2024               | 1                      |

| Applicant                                                           | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>L01EA03 nilotinib <i>Nilotinib dihydrochloride dihydrate</i></b> |                                     |                          |                        |
| Devatis GmbH                                                        | Marketing authorisation application | 27/11/2024               | 2                      |
| <b>L01EA03 nilotinib <i>Nilotinib hydrochloride dihydrate</i></b>   |                                     |                          |                        |
| Hetero Europe S.L.                                                  | Marketing authorisation application | 26/02/2025               | 3                      |
| <b>L01EA03 nilotinib <i>Nilotinib hydrochloride monohydrate</i></b> |                                     |                          |                        |
| Helm Pharmaceuticals GmbH                                           | Marketing authorisation application | 31/07/2024               | 2                      |
| <b>L01EA03 nilotinib <i>Nilotinib</i></b>                           |                                     |                          |                        |
| Amarox Pharma B.V.                                                  | Marketing authorisation application | 31/01/2025               | 3                      |
| Vivanta Generics s.r.o.                                             | Marketing authorisation application | 31/07/2025               | 3                      |
| <b>L01EF01 palbociclib <i>Palbociclib</i></b>                       |                                     |                          |                        |
| Synthon B.V.                                                        | Marketing authorisation application | 12/11/2024               | 3                      |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 30/04/2025               | 3                      |
| Teva GmbH                                                           | Marketing authorisation application | 30/05/2025               | 3                      |
| <b>L01EJ01 ruxolitinib <i>Ruxolitinib dihydrate</i></b>             |                                     |                          |                        |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 21/02/2025               | 5                      |
| <b>L01EJ01 ruxolitinib <i>Ruxolitinib hemifumarate</i></b>          |                                     |                          |                        |
| Devatis GmbH                                                        | Marketing authorisation application | 19/02/2025               | 4                      |
| G.L. Pharma GmbH                                                    | Marketing authorisation application | 27/02/2025               | 8                      |
| Genepharma S.A.                                                     | Marketing authorisation application | 27/02/2025               | 4                      |
| Reddy Holding GmbH                                                  | Marketing authorisation application | 28/08/2025               | 4                      |
| <b>L01EJ01 ruxolitinib <i>Ruxolitinib hydrochloride</i></b>         |                                     |                          |                        |
| Orion Corporation                                                   | Marketing authorisation application | 27/06/2024               | 4                      |
| Vivanta Generics s.r.o.                                             | Marketing authorisation application | 01/08/2024               | 4                      |
| Sandoz A/S                                                          | Marketing authorisation application | 03/02/2025               | 4                      |
| <b>L01EX02 sorafenib <i>Sorafenib tosilate</i></b>                  |                                     |                          |                        |
| Devatis GmbH                                                        | Marketing authorisation application | 31/07/2025               | 1                      |
| <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 mesylate</i></b>                |                                     |                          |                        |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 22/11/2024               | 2                      |
| STADA Arzneimittel AG                                               | Marketing authorisation application | 22/11/2024               | 6                      |

| Applicant                                                                                       | Nature of the application           | Application receipt date | Number of applications |
|-------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>L01EX09 nintedanib <i>Nintedanib esylate</i></b>                                             |                                     |                          |                        |
| Glenmark Arzneimittel GmbH                                                                      | Marketing authorisation application | 18/12/2023               | 2                      |
| ratiopharm GmbH                                                                                 | Marketing authorisation application | 26/09/2024               | 2                      |
| PGF Pharma International d.o.o.                                                                 | Marketing authorisation application | 02/06/2025               | 2                      |
| Laboratorios Cinfa S.A.                                                                         | Marketing authorisation application | 09/09/2025               | 2                      |
| <b>L01XA01 cisplatin <i>Cisplatin</i></b>                                                       |                                     |                          |                        |
| Amarox Pharma B.V.                                                                              | Marketing authorisation application | 30/05/2025               | 1                      |
| <b>L01XA03 oxaliplatin <i>Oxaliplatin</i></b>                                                   |                                     |                          |                        |
| Amarox Pharma B.V.                                                                              | Marketing authorisation application | 29/07/2025               | 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>                                                |                                     |                          |                        |
| Tillomed Malta Limited                                                                          | Marketing authorisation application | 02/10/2023               | 1                      |
| Accord Healthcare B.V.                                                                          | Marketing authorisation application | 04/01/2024               | 1                      |
| <b>L02BA03 fulvestrant <i>Fulvestrant</i></b>                                                   |                                     |                          |                        |
| Orion Corporation                                                                               | Marketing authorisation application | 03/11/2023               | 1                      |
| <b>L02BB04 enzalutamide <i>Enzalutamide</i></b>                                                 |                                     |                          |                        |
| Teva Nederland B.V.                                                                             | Marketing authorisation application | 27/03/2024               | 2                      |
| Day Zero ehf                                                                                    | Marketing authorisation application | 23/04/2025               | 2                      |
| Amarox Pharma B.V.                                                                              | Marketing authorisation application | 02/07/2025               | 2                      |
| Qilu Pharma Spain S.L.                                                                          | Marketing authorisation application | 31/07/2025               | 2                      |
| <b>L02BG04 letrozole <i>Letrozole</i></b>                                                       |                                     |                          |                        |
| Sandoz B.V.                                                                                     | Marketing authorisation application | 22/03/2024               | 1                      |
| Tarbis Farma S.L.                                                                               | Marketing authorisation application | 02/12/2024               | 1                      |
| <b>L02BX03 abiraterone <i>Abiraterone acetate</i></b>                                           |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                         | Marketing authorisation application | 01/08/2023               | 2                      |
| Devatis GmbH                                                                                    | Marketing authorisation application | 08/05/2025               | 1                      |
| <b>L03AX03 BCG vaccine <i>Mycobacterium bovis BCG (Danish strain 1331), live attenuated</i></b> |                                     |                          |                        |
| AJ Vaccines A/S                                                                                 | Marketing authorisation application | 10/06/2025               | 1                      |
| <b>L04AA06 mycophenolic acid <i>Mycophenolate mofetil</i></b>                                   |                                     |                          |                        |
| Amarox Pharma B.V.                                                                              | Marketing authorisation application | 23/06/2025               | 1                      |
| <b>L04AA31 teriflunomide <i>Teriflunomide</i></b>                                               |                                     |                          |                        |
| Heaton k.s.                                                                                     | Marketing authorisation application | 20/12/2023               | 1                      |

| Applicant                                                 | Nature of the application           | Application receipt date | Number of applications |
|-----------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>L04AA32 apremilast <i>Apremilast</i></b>               |                                     |                          |                        |
| Bioglan AB                                                | Marketing authorisation application | 31/10/2024               | 2                      |
| Sandoz B.V.                                               | Marketing authorisation application | 28/03/2025               | 2                      |
| Pharmathen S.A.                                           | Marketing authorisation application | 31/03/2025               | 2                      |
| <b>L04AA40 cladribine <i>Cladribine</i></b>               |                                     |                          |                        |
| Sandoz B.V.                                               | Marketing authorisation application | 25/08/2025               | 1                      |
| STADA Arzneimittel AG                                     | Marketing authorisation application | 26/08/2025               | 1                      |
| Sumar Pharma ehf.                                         | Marketing authorisation application | 26/08/2025               | 1                      |
| <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>L04AF01 tofacitinib <i>Tofacitinib citrate</i></b>     |                                     |                          |                        |
| Teva B.V.                                                 | Marketing authorisation application | 26/03/2025               | 2                      |
| STADA Arzneimittel AG                                     | Marketing authorisation application | 28/03/2025               | 4                      |
| Amarox Pharma B.V.                                        | Marketing authorisation application | 31/03/2025               | 2                      |
| Devatis GmbH                                              | Marketing authorisation application | 09/04/2025               | 2                      |
| Adalvo Limited                                            | Marketing authorisation application | 30/04/2025               | 1                      |
| <b>L04AK02 teriflunomide <i>Teriflunomide</i></b>         |                                     |                          |                        |
| STADA Nordic ApS                                          | Marketing authorisation application | 13/12/2024               | 2                      |
| Devatis GmbH                                              | Marketing authorisation application | 30/09/2025               | 2                      |
| <b>L04AX03 methotrexate <i>Methotrexate disodium</i></b>  |                                     |                          |                        |
| STADA Arzneimittel AG                                     | Marketing authorisation application | 25/01/2024               | 10                     |
| <b>L04AX05 pirfenidone <i>Pirfenidone</i></b>             |                                     |                          |                        |
| Glenmark Arzneimittel GmbH                                | Marketing authorisation application | 03/03/2025               | 2                      |
| <b>L04AX06 pomalidomide <i>Pomalidomide</i></b>           |                                     |                          |                        |
| Amarox Pharma B.V.                                        | Marketing authorisation application | 03/10/2024               | 4                      |
| <b>L04AX07 dimethyl fumarate <i>Dimethyl fumarate</i></b> |                                     |                          |                        |
| Vivanta Generics s.r.o.                                   | Marketing authorisation application | 30/09/2024               | 2                      |
| Amarox Pharma B.V.                                        | Marketing authorisation application | 22/10/2024               | 2                      |

| Applicant                                                                                   | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>M01AE01 ibuprofen <i>Ibuprofen</i></b>                                                   |                                     |                          |                        |
| Strides Nordic ApS                                                                          | Marketing authorisation application | 02/04/2024               | 3                      |
| Fairmed Healthcare GmbH                                                                     | Marketing authorisation application | 03/05/2024               | 3                      |
| Sandoz A/S                                                                                  | Marketing authorisation application | 13/12/2024               | 2                      |
| Sandoz A/S                                                                                  | Marketing authorisation application | 13/12/2024               | 4                      |
| Strides Nordic ApS                                                                          | Marketing authorisation application | 08/10/2025               | 3                      |
| Fysioline Oy                                                                                | Marketing authorisation application | 13/10/2025               | 1                      |
| <b>M01AE51 ibuprofen, combinations <i>Ibuprofen, Caffeine</i></b>                           |                                     |                          |                        |
| Teva B.V.                                                                                   | Marketing authorisation application | 09/12/2024               | 1                      |
| Alfred E. Tiefenbacher (GmbH & Co. KG)                                                      | Marketing authorisation application | 21/02/2025               | 1                      |
| <b>M01AE52 naproxen and esomeprazole <i>Naproxen, Esomeprazole magnesium trihydrate</i></b> |                                     |                          |                        |
| Orion Corporation                                                                           | Marketing authorisation application | 29/04/2025               | 1                      |
| <b>M01AH04 parecoxib <i>Parecoxib sodium</i></b>                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                 | Marketing authorisation application | 01/07/2025               | 1                      |
| <b>M01AX25 chondroitin sulfate <i>Chondroitin sulfate sodium</i></b>                        |                                     |                          |                        |
| IBSA Farmaceutici Italia S.r.l                                                              | Marketing authorisation application | 07/02/2025               | 1                      |
| Schmid Pharma B.V.                                                                          | Marketing authorisation application | 28/02/2025               | 1                      |
| <b>M02AA07 piroxicam <i>Piroxicam</i></b>                                                   |                                     |                          |                        |
| Haleon Denmark ApS                                                                          | Marketing authorisation application | 28/03/2025               | 1                      |
| <b>M02AA15 diclofenac <i>Diclofenac diethylamine</i></b>                                    |                                     |                          |                        |
| Fysioline Oy                                                                                | Marketing authorisation application | 18/07/2025               | 1                      |
| <b>M02AA15 diclofenac <i>Diclofenac sodium</i></b>                                          |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                                 | Marketing authorisation application | 26/09/2024               | 1                      |
| Haleon Denmark ApS                                                                          | Marketing authorisation application | 03/06/2025               | 1                      |
| <b>M03AC09 rocuronium bromide <i>Rocuronium bromide</i></b>                                 |                                     |                          |                        |
| Accord Healthcare B.V.                                                                      | Marketing authorisation application | 31/05/2021               | 1                      |
| Noridem Enterprises Limited                                                                 | Marketing authorisation application | 07/06/2024               | 1                      |
| Amarox Pharma B.V.                                                                          | Marketing authorisation application | 02/06/2025               | 1                      |
| <b>M03AC11 cisatracurium <i>Cisatracurium besilate</i></b>                                  |                                     |                          |                        |
| Noridem Enterprises Limited                                                                 | Marketing authorisation application | 24/02/2025               | 1                      |
| <b>M03BX01 baclofen <i>Baclofen</i></b>                                                     |                                     |                          |                        |
| 2Care4 Generics ApS                                                                         | Marketing authorisation application | 31/01/2025               | 1                      |
| <b>M04AA01 allopurinol <i>Allopurinol</i></b>                                               |                                     |                          |                        |
| Renantos Pharmavertriebsgesellschaft mbH                                                    | Marketing authorisation application | 02/05/2024               | 3                      |

| Applicant                                                                                                                                                      | Nature of the application           | Application receipt date | Number of applications |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>M04AC01 colchicine</b> <i>Colchicine</i>                                                                                                                    |                                     |                          |                        |
| Indoco Remedies Czech s.r.o.                                                                                                                                   | Marketing authorisation application | 26/01/2022               | 1                      |
| <b>M05BB04 risedronic acid, calcium and colecalciferol, sequential</b> <i>Calcium carbonate, Cholecalciferol concentrate (powder form), Risedronate sodium</i> |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                                                                                                    | Marketing authorisation application | 27/12/2024               | 1                      |
| <b>N01AH06 remifentanil</b> <i>Remifentanil hydrochloride</i>                                                                                                  |                                     |                          |                        |
| Kalceks AS                                                                                                                                                     | Marketing authorisation application | 30/04/2025               | 3                      |
| Noridem Enterprises Limited                                                                                                                                    | Marketing authorisation application | 01/07/2025               | 3                      |
| <b>N01BB02 lidocaine</b> <i>Lidocaine hydrochloride monohydrate</i>                                                                                            |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                                                    | Marketing authorisation application | 21/03/2024               | 2                      |
| <b>N01BB02 lidocaine</b> <i>Lidocaine</i>                                                                                                                      |                                     |                          |                        |
| Orion Corporation                                                                                                                                              | Marketing authorisation application | 31/01/2025               | 1                      |
| <b>N01BB09 ropivacaine</b> <i>Ropivacaine hydrochloride monohydrate</i>                                                                                        |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                                                                                                             | Marketing authorisation application | 12/12/2024               | 4                      |
| Noridem Enterprises Limited                                                                                                                                    | Marketing authorisation application | 20/01/2025               | 5                      |
| <b>N01BB51 bupivacaine, combinations</b> <i>Bupivacaine hydrochloride monohydrate, Adrenaline tartrate</i>                                                     |                                     |                          |                        |
| Macure Pharma ApS                                                                                                                                              | Marketing authorisation application | 11/04/2025               | 2                      |
| <b>N01BB58 articaine, combinations</b> <i>Articaine hydrochloride, Epinephrine</i>                                                                             |                                     |                          |                        |
| Laboratorios Normon S.A.                                                                                                                                       | Marketing authorisation application | 25/03/2025               | 2                      |
| <b>N02AA05 oxycodone</b> <i>Oxycodone hydrochloride</i>                                                                                                        |                                     |                          |                        |
| G.L. Pharma GmbH                                                                                                                                               | Marketing authorisation application | 22/05/2025               | 2                      |
| <b>N02BE01 paracetamol</b> <i>Paracetamol</i>                                                                                                                  |                                     |                          |                        |
| ratiopharm GmbH                                                                                                                                                | Marketing authorisation application | 15/07/2024               | 2                      |
| Noridem Enterprises Limited                                                                                                                                    | Marketing authorisation application | 24/03/2025               | 1                      |
| Fresenius Kabi Deutschland GmbH                                                                                                                                | Marketing authorisation application | 08/04/2025               | 1                      |
| <b>N02BE51 paracetamol, combinations excl. psycholeptics</b> <i>Ibuprofen, Paracetamol</i>                                                                     |                                     |                          |                        |
| Vale Pharmaceuticals Limited                                                                                                                                   | Marketing authorisation application | 09/10/2023               | 1                      |
| Fysioline Oy                                                                                                                                                   | Marketing authorisation application | 10/04/2025               | 1                      |
| <b>N02BE51 paracetamol, combinations excl. psycholeptics</b> <i>Paracetamol, Caffeine</i>                                                                      |                                     |                          |                        |
| Haleon Denmark ApS                                                                                                                                             | Marketing authorisation application | 17/12/2024               | 1                      |
| <b>N02BF02 pregabalin</b> <i>Pregabalin</i>                                                                                                                    |                                     |                          |                        |
| Grindeks AS                                                                                                                                                    | Marketing authorisation application | 01/08/2024               | 6                      |
| <b>N02CC01 sumatriptan</b> <i>Sumatriptan</i>                                                                                                                  |                                     |                          |                        |
| Medical Valley Invest AB                                                                                                                                       | Marketing authorisation application | 09/12/2024               | 2                      |

| Applicant                                                           | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>N02CC05 almotriptan</b> <i>Almotriptan D,L-hydrogen malate</i>   |                                     |                          |                        |
| Abacus Medicine A/S                                                 | Parallel import                     | 03/12/2024               | 1                      |
| <b>N02CX02 clonidine</b> <i>Clonidine hydrochloride</i>             |                                     |                          |                        |
| Macure Pharma ApS                                                   | Marketing authorisation application | 28/08/2024               | 1                      |
| <b>N03AA03 primidone</b> <i>Primidone</i>                           |                                     |                          |                        |
| 2Care4 Generics ApS                                                 | Marketing authorisation application | 01/10/2024               | 3                      |
| <b>N03AB02 phenytoin</b> <i>Phenytoin sodium</i>                    |                                     |                          |                        |
| Hikma Farmacêutica (Portugal) S.A.                                  | Marketing authorisation application | 03/03/2025               | 1                      |
| <b>N03AD01 ethosuximide</b> <i>Ethosuximide</i>                     |                                     |                          |                        |
| Neuraxpharm Arzneimittel GmbH                                       | Marketing authorisation application | 23/05/2025               | 1                      |
| <b>N03AF02 oxcarbazepine</b> <i>Oxcarbazepine</i>                   |                                     |                          |                        |
| Amarox Pharma GmbH                                                  | Marketing authorisation application | 11/03/2025               | 3                      |
| <b>N03AG01 valproic acid</b> <i>Sodium valproate, Valproic acid</i> |                                     |                          |                        |
| Orifarm Oy                                                          | Parallel import                     | 13/01/2025               | 1                      |
| <b>N03AG01 valproic acid</b> <i>Sodium valproate</i>                |                                     |                          |                        |
| Desitin Arzneimittel GmbH                                           | Marketing authorisation application | 30/04/2025               | 4                      |
| <b>N03AX09 lamotrigine</b> <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                      |
| <b>N03AX14 levetiracetam</b> <i>Levetiracetam</i>                   |                                     |                          |                        |
| C4 health GmbH                                                      | Marketing authorisation application | 22/12/2023               | 4                      |
| Fresenius Kabi Austria GmbH                                         | Marketing authorisation application | 28/08/2024               | 1                      |
| Kalceks AS                                                          | Marketing authorisation application | 31/01/2025               | 1                      |
| Orifarm Oy                                                          | Parallel import                     | 28/07/2025               | 1                      |
| Grindeks AS                                                         | Marketing authorisation application | 01/08/2025               | 4                      |
| <b>N03AX18 lacosamide</b> <i>Lacosamide</i>                         |                                     |                          |                        |
| As Grindex                                                          | Marketing authorisation application | 22/12/2023               | 4                      |
| Tillomed Malta Limited                                              | Marketing authorisation application | 09/07/2024               | 1                      |
| Amarox Pharma GmbH                                                  | Marketing authorisation application | 08/05/2025               | 1                      |
| Amarox Pharma B.V.                                                  | Marketing authorisation application | 01/09/2025               | 4                      |
| <b>N03AX22 perampanel</b> <i>Perampanel hydrate (4:3)</i>           |                                     |                          |                        |
| Orion Corporation                                                   | Marketing authorisation application | 31/05/2024               | 6                      |

| Applicant                                                                                                              | Nature of the application           | Application receipt date | Number of applications |
|------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>N03AX23 brivaracetam <i>Brivaracetam</i></b>                                                                        |                                     |                          |                        |
| Medical Valley Invest AB                                                                                               | Marketing authorisation application | 02/05/2024               | 5                      |
| Desitin Arzneimittel GmbH                                                                                              | Marketing authorisation application | 28/06/2024               | 5                      |
| Desitin Arzneimittel GmbH                                                                                              | Marketing authorisation application | 31/07/2024               | 1                      |
| Orion Corporation                                                                                                      | Marketing authorisation application | 30/08/2024               | 5                      |
| Glenmark Arzneimittel GmbH                                                                                             | Marketing authorisation application | 18/10/2024               | 5                      |
| Orion Corporation                                                                                                      | Marketing authorisation application | 02/06/2025               | 5                      |
| <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>N04BB01 amantadine <i>Amantadine hydrochloride</i></b>                                                              |                                     |                          |                        |
| Macure Pharma ApS                                                                                                      | Marketing authorisation application | 28/11/2024               | 1                      |
| <b>N04BC09 rotigotine <i>Rotigotine</i></b>                                                                            |                                     |                          |                        |
| Orion Corporation                                                                                                      | Marketing authorisation application | 30/09/2024               | 6                      |
| <b>N04BD03 safinamide <i>Safinamide methanesulfonate</i></b>                                                           |                                     |                          |                        |
| Vivanta Generics s.r.o.                                                                                                | Marketing authorisation application | 19/09/2023               | 2                      |
| <b>N05AA02 levomepromazine <i>Levomepromazine maleate</i></b>                                                          |                                     |                          |                        |
| Aspire Pharma (Malta) Limited                                                                                          | Marketing authorisation application | 29/03/2024               | 2                      |
| <b>N05AE05 lurasidone <i>Lurasidone hydrochloride</i></b>                                                              |                                     |                          |                        |
| Amarox Pharma GmbH                                                                                                     | Marketing authorisation application | 18/11/2024               | 3                      |
| <b>N05AH02 clozapine <i>Clozapine</i></b>                                                                              |                                     |                          |                        |
| Grindeks AS                                                                                                            | Marketing authorisation application | 27/09/2023               | 2                      |
| <b>N05AH03 olanzapine <i>Olanzapine</i></b>                                                                            |                                     |                          |                        |
| Devatis GmbH                                                                                                           | Marketing authorisation application | 30/07/2025               | 6                      |
| <b>N05AH04 quetiapine <i>Quetiapine fumarate</i></b>                                                                   |                                     |                          |                        |
| Grindeks AS                                                                                                            | Marketing authorisation application | 07/10/2022               | 4                      |
| Grindeks AS                                                                                                            | Marketing authorisation application | 10/10/2022               | 5                      |
| Amarox Pharma B.V.                                                                                                     | Marketing authorisation application | 09/10/2025               | 7                      |
| <b>N05AX Other antipsychotics <i>Sodium valproate</i></b>                                                              |                                     |                          |                        |
| Desitin Arzneimittel GmbH                                                                                              | Marketing authorisation application | 30/04/2025               | 4                      |
| <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                      |

| Applicant                                                                                | Nature of the application           | Application receipt date | Number of applications |
|------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>N05AX13 paliperidone</b> <i>Paliperidone palmitate</i>                                |                                     |                          |                        |
| Viatriis Limited                                                                         | Marketing authorisation application | 01/12/2023               | 12                     |
| Viatriis Limited                                                                         | Marketing authorisation application | 25/10/2024               | 8                      |
| Advanz Pharma Limited                                                                    | Marketing authorisation application | 03/03/2025               | 4                      |
| <b>N05AX15 cariprazine</b> <i>Cariprazine hydrochloride</i>                              |                                     |                          |                        |
| Devatis GmbH                                                                             | Marketing authorisation application | 31/07/2025               | 4                      |
| KRKA d.d. Novo mesto                                                                     | Marketing authorisation application | 30/09/2025               | 4                      |
| <b>N05BA01 diazepam</b> <i>Diazepam</i>                                                  |                                     |                          |                        |
| Macure Pharma ApS                                                                        | Marketing authorisation application | 01/11/2024               | 1                      |
| <b>N05BB01 hydroxyzine</b> <i>Hydroxyzine hydrochloride</i>                              |                                     |                          |                        |
| Abacus Medicine A/S                                                                      | Parallel import                     | 02/08/2024               | 1                      |
| <b>N05CD08 midazolam</b> <i>Midazolam maleate</i>                                        |                                     |                          |                        |
| SERB S.A.                                                                                | Marketing authorisation application | 27/02/2025               | 1                      |
| <b>N05CD08 midazolam</b> <i>Midazolam</i>                                                |                                     |                          |                        |
| Laboratoire Aguettant                                                                    | Marketing authorisation application | 31/07/2024               | 2                      |
| <b>N05CH01 melatonin</b> <i>Melatonin</i>                                                |                                     |                          |                        |
| Orion Corporation                                                                        | Marketing authorisation application | 29/11/2024               | 2                      |
| Vitabalans Oy                                                                            | Marketing authorisation application | 26/09/2025               | 3                      |
| <b>N05CM18 dexmedetomidine</b> <i>Dexmedetomidine hydrochloride</i>                      |                                     |                          |                        |
| Hameln Pharma GmbH                                                                       | Marketing authorisation application | 31/08/2023               | 1                      |
| Noridem Enterprises Limited                                                              | Marketing authorisation application | 21/10/2024               | 1                      |
| <b>N06AA09 amitriptyline</b> <i>Amitriptyline hydrochloride</i>                          |                                     |                          |                        |
| Neuraxpharm Sweden AB                                                                    | Marketing authorisation application | 03/04/2024               | 1                      |
| <b>N06AB06 sertraline</b> <i>Sertraline hydrochloride</i>                                |                                     |                          |                        |
| RIA Generics Limited                                                                     | Marketing authorisation application | 22/05/2023               | 2                      |
| <b>N06AX11 mirtazapine</b> <i>Mirtazapine</i>                                            |                                     |                          |                        |
| Devatis GmbH                                                                             | Marketing authorisation application | 08/04/2025               | 3                      |
| <b>N06AX12 bupropion</b> <i>Bupropion hydrochloride</i>                                  |                                     |                          |                        |
| Aliud Pharma GmbH&Co. KG                                                                 | Marketing authorisation application | 12/03/2024               | 2                      |
| Amarox Pharma B.V.                                                                       | Marketing authorisation application | 30/01/2025               | 2                      |
| <b>N06AX16 venlafaxine</b> <i>Venlafaxine hydrochloride</i>                              |                                     |                          |                        |
| IPCA Produtos Farmacêuticos Unipessoal Lda.                                              | Marketing authorisation application | 02/05/2024               | 3                      |
| <b>N06AX26 vortioxetine</b> <i>Vortioxetine hydrobromide benzyl alcohol hemi-solvate</i> |                                     |                          |                        |
| Orion Corporation                                                                        | Marketing authorisation application | 12/09/2025               | 4                      |

| Applicant                                                                      | Nature of the application           | Application receipt date | Number of applications |
|--------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>N06AX26 vortioxetine</b> <i>Vortioxetine hydrobromide</i>                   |                                     |                          |                        |
| Orion Corporation                                                              | Marketing authorisation application | 16/01/2025               | 4                      |
| Biofarm Sp.z.o.o                                                               | Marketing authorisation application | 07/02/2025               | 2                      |
| Accord Healthcare Ireland Limited                                              | Marketing authorisation application | 28/02/2025               | 4                      |
| STADA Arzneimittel AG                                                          | Marketing authorisation application | 16/05/2025               | 4                      |
| Sandoz Pharmaceuticals d.d                                                     | Marketing authorisation application | 01/09/2025               | 4                      |
| Teva GmbH                                                                      | Marketing authorisation application | 01/09/2025               | 4                      |
| <b>N06BA02 dexamfetamine</b> <i>Dexamphetamine sulphate</i>                    |                                     |                          |                        |
| 2Care4 Generics ApS                                                            | Marketing authorisation application | 03/03/2025               | 3                      |
| ACE Pharmaceuticals BV                                                         | Marketing authorisation application | 26/03/2025               | 1                      |
| <b>N06BA04 methylphenidate</b> <i>Methylphenidate hydrochloride</i>            |                                     |                          |                        |
| Laboratorios Liconsa S.A.                                                      | Marketing authorisation application | 02/04/2025               | 5                      |
| <b>N06BA09 atomoxetine</b> <i>Atomoxetine hydrochloride</i>                    |                                     |                          |                        |
| Amarox Pharma GmbH                                                             | Marketing authorisation application | 30/04/2025               | 7                      |
| 2Care4 Generics ApS                                                            | Marketing authorisation application | 31/07/2025               | 1                      |
| <b>N06BA12 lisdexamfetamine</b> <i>Lisdexamfetamine dimesylate</i>             |                                     |                          |                        |
| Aspire Pharma (Malta) Limited                                                  | Marketing authorisation application | 21/01/2025               | 6                      |
| Sandoz A/S                                                                     | Marketing authorisation application | 21/01/2025               | 6                      |
| <b>N06DA03 rivastigmine</b> <i>Rivastigmine</i>                                |                                     |                          |                        |
| Sandoz A/S                                                                     | Marketing authorisation application | 01/07/2024               | 3                      |
| Strides Nordic ApS                                                             | Marketing authorisation application | 02/09/2024               | 3                      |
| <b>N06DX01 memantine</b> <i>Memantine hydrochloride</i>                        |                                     |                          |                        |
| UAB Baltijos Bite                                                              | Marketing authorisation application | 01/12/2023               | 2                      |
| <b>N07BA03 varenicline</b> <i>Varenicline tartrate</i>                         |                                     |                          |                        |
| Viatis Limited                                                                 | Marketing authorisation application | 29/02/2024               | 3                      |
| <b>N07BB01 disulfiram</b> <i>Disulfiram</i>                                    |                                     |                          |                        |
| Macure Pharma ApS                                                              | Marketing authorisation application | 25/03/2025               | 1                      |
| <b>N07XX08 tafamidis</b> <i>Tafamidis</i>                                      |                                     |                          |                        |
| Cipla Europe NV                                                                | Marketing authorisation application | 28/03/2025               | 1                      |
| Adalvo Limited                                                                 | Marketing authorisation application | 29/07/2025               | 1                      |
| <b>P03AX Other ectoparasiticides, incl. scabicides</b> <i>Benzyl benzoate</i>  |                                     |                          |                        |
| Sun-Farm Sp. z o.o.                                                            | Marketing authorisation application | 28/06/2024               | 2                      |
| <b>QA03FA01 metoclopramide</b> <i>Metoclopramide hydrochloride monohydrate</i> |                                     |                          |                        |
| ADOH B.V.                                                                      | Marketing authorisation application | 11/04/2024               | 1                      |

| Applicant                                                                                                                                                                                     | Nature of the application           | Application receipt date | Number of applications |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| QA06AD11 lactulose <i>Lactulose</i>                                                                                                                                                           |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                                                                                        | Marketing authorisation application | 03/02/2025               | 1                      |
| QC03CA01 furosemide <i>Furosemide</i>                                                                                                                                                         |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                                                                                        | Marketing authorisation application | 22/09/2025               | 1                      |
| QC09AA07 benazepril <i>Benazepril hydrochloride</i>                                                                                                                                           |                                     |                          |                        |
| Virbac                                                                                                                                                                                        | Marketing authorisation application | 26/02/2024               | 1                      |
| QC09CA07 telmisartan <i>Telmisartan</i>                                                                                                                                                       |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                                                                                        | Marketing authorisation application | 07/03/2022               | 1                      |
| QD08AG03 iodine <i>Iodine</i>                                                                                                                                                                 |                                     |                          |                        |
| Delaval                                                                                                                                                                                       | Marketing authorisation application | 11/12/2024               | 2                      |
| QG52X VARIOUS PRODUCTS FOR THE CARE OF TEATS AND UDDER <i>Hydrocortisone aceponate</i>                                                                                                        |                                     |                          |                        |
| Virbac                                                                                                                                                                                        | Marketing authorisation application | 26/11/2024               | 1                      |
| QH02AB02 dexamethasone <i>Dexamethasone sodium phosphate</i>                                                                                                                                  |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                                                                                        | Marketing authorisation application | 20/07/2020               | 1                      |
| QH02AB06 prednisolone <i>Prednisolone</i>                                                                                                                                                     |                                     |                          |                        |
| Axience                                                                                                                                                                                       | Marketing authorisation application | 02/04/2025               | 1                      |
| QH03BB02 thiamazole <i>Thiamazole</i>                                                                                                                                                         |                                     |                          |                        |
| Virbac                                                                                                                                                                                        | Marketing authorisation application | 28/08/2024               | 1                      |
| QI01AD09 Avian infectious bursal disease virus vaccine (Gumboro disease) <i>Infectious bursal disease virus, strain LC 75, Live</i>                                                           |                                     |                          |                        |
| Elanco GmbH                                                                                                                                                                                   | Marketing authorisation application | 02/06/2025               | 1                      |
| QI02AB17 Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia <i>Escherichia coli, strain 5117 J5, inactivated, Staphylococcus aureus, strain DSM 4910, inactivated</i> |                                     |                          |                        |
| Boehringer Ingelheim Vetmedica GmbH                                                                                                                                                           | Marketing authorisation application | 03/12/2024               | 1                      |
| QI02AE05 mycoplasma <i>Mycoplasma bovis, strain N2805-1, live</i>                                                                                                                             |                                     |                          |                        |
| Zoetis Animal Health ApS                                                                                                                                                                      | Marketing authorisation application | 09/07/2025               | 1                      |
| QI02AP01 Trichophyton vaccine <i>Trichophyton verrucosum, live, attenuated</i>                                                                                                                |                                     |                          |                        |
| Salfarm Danmark A/S                                                                                                                                                                           | Marketing authorisation application | 08/03/2024               | 1                      |
| QI05AA01 Equine influenza virus vaccine <i>Equine Influenza virus H3N8, A/Equine/Limerick/2010, Inactivated, Equine influenza virus H3N8, A/Equine/Brno/08, Inactivated, Tetanus toxoid</i>   |                                     |                          |                        |
| Bioveta a.s.                                                                                                                                                                                  | Marketing authorisation application | 15/11/2024               | 1                      |
| QI05AA01 Equine influenza virus vaccine <i>Equine Influenza virus H3N8, A/Equine/Limerick/2010, Inactivated, Equine influenza virus H3N8, A/Equine/Brno/08, Inactivated</i>                   |                                     |                          |                        |
| Bioveta a.s.                                                                                                                                                                                  | Marketing authorisation application | 15/11/2024               | 1                      |
| QJ01BA90 florfenicol <i>Florfenicol</i>                                                                                                                                                       |                                     |                          |                        |
| Interchemie Werken De Adelaar Eesti AS                                                                                                                                                        | Marketing authorisation application | 18/06/2025               | 1                      |

| Applicant                                                                                                                  | Nature of the application           | Application receipt date | Number of applications |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <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>Sulfadiazine, Trimethoprim</i></b>                         |                                     |                          |                        |
| Dopharma Research B.V.                                                                                                     | Marketing authorisation application | 22/01/2025               | 1                      |
| <b>QJ01EW10 sulfadiazine and trimethoprim, incl. derivatives <i>Trimethoprim, Sulfadiazine</i></b>                         |                                     |                          |                        |
| CP-Pharma Handelsgesellschaft mbH                                                                                          | Marketing authorisation application | 28/05/2025               | 2                      |
| <b>QM01AC06 meloxicam <i>Meloxicam</i></b>                                                                                 |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 13/09/2021               | 1                      |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 21/09/2021               | 1                      |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 08/10/2021               | 1                      |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 11/11/2021               | 1                      |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 03/11/2022               | 2                      |
| Cyton AH Biosciences GmbH                                                                                                  | Marketing authorisation application | 22/10/2024               | 1                      |
| <b>QM01AE03 ketoprofen <i>Ketoprofen</i></b>                                                                               |                                     |                          |                        |
| VetViva Richter GmbH                                                                                                       | Marketing authorisation application | 20/03/2025               | 1                      |
| <b>QM01AE91 carprofen <i>Carprofen</i></b>                                                                                 |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 07/12/2022               | 2                      |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 09/09/2024               | 7                      |
| Norbrook Laboratories (Ireland) Limited                                                                                    | Marketing authorisation application | 25/09/2024               | 1                      |
| <b>QM01AG02 tolfenamic acid <i>Tolfenamic acid</i></b>                                                                     |                                     |                          |                        |
| HuVepharma                                                                                                                 | Marketing authorisation application | 08/10/2024               | 1                      |
| <b>QM01AH91 robenacoxib <i>Robenacoxib</i></b>                                                                             |                                     |                          |                        |
| KRKA d.d. Novo mesto                                                                                                       | Marketing authorisation application | 25/04/2025               | 1                      |
| KRKA d.d. Novo mesto                                                                                                       | Marketing authorisation application | 28/04/2025               | 1                      |
| <b>QM01AX90 pentosan polysulphate <i>Pentosan polysulfate sodium</i></b>                                                   |                                     |                          |                        |
| Forte Healthcare Licencing Limited                                                                                         | Marketing authorisation application | 05/03/2025               | 1                      |
| <b>QN01AX99 other general anesthetics, combinations <i>Tiletamine hydrochloride, Zolazepam hydrochloride</i></b>           |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 18/06/2025               | 1                      |
| <b>QN01BA52 procaine, combinations <i>Procaine hydrochloride, Adrenaline tartrate</i></b>                                  |                                     |                          |                        |
| Forte Healthcare Licencing Limited                                                                                         | Marketing authorisation application | 04/02/2025               | 1                      |
| <b>QN02AC52 methadone, combinations excl. psycholeptics <i>Levomethadone hydrochloride, Fenpipramide hydrochloride</i></b> |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 28/02/2022               | 2                      |
| <b>QN02AE01 buprenorphine <i>Buprenorphine hydrochloride</i></b>                                                           |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                     | Marketing authorisation application | 14/02/2025               | 1                      |

| Applicant                                                                                   | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>QN02AF01 butorphanol</b> <i>Butorphanol Tartrate</i>                                     |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 08/04/2025               | 1                      |
| <b>QN02AX02 tramadol</b> <i>Tramadol hydrochloride</i>                                      |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 05/12/2022               | 6                      |
| <b>QN03AA02 phenobarbital</b> <i>Phenobarbital</i>                                          |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 13/09/2023               | 3                      |
| <b>QN04BC02 Pergolide</b> <i>Pergolide mesilate</i>                                         |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 12/04/2023               | 3                      |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 07/01/2025               | 1                      |
| <b>QN05CM18 Dexmedetomidine</b> <i>Dexmedetomidine hydrochloride</i>                        |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 15/09/2022               | 1                      |
| <b>QN05CM90 detomidine</b> <i>Detomidine hydrochloride for veterinary use</i>               |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 14/04/2022               | 1                      |
| <b>QN05CM91 medetomidine</b> <i>Medetomidine hydrochloride</i>                              |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                      | Marketing authorisation application | 15/09/2022               | 1                      |
| <b>QN05CM92 xylazine</b> <i>Xylazine hydrochloride</i>                                      |                                     |                          |                        |
| Forte Healthcare Licencing Limited                                                          | Marketing authorisation application | 01/04/2025               | 1                      |
| <b>QN51AA01 pentobarbital</b> <i>Pentobarbital sodium</i>                                   |                                     |                          |                        |
| Wirtschaftsgenossenschaft deutscher Tieraerzte eG                                           | Marketing authorisation application | 21/08/2025               | 1                      |
| <b>QP51BC03 diclazuril</b> <i>Diclazuril</i>                                                |                                     |                          |                        |
| HuVepharma                                                                                  | Marketing authorisation application | 22/01/2024               | 1                      |
| <b>QP52AA51 praziquantel, combinations</b> <i>Praziquantel, Pyrantel embonate, Febantel</i> |                                     |                          |                        |
| Chanelle Pharmaceuticals Manufacturing Limited                                              | Marketing authorisation application | 08/06/2023               | 2                      |
| <b>QP53AC55 flumethrin, combinations</b> <i>Flumethrin, Imidacloprid, Titanium dioxide</i>  |                                     |                          |                        |
| Beaphar B.V.                                                                                | Marketing authorisation application | 16/09/2024               | 1                      |
| <b>QP53AC55 flumethrin, combinations</b> <i>Flumethrin, Imidacloprid</i>                    |                                     |                          |                        |
| Beaphar B.V.                                                                                | Marketing authorisation application | 16/09/2024               | 2                      |
| <b>QP53AC55 flumethrin, combinations</b> <i>Imidacloprid, Flumethrin</i>                    |                                     |                          |                        |
| Virbac                                                                                      | Marketing authorisation application | 03/07/2024               | 3                      |
| <b>QP54AA01 ivermectin</b> <i>Ivermectin</i>                                                |                                     |                          |                        |
| Chanelle Pharmaceuticals Manufacturing Limited                                              | Marketing authorisation application | 17/10/2023               | 1                      |
| <b>QP54AA51 ivermectin, combinations</b> <i>Ivermectin, Praziquantel</i>                    |                                     |                          |                        |
| Bioveta a.s.                                                                                | Marketing authorisation application | 10/01/2025               | 1                      |

| Applicant                                                                                                                       | Nature of the application           | Application receipt date | Number of applications |
|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>QP54AB51 milbemycin oxime, combinations</b> <i>Milbemycin oxime, Praziquantel</i>                                            |                                     |                          |                        |
| Chanelle Pharmaceuticals Manufacturing Limited                                                                                  | Marketing authorisation application | 27/10/2017               | 1                      |
| ALFAMED                                                                                                                         | Marketing authorisation application | 14/09/2023               | 4                      |
| Chanelle Pharmaceuticals Manufacturing Limited                                                                                  | Marketing authorisation application | 23/01/2024               | 1                      |
| Chanelle Pharmaceuticals Manufacturing Limited                                                                                  | Marketing authorisation application | 29/01/2024               | 2                      |
| <b>QR03CC13 clenbuterol</b> <i>Clenbuterol hydrochloride</i>                                                                    |                                     |                          |                        |
| Alfasan Nederland B.V.                                                                                                          | Marketing authorisation application | 05/03/2024               | 1                      |
| <b>QS01AA01 chloramphenicol</b> <i>Chloramphenicol</i>                                                                          |                                     |                          |                        |
| Domes Pharma                                                                                                                    | Marketing authorisation application | 24/06/2025               | 1                      |
| <b>R01AA07 xylometazoline</b> <i>Xylometazoline hydrochloride</i>                                                               |                                     |                          |                        |
| Vianex S.A.                                                                                                                     | Marketing authorisation application | 01/11/2024               | 2                      |
| <b>R01AD58 fluticasone, combinations</b> <i>Azelastine hydrochloride, Fluticasone propionate</i>                                |                                     |                          |                        |
| Adalvo Limited                                                                                                                  | Marketing authorisation application | 02/06/2025               | 2                      |
| <b>R01BA52 pseudoephedrine, combinations</b> <i>Pseudoephedrine hydrochloride, Chlorphenamine maleate</i>                       |                                     |                          |                        |
| UAB Baltijos Bite                                                                                                               | Marketing authorisation application | 28/06/2024               | 1                      |
| <b>R02AA03 dichlorobenzyl alcohol</b> <i>Amylmetacresol, 2,4-Dichlorobenzylalcohol</i>                                          |                                     |                          |                        |
| Mapaex Consumer Healthcare (Ireland) Private Limited                                                                            | Marketing authorisation application | 03/10/2025               | 2                      |
| Mapaex Consumer Healthcare (Ireland) Private Limited                                                                            | Marketing authorisation application | 06/10/2025               | 1                      |
| <b>R02AA06 cetylpyridinium</b> <i>Cetylpyridinium chloride, Lidocaine hydrochloride monohydrate</i>                             |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                                                                     | Marketing authorisation application | 22/04/2025               | 1                      |
| <b>R02AX01 flurbiprofen</b> <i>Flurbiprofen</i>                                                                                 |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                                                                     | Marketing authorisation application | 03/11/2023               | 1                      |
| Naiax Pharma S.L.                                                                                                               | Marketing authorisation application | 28/08/2024               | 1                      |
| Naiax Pharma S.L.                                                                                                               | Marketing authorisation application | 29/08/2024               | 1                      |
| <b>R03AC02 salbutamol</b> <i>Salbutamol sulfate</i>                                                                             |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                     | Marketing authorisation application | 20/02/2025               | 3                      |
| <b>R03AK06 salmeterol and fluticasone</b> <i>Salmeterol, Fluticasone</i>                                                        |                                     |                          |                        |
| PGF Pharma International d.o.o.                                                                                                 | Marketing authorisation application | 17/07/2025               | 2                      |
| <b>R03AL02 salbutamol and ipratropium bromide</b> <i>Ipratropium bromide, Salbutamol sulfate</i>                                |                                     |                          |                        |
| Noridem Enterprises Limited                                                                                                     | Marketing authorisation application | 30/09/2025               | 1                      |
| <b>R03AL04 indacaterol and glycopyrronium bromide</b> <i>Indacaterol maleate, Glycopyrronium bromide</i>                        |                                     |                          |                        |
| Genetic S.p.A.                                                                                                                  | Marketing authorisation application | 24/07/2024               | 1                      |
| <b>R05X OTHER COLD PREPARATIONS</b> <i>Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide, Chlorphenamine maleate</i> |                                     |                          |                        |
| UAB Baltijos Bite                                                                                                               | Marketing authorisation application | 28/06/2024               | 1                      |

| Applicant                                                                           | Nature of the application           | Application receipt date | Number of applications |
|-------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>R06AA04 clemastine</b> <i>Clemastine fumarate</i>                                |                                     |                          |                        |
| Macure Healthcare Limited                                                           | Marketing authorisation application | 17/01/2025               | 1                      |
| <b>R06AE03 cyclizine</b> <i>Cyclizine lactate</i>                                   |                                     |                          |                        |
| 2Care4 Generics ApS                                                                 | Marketing authorisation application | 28/02/2025               | 1                      |
| <b>R06AE07 cetirizine</b> <i>Cetirizine dihydrochloride</i>                         |                                     |                          |                        |
| Haleon Ireland Limited                                                              | Marketing authorisation application | 30/04/2024               | 2                      |
| <b>R06AX26 fexofenadine</b> <i>Fexofenadine hydrochloride</i>                       |                                     |                          |                        |
| Haleon Denmark ApS                                                                  | Marketing authorisation application | 17/12/2024               | 1                      |
| <b>R06AX27 desloratadine</b> <i>Desloratadine</i>                                   |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                         | Marketing authorisation application | 31/08/2023               | 1                      |
| Orion Corporation                                                                   | Marketing authorisation application | 27/09/2024               | 1                      |
| ratiopharm GmbH                                                                     | Marketing authorisation application | 20/08/2025               | 1                      |
| <b>R06AX29 bilastine</b> <i>Bilastine monohydrate</i>                               |                                     |                          |                        |
| Kappler Pharma Consult GmbH                                                         | Marketing authorisation application | 30/08/2024               | 1                      |
| <b>R07AX02 ivacaftor</b> <i>Ivacaftor</i>                                           |                                     |                          |                        |
| Accord Healthcare B.V.                                                              | Marketing authorisation application | 02/05/2024               | 1                      |
| STADA Arzneimittel AG                                                               | Marketing authorisation application | 30/09/2024               | 1                      |
| Lupin Europe GmbH                                                                   | Marketing authorisation application | 31/01/2025               | 2                      |
| Sandoz B.V.                                                                         | Marketing authorisation application | 02/05/2025               | 1                      |
| Genepharma S.A.                                                                     | Marketing authorisation application | 12/05/2025               | 2                      |
| <b>S01BA Corticosteroids, plain</b> <i>Clobetasol propionate</i>                    |                                     |                          |                        |
| Laboratorios Salvat S.A.                                                            | Marketing authorisation application | 23/02/2024               | 1                      |
| <b>S01BA01 dexamethasone</b> <i>Dexamethasone sodium phosphate</i>                  |                                     |                          |                        |
| Laboratoires Théa                                                                   | Marketing authorisation application | 01/07/2024               | 1                      |
| Pharmathen S.A.                                                                     | Marketing authorisation application | 20/05/2025               | 1                      |
| <b>S01BC04 flurbiprofen</b> <i>Flurbiprofen sodium dihydrate</i>                    |                                     |                          |                        |
| Horus Pharma                                                                        | Marketing authorisation application | 28/08/2025               | 1                      |
| <b>S01BC11 bromfenac</b> <i>Bromfenac sodium sesquihydrate</i>                      |                                     |                          |                        |
| Blumont Ofta Trading Limited                                                        | Marketing authorisation application | 02/09/2024               | 1                      |
| Laboratorios Salvat S.A.                                                            | Marketing authorisation application | 17/09/2024               | 1                      |
| <b>S01EC04 brinzolamide</b> <i>Brinzolamide</i>                                     |                                     |                          |                        |
| Hexal A/S                                                                           | Marketing authorisation application | 31/07/2024               | 1                      |
| <b>S01EC54 brinzolamide, combinations</b> <i>Brinzolamide, Brimonidine tartrate</i> |                                     |                          |                        |
| Pharmaselect International Beteiligungs GmbH                                        | Marketing authorisation application | 01/04/2025               | 1                      |

| Applicant                                                                                        | Nature of the application           | Application receipt date | Number of applications |
|--------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| <b>S01ED51 timolol, combinations <i>Bimatoprost, Timolol</i></b>                                 |                                     |                          |                        |
| Laboratoires Thea                                                                                | Marketing authorisation application | 12/02/2024               | 1                      |
| <b>S01ED51 timolol, combinations <i>Dorzolamide hydrochloride, Timolol maleate</i></b>           |                                     |                          |                        |
| Genetic S.p.A.                                                                                   | Marketing authorisation application | 26/04/2024               | 1                      |
| <b>S01ED51 timolol, combinations <i>Latanoprost, Timolol maleate</i></b>                         |                                     |                          |                        |
| Laboratorios Salvat S.A.                                                                         | Marketing authorisation application | 09/07/2024               | 1                      |
| <b>S01ED51 timolol, combinations <i>Latanoprost, Timolol</i></b>                                 |                                     |                          |                        |
| Creative Pharma Solutions s.r.o.                                                                 | Marketing authorisation application | 30/06/2025               | 1                      |
| Sandoz A/S                                                                                       | Marketing authorisation application | 01/07/2025               | 1                      |
| <b>S01EE01 latanoprost <i>Latanoprost</i></b>                                                    |                                     |                          |                        |
| Pharmathen S.A.                                                                                  | Marketing authorisation application | 07/03/2025               | 1                      |
| Bausch + Lomb Ireland Limited                                                                    | Marketing authorisation application | 21/03/2025               | 1                      |
| Genetic S.p.A.                                                                                   | Marketing authorisation application | 21/03/2025               | 2                      |
| Laboratorios Salvat S.A.                                                                         | Marketing authorisation application | 09/05/2025               | 1                      |
| <b>S01EE03 bimatoprost <i>Bimatoprost</i></b>                                                    |                                     |                          |                        |
| GHN Pharma Nordic AB                                                                             | Marketing authorisation application | 24/02/2025               | 1                      |
| <b>S01EE04 travoprost <i>Travoprost</i></b>                                                      |                                     |                          |                        |
| Blumont Ofta Trading Limited                                                                     | Marketing authorisation application | 30/09/2024               | 1                      |
| <b>S01XA12 dexpanthenol <i>Dexpanthenol</i></b>                                                  |                                     |                          |                        |
| Dr. Gerhard Mann Chem.-Pharm. fabrik GmbH                                                        | Marketing authorisation application | 25/06/2024               | 1                      |
| <b>V01AA02 grass pollen <i>Timothy</i></b>                                                       |                                     |                          |                        |
| ALK-Abello A/S                                                                                   | Marketing authorisation application | 06/10/2025               | 1                      |
| <b>V03AB34 fomepizole <i>Fomepizole</i></b>                                                      |                                     |                          |                        |
| Waymade B.V.                                                                                     | Marketing authorisation application | 19/09/2025               | 1                      |
| <b>V04CX01 indocyanine green <i>Indocyanine green</i></b>                                        |                                     |                          |                        |
| Provepharm                                                                                       | Marketing authorisation application | 07/10/2024               | 1                      |
| <b>V07AB Solvents and diluting agents, incl. irrigating solutions <i>Sodium chloride</i></b>     |                                     |                          |                        |
| Noridem Enterprises Limited                                                                      | Marketing authorisation application | 18/02/2025               | 1                      |
| <b>V07AB Solvents and diluting agents, incl. irrigating solutions <i>Water for injection</i></b> |                                     |                          |                        |
| Noridem Enterprises Limited                                                                      | Marketing authorisation application | 29/11/2024               | 1                      |
| <b>V09AA01 technetium (99mTc) exametazime <i>Exametazime</i></b>                                 |                                     |                          |                        |
| Radiopharmacy Laboratorium Kft.                                                                  | Marketing authorisation application | 28/08/2025               | 1                      |

| Applicant                                                                                                   | Nature of the application           | Application receipt date | Number of applications |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|------------------------|
| V09HA02 technetium (99mTc) exametazime labelled cells <i>Exametazime</i><br>Radiopharmacy Laboratorium Kft. | Marketing authorisation application | 28/08/2025               | 1                      |