

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-1/25 on January 30, 2025

| N | Trade name   | Common name of the active substance   | Pharmaceutical form | Strength and packaging, presentation | All manufacturing sites involved in the medicinal product manufacturing process (name, location)   | Country | Registration certificate holder (name, location)  | Country | Legal status for supply | Conclusion number and date |
|---|--|---|---------------------|--------------------------------------|--|---------|---|---------|-------------------------|----------------------------|
| 1 | Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard | amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate) | tablets dispersible | 125mg+31,25mg; (14/7x2) in blister   | Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager | Russia  | Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278 | Russia  | PoM                     | 22657<br>30.01.2025        |
| 2 | Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard | amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate) | tablets dispersible | 250mg+62,5mg; (14/7x2) in blister    | Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager | Russia  | Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278 | Russia  | PoM                     | 22658<br>30.01.2025        |
| 3 | Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard | amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate) | tablets dispersible | 500mg+125mg; (14/7x2) in blister     | Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager | Russia  | Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278 | Russia  | PoM                     | 22659<br>30.01.2025        |

|    |  |   |                        |  |  |         |   |         |     |                     |
|----|--|---|------------------------|--|--|---------|---|---------|-----|---------------------|
| 4  | Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard | amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate) | tablets dispersible    | 875mg+125mg: (14/7x2) in blister                   | Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager | Russia  | Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278 | Russia  | PoM | 22660<br>30.01.2025 |
| 5  | AqVirubicin  | epirubicin (epirubicin hydrochloride)   | solution for injection | 2mg/ml; glass vial 5ml                             | AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control  | Germany | Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi  | Georgia | PoM | 22661<br>30.01.2025 |
| 6  | AqVirubicin  | epirubicin (epirubicin hydrochloride)   | solution for injection | 2mg/ml; glass vial 25ml                            | AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control  | Germany | Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi  | Georgia | PoM | 22662<br>30.01.2025 |
| 7  | Validol Tatpharm                                     | levomenthol solution in menthyl isovalerate                                   | tablets sublingual     | 60mg; (100/10x10) in blister                       | Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260  | Russia  | Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260                                     | Russia  | PoM | 22663<br>30.01.2025 |
| 8  | Clivas Plus  | rosuvastatin (rosuvastatin calcium), ezetimibe                                | tablets film-coated    | 10mg+10mg; (30/3x10) in blister                    | ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009   | Greece  | Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev  | Ukraine | PoM | 22664<br>30.01.2025 |
| 9  | Clivas Plus  | rosuvastatin (rosuvastatin calcium), ezetimibe                                | tablets film-coated    | 20mg+10mg; (30/3x10) in blister                    | ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009   | Greece  | Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev  | Ukraine | PoM | 22665<br>30.01.2025 |
| 10 | Clivas Plus  | rosuvastatin (rosuvastatin calcium), ezetimibe                                | tablets film-coated    | 40mg+10mg; (30/3x10) in blister                    | ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009   | Greece  | Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev  | Ukraine | PoM | 22666<br>30.01.2025 |
| 11 | Paracetamol B. Braun                                 | paracetamol   | solution for iinfusion | 10mg/ml; 50ml plastic bottle, 100ml plastic bottle | B. Braun Medical S.A., Ctra. de Terrassa, 121, Rubi (Barcelona) 08191  | Spain   | B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, 34212  | Germany | PoM | 22667<br>30.01.2025 |

## LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 01-1/25 on January 30,  
2025

| N | Trade name | Common name of the active substance | Pharmaceutical form        | Strength and packaging, presentation                                       | All manufacturing sites involved in the medicinal product manufacturing process (name, location)  | Country | Registration certificate holder (name, location)    | Country | Legal status for supply | Conclusion number and date      |
|---|------------|-------------------------------------|----------------------------|--|---|---------|---|---------|-------------------------|---------------------------------|
| 1 | Ovitrelle  | choriogonadotropin alfa             | solution for s/c injection | 250mcg/0,5ml; (1) glass pre-filled syringe with needle in plastic pack     | Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)  | Italy   | Merck LLC, 35 Valovaya Street, Moscow 115054        | Russia  | PoM                     | 22689<br>(009514)<br>30.01.2025 |
| 2 | Verospiron | spironolactone                      | tablets                    | 25mg; (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) in blister | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest   | Hungary | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest | Hungary | PoM                     | 22690<br>(009834)<br>30.01.2025 |
| 3 | Verospiron | spironolactone                      | tablets                    | 25mg; (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) in blister | GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological) | Russia  | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest | Hungary | PoM                     | 22691<br>(009834)<br>30.01.2025 |

|   |            |   |         |  |   |        |  |         |     |                                 |
|---|------------|---|---------|--|---|--------|--|---------|-----|---------------------------------|
| 4 | Verospiron | spironolactone  | tablets | 25mg; (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) in blister   | GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia-packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia-quality control (microbiological) | Russia | Gyomroi ut 19-21, 1103 Budapest  | Hungary | PoM | 22692<br>(009834)<br>30.01.2025 |
| 5 | JO CET     | salbutamol (salbutamol sulfate), bromhexine hydrochloride, guaifenesin, menthol (levomenthol) | syrup   | 1mg/5ml+2mg/5ml+50mg/5ml+0,5mg/5ml; 100ml plastic container and measuring cup 15ml, 200ml plastic container and measuring cup 15ml | Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Plot No 215-216, G.I.D.C Industrial Area, Panoli: 394 116, Dist: Bharuch, Gujarat State  | India  | Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Neelam Centre, B wing, 4th floor, Hind Cycle Road, Worli, Gujarat State, Mumbai 400 030 | India   | PoM | 22693<br>(009834)<br>30.01.2025 |

## LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 01-1/25 on January 30, 2025

| N | Trade name                 | Common name of the active substance                                     | Pharmaceutical form                         | Strength and packaging, presentation                    | All manufacturing sites involved in the medicinal product manufacturing process (name, location)   | Country             | Registration certificate holder (name, location)   | Country             | Legal status for supply | Conclusion number and date |
|---|----------------------------|---|---|---|--|---------------------|--|---------------------|-------------------------|----------------------------|
| 1 | Coldrex MaxGrip            | paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid | powder for oral solution with lemon flavour | 1000mg+10mg+40mg; (10) sachets 6,427g                   | SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcalá de Henares, Madrid   | Spain               | STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel                                       | Germany             | OTC                     | 22676<br>30.01.2025        |
| 2 | Tinctura menthae piperitae | folium menthae piperite, oil menthae piperitae                          | tincture                                    | 50mg/ml+ 50mg/ml; glass bottle 30ml                     | ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079 for   | Republic of Armenia | IE Sergey Sergeevich Patvakanov, Apartment 44, Building 10, Antarayin 1-st District, Tsaghkadzor | Republic of Armenia | OTC                     | 22677<br>30.01.2025        |
| 3 | Metrofungyn                | miconazole (miconazole nitrate), metronidazole                          | capsules vaginal                            | 100mg+100mg; (10/2x5/)                                  | Minskintercaps U.V., 26/3 bild. No2, Inzhenemaya str., 220075, Minsk   | Republic of Belarus | Minskintercaps U.V., 26, Inzhenemaya str., 220075, Minsk   | Republic of Belarus | PoM                     | 22678<br>30.01.2025        |
| 4 | Co-Diroton                 | lisinopril (lisinopril dihydrate), hydrochlorothiazide                  | tablets                                     | 20mg+12,5mg; (10/1x10) in blister, (30/3x10) in blister | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland Sp. z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control | Hungary             | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest  | Hungary             | PoM                     | 22679<br>30.01.2025        |

|    |                                       |  |  |  |  |                     |   |                     |     |                     |
|----|---------------------------------------|--|--|--|--|---------------------|---|---------------------|-----|---------------------|
| 5  | Co-Diroton                            | lisinopril (lisinopril dihydrate), hydrochlorothiazide | tablets                                | 10mg+12,5mg; (10/1x10) in blister, (30/3x10) in blister          | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland Sp. z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control | Hungary             | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest   | Hungary             | PoM | 22680<br>30.01.2025 |
| 6  | PARACETAMOL<br>GIGA farm              | paracetamol  | tablets                                | 500mg; (200/20x10) in blister                                    | Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building   | Republic of Armenia | Giga Farm LLC, 3101, Gogunts st. 3/5, Gyumri  | Republic of Armenia | OTC | 22681<br>30.01.2025 |
| 7  | Nuvaring                              | etonogestrel, ethinylestradiol                         | vaginal delivery system (vaginal ring) | 11,7mg+2,7mg; (1) sachet   | N.V. Organon, Kloosterstraat 6, 5349 AB Oss  | Switzerland         | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern  | Switzerland         | PoM | 22682<br>30.01.2025 |
| 8  | Atracurium Besylate Injection 10mg/ml | atracurium (atracurium besylate)                       | solution for injection                 | 10mg/ml; (5) ampoules 2,5ml                                      | Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat  | India               | Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat | India               | PoM | 22683<br>30.01.2025 |
| 9  | Atracurium Besylate Injection         | atracurium (atracurium besylate)                       | solution for injection                 | 10mg/ml; (5) ampoules 5ml  | Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat   | India               | Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat | India               | PoM | 22684<br>30.01.2025 |
| 10 | Azimac                                | azithromycin (azithromycin dihydrate)                  | capsules                               | 250mg; (6/2x3) in blister  | GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi  | Georgia             | GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi   | Georgia             | PoM | 22685<br>30.01.2025 |
| 11 | Azimac                                | azithromycin (azithromycin dihydrate)                  | capsules                               | 500mg; (3/1x3) in blister  | GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi  | Georgia             | GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi   | Georgia             | PoM | 22686<br>30.01.2025 |
| 12 | Magnesium sulfate                     | magnesium sulfate                                      | solution for i/v and i/m injection     | 250mg/ml; (10) ampoules 5ml and (10) ampoules 5ml label banderol | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, ul. Chapaeva, Borisov, Minsk region   | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region            | Republic of Belarus | PoM | 22687<br>30.01.2025 |

## LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 01-1/25 on January 30, 2025

| N | Trade name | Common name of the active substance   | Pharmaceutical form        | Strength and packaging presentation                                     | All manufacturing sites involved in the medicinal product manufacturing process (name, location)  | Country         | Registration certificate holder (name, location)                                | Country     | Legal status for supply | Conclusion number and date |
|---|------------|---------------------------------------|----------------------------|---|---|-----------------|---|-------------|-------------------------|----------------------------|
| 1 | Arbidol    | umifenovir (umifenovir hydrochloride) | capsules                   | 100mg; (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18   | Russia          | JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112 | Russia      | OTC                     | 22668<br>30.01.2025        |
| 2 | Puregon    | follitropin beta (recombinant)        | solution for s/c injection | 300IU/0,36ml; cartridge 0,42ml and (6/2x3) needles                      | N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager | the Netherlands | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern                          | Switzerland | PoM                     | 22669<br>30.01.2025        |
| 3 | Puregon    | follitropin beta (recombinant)        | solution for s/c injection | 600IU/0,72ml; cartridge 0,78ml and (6/2x3) needles                      | N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager | the Netherlands | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern                          | Switzerland | PoM                     | 22670<br>30.01.2025        |
| 4 | ODESTON    | hymecromone                           | tablets                    | 200mg; (50/5x10) in blister   | Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice  | Poland          | Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow       | Poland      | OTC                     | 22671<br>30.01.2025        |

|   |           |  |                          |  |   |         |   |             |     |                     |
|---|-----------|--|--------------------------|--|---|---------|---|-------------|-----|---------------------|
| 5 | Diprosan  | betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate) | suspension for injection | 5mg/ml+2mg/ml; (5) ampoules 1ml                                      | Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220   | Belgium | Organon Central East GmbH, Weystasse 20, 6006 Luzern                          | Switzerland | PoM | 22672<br>30.01.2025 |
| 6 | Tot` Hema | iron (iron gluconate), manganese (manganese gluconate), copper (copper gluconate)          | solution oral            | 50mg/10ml+1,33mg/10ml+0,7mg/10ml; (20/2x10) ampoules 10ml in blister | Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150  | France  | Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil | France      | PoM | 22673<br>30.01.2025 |
| 7 | ACC 100   | acetylcysteine   | powder for oral solution | 100mg; (20) sachets 3g   | Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, 40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological) | Germany | Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana               | Slovenia    | OTC | 22674<br>30.01.2025 |
| 8 | ACC 200   | acetylcysteine   | powder for oral solution | 200mg; (20) sachets 3g   | Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, 40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological) | Germany | Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana               | Slovenia    | OTC | 22675<br>30.01.2025 |



## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/25 on January 30,  
2025

| N | Trade name          | Common name of the active substance              | Pharmaceutical form | Strength and packaging, presentation | All manufacturing sites involved in the medicinal product manufacturing process (name, location)   | Country | Registration certificate holder (name, location)                                | Country | Legal status for supply | Conclusion number and date |
|---|---------------------|--|---------------------|--------------------------------------|--|---------|---|---------|-------------------------|----------------------------|
| 1 | Canephron N         | centauri herba, levistici radix, rosmarini folia | tablets coated      | 18mg+18mg+18mg; (60/3x20) in blister | Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz - packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer | Germany | Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz       | Germany | OTC                     | 20500/1/1<br>30.01.2025    |
| 2 | Rinostop-Oticipharm | xylometazoline (xylometazoline hydrochloride)    | spray nasal         | 0,5mg/ml;15ml plastic vial           | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18  | Russia  | JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112 | Russia  | OTC                     | 19319/1/1<br>30.01.2025    |

|   |                     |  |   |   |  |         |  |         |     |                         |
|---|---------------------|--|---|---|--|---------|--|---------|-----|-------------------------|
| 3 | Rinostop-Oticipharm | xylometazoline (xylometazoline hydrochloride)  | spray nasal                                   | 1mg/ml; 15ml plastic vial   | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18  | Russia  | JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112                    | Russia  | PoM | 19320/1/1<br>30.01.2025 |
| 4 | Polydexa            | neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone (dexamethasone sodium metasulfobenzoate) | drops ear                                     | 1g (650000U)/100ml+1000000U/100ml+0,1g/100ml; 10,5ml bottle-dropper | Pharmaster, Zone Industrielle de Krafft, 67150 Erstein- bulk manufacturer, packager, batch releaser, QUALI CONTROLE, 29 rue Paul Vaillant Couturier, 60110 MERU, France- quality control (physicochemical), SOLVIAS FRANCE, Zone Industrielle, rue du Canal d' Alsace, 68490 HOMBOURG, France- quality control (microbiological) | France  | Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux | France  | PoM | 20871/1/1<br>30.01.2025 |
| 5 | Bifren              | phenibut   | capsules                                      | 250mg; (20/2x10) in blister, (60/6x10) in blister                   | Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev  | Ukraine | Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev                                       | Ukraine | PoM | 22027/1/1<br>30.01.2025 |
| 6 | Peo                 | ceftriaxone (ceftriaxone sodium)   | powder for solution for i/m and i/v injection | 1000mg; glass vial  | Laboratorio Reig Jofre, S.A., C/ Jarama 111 Poligono Industrial, Toledo, 45007 Toledo  | Spain   | GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi  | Georgia | PoM | 19081/2/1<br>30.01.2025 |

|   |                                     |              |                     |   |  |        |   |         |     |                         |
|---|-------------------------------------|--------------|---------------------|---|--|--------|---|---------|-----|-------------------------|
| 7 | Adaptol                             | temgicoluril | capsules            | 300mg; (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister | Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114                          | Latvia | Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114 | Latvia  | PoM | 20547/2/2<br>30.01.2025 |
| 8 | Adaptol                             | temgicoluril | tablets             | 500mg; (20/2x10) in blister   | Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114                          | Latvia | Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114 | Latvia  | PoM | 20597/2/2<br>30.01.2025 |
| 9 | IBUPROFEN 400mg film-coated tablets | ibuprofen    | tablets film-coated | 400mg; (100/10x10) in blister   | M/s Medopharm, No. 34-B, Industrial Area, Malur-563 160, Kolar District, Karnataka | India  | Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg        | Germany | OTC | 22294/1/1<br>30.01.2025 |

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/25 on January 30, 2025

| N | Trade name  | Common name of the active substance                      | Pharmaceutical form    | Strength and packaging presentation   | All manufacturing sites involved in the medicinal product manufacturing process (name, location)  | Country | Registration certificate holder (name, location)   | Country | Legal status for supply | Conclusion number and date |
|---|-------------|--|------------------------|---------------------------------------|---|---------|--|---------|-------------------------|----------------------------|
| 1 | Paracetamol | paracetamol  | tablets                | 500mg; (10) in blister, (10) in strip | Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856   | Russia  | Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856                       | Russia  | OTC                     | 18490/1<br>30.01.2025      |
| 2 | Hexalyse    | biclotymol, lysozyme (lysozyme hydrochloride), enoxolone | tablets orodispersible | 5mg+5mg+5mg (30/3x10) in blister      | Laboratoires Bouchara-Recordati, Parc Mecatronique 03410 Saint Victor   | France  | Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux | France  | OTC                     | 19457/4<br>30.01.2025      |
| 3 | Liprimar ST | atorvastatin (atorvastatin calcium)                      | tablets film-coated    | 10mg; (30/3x10) in blister            | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505                               | USA     | PoM                     | 21149/2/1<br>30.01.2025    |
| 4 | Liprimar ST | atorvastatin (atorvastatin calcium)                      | tablets film-coated    | 20mg; (30/3x10) in blister            | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505                               | USA     | PoM                     | 21150/2/1<br>30.01.2025    |

|    |             |                                     |                     |   |   |         |  |     |     |                         |
|----|-------------|-------------------------------------|---------------------|---|---|---------|--|-----|-----|-------------------------|
| 5  | Liprimar ST | atorvastatin (atorvastatin calcium) | tablets film-coated | 40mg; (30/3x10) in blister                        | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 21151/2/1<br>30.01.2025 |
| 6  | Liprimar ST | atorvastatin (atorvastatin calcium) | tablets film-coated | 80mg; (30/3x10) in blister                        | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 21152/2/1<br>30.01.2025 |
| 7  | Sermion     | nicergoline                         | tablets coated      | 5mg; (30/2x15) in blister                         | Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno(AP)   | Italy   | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 19178/6/3<br>30.01.2025 |
| 8  | Viagra      | sildenafil (sildenafil citrate)     | tablets film-coated | 25mg; (4/1x4) in blister                          | Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse  | France  | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 22086/1<br>30.01.2025   |
| 9  | Viagra      | sildenafil (sildenafil citrate)     | tablets film-coated | 50mg; (1) in blister, (4/1x4) in blister          | Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse  | France  | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 22275/1<br>30.01.2025   |
| 10 | Viagra      | sildenafil (sildenafil citrate)     | tablets film-coated | 100mg; (1) in blister, (4/1x4) in blister         | Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse  | France  | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 22276/1<br>30.01.2025   |
| 11 | Lyrica      | pregabalin                          | capsules hard       | 75mg; (14/1x14) in blister, (56/4x14) in blister  | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau  | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 19207/5/2<br>30.01.2025 |
| 12 | Lyrica      | pregabalin                          | capsules hard       | 150mg; (14/1x14) in blister, (56/4x14) in blister | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau  | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | 19208/5/2<br>30.01.2025 |

|    |                    |   |   |  |  |         |   |         |     |                         |
|----|--------------------|---|---|--|--|---------|---|---------|-----|-------------------------|
| 13 | Lyrica             | pregabalin  | capsules hard                               | 300mg; (14/1x14) in blister, (56/4x14) in blister                      | Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau   | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505            | USA     | PoM | 19209/4/2<br>30.01.2025 |
| 14 | Xalatan            | latanoprost   | drops eye                                   | 50mcg/ml; 2,5ml plastic container                                      | Pfizer Manufacturing Belgium, Rijksweg 12, Puurs-Sint-Amands, 2870   | Belgium | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505            | USA     | PoM | 22030/1<br>30.01.2025   |
| 15 | Arbidol            | umifenovir (umifenovir hydrochloride)   | capsules                                    | 100mg (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18  | Russia  | JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112 | Russia  | OTC | 19468/3<br>30.01.2025   |
| 16 | Coldrex MaxGrip    | paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid                     | powder for oral solution with lemon flavour | 1000mg+10mg+40mg; (10) sachets 6,427g                                  | SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid   | Spain   | STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel                      | Germany | OTC | 18670/3/1<br>30.01.2025 |
| 17 | Fentanyl Kalceks   | fentanyl (fentanyl citrate)   | solution for injection                      | 0,05mg/ml; (10/2x5) ampoules 2ml in plastic liner                      | Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control | Latvia  | Kalceks JSC, 71E Krustpils Street, Riga, LV-1057                                | Latvia  | PoM | 19795/3/1<br>30.01.2025 |
| 18 | Trachisan Lozenges | lidocaine (lidocaine hydrochloride), chlorhexidine (chlorhexidine digluconate), tyrothricin | lozenges                                    | 1mg+1mg+0,5mg; (20/2x10) in blister                                    | Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden   | Germany | Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden  | Germany | OTC | 19696/3<br>30.01.2025   |
| 19 | Vurdon-Neo         | diclofenac (diclofenac sodium)  | solution for injection                      | 25mg/ml; (5) ampoules 3ml in blister                                   | Help S.A., Pedini Ioanninon, Ioannina, 45500   | Greece  | Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki                     | Greece  | PoM | 22357/1<br>30.01.2025   |
| 20 | Enterogermina      | spores of polyan-tibiotic-resistant Bacillus clausii  | suspension oral                             | 2x10 <sup>9</sup> /5ml; (10) plastic vials 5ml                         | Opella Healthcare Italy S.R.L., Viale Europa, 11, 21040 Origgio (VA)   | Italy   | Opella Healthcare Italy S.R.L., Viale Luigi Bodio 37/b, 20158 Milano(MI)        | Italy   | OTC | 19188/4/1<br>30.01.2025 |

|    |                         |                                       |   |   |  |                     |  |                     |     |                         |
|----|-------------------------|---------------------------------------|---|---|--|---------------------|--|---------------------|-----|-------------------------|
| 21 | Paracetamol<br>GIGAfarm | paracetamol                           | tablets   | 500mg; (200/20x10) in blister               | Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building   | Republic of Armenia | Giga Farm LLC, Gogunts st. 3/5, Gyumri   | Republic of Armenia | OTC | 19258/1<br>30.01.2025   |
| 22 | Ketonal                 | ketoprofen                            | solution for injection  | 50mg/ml; (10) ampoules 2ml                  | Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana   | Slovenia            | Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana   | Slovenia            | PoM | 22137/1<br>30.01.2025   |
| 23 | Katarel                 | tenoxicam                             | powder lyophilized and solvent for solution for i/m/i/v injection | 20mg; glass vial and solvent in ampoule 2ml | Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009  | Greece              | J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ   | UK                  | PoM | 20295/1<br>30.01.2025   |
| 24 | ATRIUM                  | atracurium (atracurium besylate)      | solution for injection  | 10mg/ml; (5) ampoules 2,5ml                 | Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat   | India               | Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat | India               | PoM | 18806/1<br>30.01.2025   |
| 25 | Azimac                  | azithromycin (azithromycin dihydrate) | capsules  | 250mg; (6/2x3) in blister                   | GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi  | Georgia             | GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi  | Georgia             | PoM | 18834/2/1<br>30.01.2025 |
| 26 | Azimac                  | azithromycin (azithromycin dihydrate) | capsules  | 500mg; (3/1x3) in blister                   | GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi  | Georgia             | GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi  | Georgia             | PoM | 18835/2/1<br>30.01.2025 |
| 27 | Zithrocyn               | azithromycin (azithromycin dihydrate) | tablets film-coated   | 500mg; (3/1x3) in blister                   | A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- secondary packager, quality control, batch releaser, Centurion Laboratories Pvt. Ltd., P-2 Savli Bio-Tech Park, At Manjusar, Tal-Savli, Vadodara-390016, India- bulk manufacturer, primary packager | Republic of Armenia | A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan  | Republic of Armenia | PoM | 18949/2/1<br>30.01.2025 |
| 28 | Magnesium sulfate       | magnesium sulfate                     | solution for i/v and i/m injection                                | 250mg/ml; (10) ampoules 5ml                 | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, No11/1 ul. Chapaeva, Borisov, Minsk region  | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region           | Republic of Belarus | PoM | 18987/1/1<br>30.01.2025 |

## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting  
decision N 01-1/25 on January 30, 2025

| N | Trade name       | Common name of the active substance  | Pharmaceutical form   | Strength and packaging, presentation  | All manufacturing sites involved in the medicinal product manufacturing process (name, location)  | Country | Registration certificate holder (name, location)                                  | Country | Legal status for supply | Conclusion number and date |
|---|------------------|--|-----------------------|---|---|---------|---|---------|-------------------------|----------------------------|
| 1 | Bretaris Genuair | aclidinium (aclidinium bromide)  | powder for inhalation | 322mcg/dose; (1) inhaler (30 unit doses), (1) inhaler (60 unit doses), (3) inhaler (180/3x60/ unit doses) | Industrias Farmaceuticas Almirall S.A., Ctra. De Martorel 41-61, 08740 Sant Andreu de la Barca, Barcelona   | Spain   | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin                                | Germany | PoM                     | 000310<br>17.01.2025       |
| 2 | Cevikap          | ascorbic acid  | drops oral            | 100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml  | Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control | Poland  | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland  | OTC                     | 003564<br>17.01.2025       |
| 3 | Tantum Verde     | benzydamine (benzydamine hydrochloride)  | spray for local use   | 0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser                                      | Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona   | Italy   | Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome                             | Italy   | OTC                     | 000747<br>17.01.2025       |
| 4 | Triplixam        | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated   | 5mg+1,25mg+5mg; (30) plastic container  | Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland   | Ireland | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex                    | France  | PoM                     | 002311<br>17.01.2025       |
| 5 | Triplixam        | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated   | 5mg+1,25mg+5mg; (30) plastic container, (90) plastic container  | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow   | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex                    | France  | PoM                     | 002311<br>17.01.2025       |



|    |           |  |                     |   |   |         |  |        |     |                      |
|----|-----------|--|---------------------|---|---|---------|--|--------|-----|----------------------|
| 6  | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 5mg+1,25mg+5mg; (30) plastic container                          | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 7  | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 5mg+2,5mg+10mg; (30) plastic container                          | Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284  | Ireland | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 8  | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 5mg+2,5mg+10mg; (30) plastic container, (90) plastic container  | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow   | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 9  | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 5mg+2,5mg+10mg; (30) plastic container                          | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 10 | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 10mg+1,25mg+5mg; (30) plastic container                         | Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284  | Ireland | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 11 | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 10mg+1,25mg+5mg; (30) plastic container, (90) plastic container | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow   | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 12 | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 10mg+1,25mg+5mg; (30) plastic container                         | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control | Russia  | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |
| 13 | Triplixam | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated | 10mg+2,5mg+10mg; (30) plastic container                         | Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284  | Ireland | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | 002311<br>17.01.2025 |

|    |              |  |                                      |   |  |             |  |             |     |                      |
|----|--------------|--|--------------------------------------|---|--|-------------|--|-------------|-----|----------------------|
| 14 | Triplixam    | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated                  | 10mg+2,5mg+10mg; (30) plastic container, (90) plastic container | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow  | Russia      | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France      | PoM | 002311<br>17.01.2025 |
| 15 | Triplixam    | amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine) | tablets film-coated                  | 10mg+2,5mg+10mg; (30) plastic container                         | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control                   | Russia      | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France      | PoM | 002311<br>17.01.2025 |
| 16 | Preductal MR | trimetazidine (trimetazidine dihydrochloride)                                    | tablets film-coated modified-release | 35mg; (60/2x30) in blister                                      | Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy   | France      | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France      | PoM | 000386<br>30.01.2025 |
| 17 | Preductal MR | trimetazidine (trimetazidine dihydrochloride)                                    | tablets film-coated modified-release | 35mg; (60/2x30) in blister                                      | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow  | Russia      | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France      | PoM | 000386<br>30.01.2025 |
| 18 | Alecensa     | alectinib (alectinib hydrochloride)  | capsules hard                        | 150mg; (56/8x7) in blister, (224/4x56) in blister               | F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel- batch releaser, Excella GmbH & Co. KG, Nummerger Strasse 12, 90537 Feucht, Germany- bulk manufacturer, Delpharm Milano S.r.l., Via Carnevale 1, 20054 Segrate, Milano, Italy- packager, quality control | Switzerland | F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel    | Switzerland | PoM | 000150<br>30.01.2025 |