

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/23 on December 15, 2023

| 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 | Pantocalcin | hopantenic acid (calcium hopantenate) | solution for internal use | 150mg/ml; 75ml plastic bottle, 150ml plastic bottle | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological) | Russia | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2 | Russia | PoM | 21806 15.12.2023 |
| 2 | Zemplar | paricalcitol | solution for injection | 5mcg/ml; (5) vials 1ml in carton tray, (5) vials 1ml in plastic tray | AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC- Campoverde di Aprilia 04011- batch releaser, AVARA LISCATE PHARMACEUTICAL SERVICES S.p.A., VIA FOSSE ARDEATINE, 2, LISCATE, 20050, Italy- bulk manufacturer, packager, quality control | Italy | AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham | Switzerland | PoM | 21807 15.12.2023 |
| 3 | Kinezia | fampridine | tablets film-coated prolonged-release | 10mg; (27/3x9) in blister, (54/6x9) in blister | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, batch releaser, Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 1, Russia- quality control (physicochemical), Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological) | Russia | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2. | Russia | PoM | 21808 15.12.2023 |

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|---|---------------|--|--------------------------|--------------------------------------|---|----------|---|-------------|-----|---------------------|
| 4 | Uperio | sacubitril, valsartan (valsartan sodium) | tablets film-coated | 24,3mg+25,7mg; (28/2x14) in blister | Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, quality control (phisicochemical), Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- quality control (microbiological) | Slovenia | Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel | Switzerland | PoM | 21809 15.12.2023 |
| 5 | Uperio | sacubitril, valsartan (valsartan sodium) | tablets film-coated | 48,6mg+51,4mg; (28/2x14) in blister | Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, quality control (phisicochemical), Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- quality control (microbiological) | Slovenia | Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel | Switzerland | PoM | 21810 15.12.2023 |
| 6 | Uperio | sacubitril, valsartan (valsartan sodium) | tablets film-coated | 97,2mg+102,8mg; (28/2x14) in blister | Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, quality control (phisicochemical), Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- quality control (microbiological) | Slovenia | Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel | Switzerland | PoM | 21811 15.12.2023 |
| 7 | Panto-Denk 40 | pantoprazole (pantoprazole sodium sesquihydrate) | tablets gastro-resistant | 40mg; (28/2x14) in blister | Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21812 15.12.2023 |

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 12-1/23 on December 15, 2023

| 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 | Suprastinex | levocetirizine (levocetirizine dihydrochloride) | tablets film-coated | 5mg; (7/1x7) in blister, (14/2x7) in blister, (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister | Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38 | Hungary | OTC | 21813 (003152) 15.12.2023 |
| 2 | Verapamil Alkaloid | verapamil (verapamil hydrochloride) | tablets coated | 40mg; (30/2x15) in blister | Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje | Republic of North Macedonia | Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje | Republic of North Macedonia | PoM | 21814 (000724) 15.12.2023 |
| 3 | Verapamil Alkaloid | verapamil (verapamil hydrochloride) | tablets coated | 80mg; (30/2x15) in blister | Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje | Republic of North Macedonia | Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje | Republic of North Macedonia | PoM | 21815 (000724) 15.12.2023 |
| 4 | Citomed | citicoline (citicoline sodium) | solution oral | 100mg/ml; glass bottle 30ml and measuring syringe, glass bottle 100ml and measuring syringe | Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22 | Republic of Armenia | Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22 | Republic of Armenia | PoM | 21816 (004921) 15.12.2023 |

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/23 on December 15, 2023

| 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 | Doxitus | doxofylline | syrup | 100mg/5ml; 100ml glass bottle and measuring cup | Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22 | Republic of Armenia | Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22 | Republic of Armenia | PoM | 21817 15.12.2023 |
| 2 | Zavicefta | ceftazidime (ceftazidime pentahydrate), avibactam (avibactam sodium) | powder for solution for infusion | 2g+0,5g; (10) glass vials 20ml | ACS DOBFAR SpA, Via Alesandro Fleming, 2, Verona, 37135 | Italy | Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ | UK | PoM | 21818 15.12.2023 |
| 3 | Sinecod | butamirate (butamirate citrate) | drops oral | 5mg/ml; glass vial 20ml with dropper | GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | OTC | 21819 15.12.2023 |
| 4 | Indometacin | indometacin | ointment for external use | 100mg/g; aluminium tube 40g | Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64, No2, ul. Chapaeva, Borisov, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, Chapaev str., Borisov 222518, Minsk region | Republic of Belarus | OTC | 21820 15.12.2023 |
| 5 | Alka-Seltzer | acetylsalicylic acid, citric acid, sodium bicarbonate | tablets effervescent | 324mg+965mg+1625mg; (10/5x2) in strip | Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen | Germany | JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow | Russia | OTC | 21821 15.12.2023 |
| 6 | TheraFlu | paracetamol, pheniramine (pheniramine maleate), phenylephrine (phenylephrine hydrochloride), ascorbic acid | powder for oral solution with lemon flavour | 325mg+20mg+10mg+50mg; (10) sachets 22,1g | Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans Cedex 02 | France | GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | OTC | 21822 15.12.2023 |
| 7 | Paracetamol Sopharma 500mg tablets | paracetamol | tablets | 500mg; (10/1x10) in blister, (20/2x10) in blister | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | OTC | 21823 15.12.2023 |

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|----|--------------------------------------|---|--|---|---|---------------------|---|---------------------|-----|---------------------|
| 8 | Paracetamol Sopharma 120mg/5ml syrup | paracetamol | syrup | 120mg/5ml; 125ml glass bottle and measuring cup, 125ml plastic bottle and measuring cup | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control | Bulgaria | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | OTC | 21824 15.12.2023 |
| 9 | Ismigen | lyophilized bacterial lysate | tablets sublingual | 50mg; (10/1x10) in blister, (30/3x10) in blister | GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi- secondary packager, quality control, batch releaser, Bruschettni S.r.l., Via Isonzo, 6, 16147 Genova, Italy- bulk manufacturer, primary packager | Georgia | GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi | Georgia | PoM | 21825 15.12.2023 |
| 10 | Rosuvastatin Denk 5mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 5mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21826 15.12.2023 |
| 11 | Rosuvastatin Denk 10mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 10mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21827 15.12.2023 |
| 12 | Rosuvastatin Denk 20mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 20mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21828 15.12.2023 |
| 13 | Flucona-Denk 100 | fluconazole | capsules hard | 100mg; (10/1x10) in blister | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21829 15.12.2023 |
| 14 | Flucona-Denk 150 | fluconazole | capsules hard | 150mg; (1) in blister | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 21830 15.12.2023 |
| 15 | Fervex | paracetamol, ascorbic acid, pheniramine (pheniramine maleate) | powder for oral solution with lemon flavor, sugar free | 500mg+200mg+25mg; (8) sachets 4,95g | UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage | France | UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison | France | OTC | 21831 15.12.2023 |
| 16 | Nystatin | nystatin | film-coated tablets | 500000IU; (20/2x10) in blister | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 24, No3/2, Stroiteley str., Borisov, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov, Minsk region | Republic of Belarus | PoM | 21832 15.12.2023 |

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|----|-------------------------------|---------------------------------------|--------------------------|------------------------------------|---|---------------------|--|---------------------|-----|---------------------|
| 17 | Fenistil gel | dimetindene (dimetindene maleate) | gel | 1mg/g; aluminium tube 30g | GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | OTC | 21833 15.12.2023 |
| 18 | Efferalgan | paracetamol | suppositories rectal | 80mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison | France | OTC | 21834 15.12.2023 |
| 19 | Efferalgan | paracetamol | suppositories rectal | 150mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison | France | OTC | 21835 15.12.2023 |
| 20 | Efferalgan | paracetamol | suppositories rectal | 300mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison | France | OTC | 21836 15.12.2023 |
| 21 | Balzac liniment of Vishnevsky | birch tar, xeroform | liniment | 30mg/g+30mg/g; aluminium tube 40g | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No2, ul. Chapaeva, Borisov, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region | Republic of Belarus | OTC | 21837 15.12.2023 |
| 22 | Insulatard Penfill | insulin human | suspension for injection | 100IU/ml; (5) glass cartridges 3ml | Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd | Denmark | Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd | Denmark | PoM | 21838 15.12.2023 |
| 23 | Bromhexin | bromhexine (bromhexine hydrochloride) | tablets | 8mg; (20/1x20) in blister | Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18 | Russia | Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18 | Russia | OTC | 21839 15.12.2023 |

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/23 on December 15,
2023

| 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 | Exoderil | naftifine hydrochloride | solution for external use | 10mg/g; 10ml glass bottle, 20 ml glass bottle | Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH., Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager, quality control | Slovenia | Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl | Austria | OTC | 20725/1/1 15.12.2023 |
| 2 | Exoderil | naftifine (naftifine hydrochloride) | solution for external use | 10mg/ml; glass vial 10ml, glass vial 20ml | Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl- batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH., Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager, quality control | Austria | Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl | Austria | OTC | 21257/2/1 15.12.2023 |

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|---|-----------------------------|--|------------------------------------|--|--|---------------------|--|---------------------|-----|-------------------------|
| 3 | RotaTeq | rotavirus type G1, rotavirus type G2, rotavirus type G3, rotavirus type G4, rotavirus type P1A | solution oral | not less than 2,2x10 ⁶ IU+not less than 2,8x10 ⁶ IU+not less than 2,2x10 ⁶ IU+not less than 2x10 ⁶ IU+not less than 2,3x10 ⁶ IU; (1) plastic tube 2ml, (10) plastic tubes 2ml | Merck Sharp & Dohme B.V. Waarderweg 39, Haarlem 2031 BN- batch releaser, Merck Sharp & Dohme LLC, 770 Summeytown Pike, West Point, Pennsylvania(PA) 19486, USA- bulk manufacturer, packager | the Netherlands | Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern | Switzerland | PoM | 21576/1/1 15.12.2023 |
| 4 | Dimedrol | diphenhydramine (diphenhydramine hydrochloride) | solution for i/m and i/v injection | 10mg/ml; (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella, (10) ampoules 1ml CAMA | Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, Chapayev str., Borisov 222518, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, Chapayev str., Borisov 222518, Minsk region | Republic of Belarus | PoM | 20780/1/1 15.12.2023 |
| 5 | L-Thyroxin 50 Berlin-Chemie | levothyroxine sodium | tablets | 50mcg; (100/4x25/) in blister | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical) | Germany | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin | Germany | PoM | 20790/1/1 15.12.2023 |

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|---|------------------------------|----------------------|---------|--------------------------------|--|---------|--|---------|-----|-------------------------|
| 6 | L-Thyroxin 75 Berlin-Chemie | levothyroxine sodium | tablets | 75mcg; (100/4x25/) in blister | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical) | Germany | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin | Germany | PoM | 20791/1/1 15.12.2023 |
| 7 | L-Thyroxin 100 Berlin-Chemie | levothyroxine sodium | tablets | 100mcg; (100/4x25/) in blister | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical) | Germany | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin | Germany | PoM | 20792/1/1 15.12.2023 |
| 8 | L-Thyroxin 125 Berlin-Chemie | levothyroxine sodium | tablets | 125mcg; (100/4x25/) in blister | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical) | Germany | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin | Germany | PoM | 20793/1/1 15.12.2023 |

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| 9 | L-Thyroxin 150 Berlin-Chemie | levothyroxine sodium | tablets | 150mcg; (100/4x25) in blister | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical) | Germany | Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin | Germany | PoM | 20794/1/1 15.12.2023 |
| 10 | Diprospan | 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, Weyrstrasse 20, 6006 Luzern | Switzerland | PoM | 19021/6/2 15.12.2023 |
| 11 | Celestoderm-V with Garamycin | betamethasone (betamethasone valerate), gentamicin (gentamicin sulfate) | ointment | 1mg/g+1mg/g; 30g aluminium tube | Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220 | Belgium | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern | Switzerland | PoM | 18752/5/2 15.12.2023 |
| 12 | Celestoderm-V | betamethasone (betamethasone 17-valerate) | ointment | 1mg/g; aluminium tube 30g | Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220 | Belgium | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern | Switzerland | PoM | 18483/3/2 15.12.2023 |

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| 13 | Progestogel | progesterone | gel for external use | 10mg/g; 80g aluminium tube and dosator | Besins Manufacturing Belgium, Groot-Bijgaardenstraat, 128-1620, Drogenbos- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Quali Controle, 9 rue Francois Truffaut, Meru, 60110, France- quality control (microbiological) | Belgium | Besins Healthcare SA, Rue Washington 80, Ixelles 1050 | Belgium | PoM | 21323/1/1 15.12.2023 |
| 14 | Valerianae tincture | valerianae extract | tincture | 200mg/ml; glass vial 30ml | Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region | Republic of Belarus | Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region | Republic of Belarus | OTC | 19644/2/1 15.12.2023 |
| 15 | Glucose | dextrose | solution for i/v injection | 400mg/ml; (10) ampoules 5ml CAMA, (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella | Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region | Republic of Belarus | Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region | Republic of Belarus | PoM | 20550/1/1 15.12.2023 |
| 16 | Balzac liniment of Vishnevsky | birch tar, xeroform | liniment | 30mg/g; 30mg/g; aluminium tube 40g | Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64, No2, ul. Chapaeva, Borisov, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, Chapaev str., Borisov 222518, Minsk region | Republic of Belarus | OTC | 18544/1/1 15.12.2023 |

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| 17 | Roxera Plus | rosuvastatin (rosuvastatin calcium), ezetimibe | tablets film-coated | 10mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) in blister | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia | PoM | 19363/2/1 15.12.2023 |
| 18 | Roxera Plus | rosuvastatin (rosuvastatin calcium), ezetimibe | tablets film-coated | 20mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) in blister | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia | PoM | 19420/2/1 15.12.2023 |

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/23 on December 15, 2023

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|---|-------------|---|---------------------------|---|---|---------|---|---------|-------------------------|----------------------------|
| 1 | Tetracyclin | tetracycline (tetracycline hydrochloride) | tablets film-coated | 100mg; (20/2x10) in blister, (20) plastic container | Biosintez PJSC, Druzhby st. 4, 440033, Penza | Russia | Biosintez PJSC, Druzhby st. 4, 440033, Penza | Russia | PoM | 18859/1 15.12.2023 |
| 2 | Zyrtec | cetirizine (cetirizine dihydrochloride) | drops oral | 10mg/ml; 10ml glass bottle | Aesica Pharmaceuticals S.r.l., Via Praglia, 15-10044 Pianezza (TO) | Italy | GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9S | UK | OTC | 20631/3 15.12.2023 |
| 3 | Zyrtec | cetirizine (cetirizine dihydrochloride) | tablets film-coated | 10mg; (7/1x7) in blister | Aesica Pharmaceuticals S.r.l., Via Praglia, 15-10044 Pianezza (TO) - packager, quality control, batch releaser, UCB Farchim S.A., Z.I. de Planchy, Chemin de Croix Blanche 10, CH-1630 Bulle, Switzerland-bulk manufacturer | Italy | GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9S | UK | OTC | 19624/4 15.12.2023 |
| 4 | Najatox | naja common dry venom, methylsalicylate, camphora, eucalipt oil | ointment for external use | 12MU/100g+4g/100g+3g/100g+2g/100g; aluminium tube 20g | Mekophar Chemical-Pharmaceutical JSC, 297/5 Ly Thoung Kiet, Ward 15, District 11, Ho Chi Minh | Vietnam | Mekophar Chemical-Pharmaceutical JSC, 297/5 Ly Thoung Kiet, Ward 15, District 11, Ho Chi Minh | Vietnam | OTC | 18414/1 15.12.2023 |
| 5 | CoPlavix | clopidogrel, acetylsalicylic acid | tablets film-coated | 75mg+100mg; (30/3x10) in blister | Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex | France | Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris | France | PoM | 21027/1 15.12.2023 |

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| 6 | Mastodynon | agnus castus A11, blue cohosh D4, european cyclamen D4, strychnos ignatia D6, iris versicolor D2, tiger lily D3 | drops oral homeopathic | 0,2g/g+0,1g/g+0,1g/g+0,1g/g+0,2g/g+0,1g/g; 50ml glass bottle | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt | Germany | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt | Germany | OTC | 21475/1 15.12.2023 |
| 7 | Sinupret forte | gentian root, primula flower, common sorrel herb, elder flower, ver-bena herb | tablets coated | 36mg+12mg+36mg+36mg+36mg; (20/1x20/) in blister | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt-packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany-bulk manufacturer | Germany | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt | Germany | OTC | 21074/1 15.12.2023 |
| 8 | Cyclodynon | agnus castus dry extract | tablets film-coated | 4mg; (30/2x15/) in blister | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt-packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, Ennigerloh, North Rhine, Westphalia, 59320, Germany- bulk manufacturer | Germany | Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt | Germany | OTC | 21491/1 15.12.2023 |
| 9 | Betaderm | betamethasone (betamethasone dipropionate), gentamicin (gentamicin sulfate) | ointment for external use | 0,5mg/g+1mg/g; aluminium tube 15g | Pharmaceutical Works Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora | Poland | Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow | Russia | PoM | 20025/2 15.12.2023 |
| 10 | DuTamsul | dutasteride, tamsulosin (tamsulosin hydrochloride) | capsules hard | 0,5mg+0+4mg; (30) plastic container | Laboratorios Leon Farma S.A., Poligono Industrial Navatejera, C/ La Vallina s/n, Villaquilambre, 24008 Leon-bulk manufacturer, packager, quality control (phiscochemical), batch releaser, LABORATORIO ECHEVARNE, S.A./C/ Provenca, No 312, Bajos, Barcelona, 08037, Spain- quality control (microbiological) | Spain | Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria | Austria | PoM | 21273/1 15.12.2023 |

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| 11 | Flucona-Denk 150 | fluconazole | capsules hard | 150mg; (1) in blister | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 18142/3 15.12.2023 |
| 12 | Flucona-Denk 100 | fluconazole | capsules hard | 100mg; (10/1x10) in blister | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 18141/3 15.12.2023 |
| 13 | Rosuvastatin Denk 5mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 5mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 18257/3 15.12.2023 |
| 14 | Rosuvastatin Denk 10mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 10mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 18258/4 15.12.2023 |
| 15 | Rosuvastatin Denk 20mg | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 20mg; (30/3x10) in blister | Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski | Poland | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany | PoM | 18259/4 15.12.2023 |
| 16 | Diprosalic | betamethasone (betamethasone dipropionate), salicylic acid | ointment | 0,5mg/g+30mg/g; 30g aluminium tube | Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220 | Belgium | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern | Switzerland | PoM | 21575/1 15.12.2023 |
| 17 | Diprosalic | betamethasone (betamethasone dipropionate), salicylic acid | lotion | 0,5mg/g+20mg/g; 30ml plastic container-dropper | Genexi HSC, 2 Rue Louis Pasteur, 14200 Herouville Saint- Clair | France | Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern | Switzerland | PoM | 18902/5/1 15.12.2023 |
| 18 | Omepraz | omeprazole | capsules | 20mg; (30/3x10) in blister | S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A | Romania | S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A | Romania | PoM | 17747/1 15.12.2023 |
| 19 | Efferalgan | paracetamol | suppositories rectal | 80mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier-92500 Rueil- Malmaison | France | OTC | 18322/5 15.12.2023 |
| 20 | Efferalgan | paracetamol | suppositories rectal | 150mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier-92500 Rueil- Malmaison, | France | OTC | 18323/5 15.12.2023 |
| 21 | Efferalgan | paracetamol | suppositories rectal | 300mg; (10/2x5) | UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN | France | UPSA SAS, 3, rue Joseph Monier-92500 Rueil- Malmaison | France | OTC | 18324/6 15.12.2023 |

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| 22 | Ismigen | lyophilized bacterial lysate | tablets sublingual | 50mg; (10/1x10) and (30/3x10) in blister | GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi- batch releaser, secondary packager, Bruschetti S.r.l., Via Isonzo, 6, 16147 Genova, Italy - bulk manufacturer, primary packager | Georgia | GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi | Georgia | PoM | 18026/1 15.12.2023 |
| 23 | Paracetamol Sopharma 500mg tablets | paracetamol | tablets | 500mg; (10/1x10) and (20/2x10) blisters | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | OTC | 18119/4 15.12.2023 |
| 24 | Paracetamol Sopharma 120mg/5ml syrup | paracetamol | syrup | 120mg/5ml; 125ml glass or plastic bottle and measuring cup | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabovo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager | Bulgaria | Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia | Bulgaria | OTC | 18237/3 15.12.2023 |
| 25 | Acnamino MR 100mg Capsules | minocycline (minocycline hydrochloride) | capsules hard | 100mg; (56/8x7) in blister | Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd., 9 HaShalom Road, Nesher, Israel- quality control (microbiological) | UK | Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB | UK | PoM | 21674/1 15.12.2023 |
| 26 | Dermovate | clobetasol (clobetasol propionate) | ointment | 0,5mg/g; aluminium tube 25g | Delpharm Poznan Spolka Akcyjna, 189 Grunwaldzka street, 60-322 Poznan | Poland | GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS | UK | PoM | 21726/1 15.12.2023 |
| 27 | Dermovate | clobetasol (clobetasol propionate) | cream | 0,5mg/g; aluminium tube 25g | Delpharm Poznan Spolka Akcyjna, 189 Grunwaldzka street, 60-322 Poznan | Poland | GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS | UK | PoM | 21727/1 15.12.2023 |

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| 28 | CITOLEPT | citicoline (citicoline sodium) | solution for i/v and i/m injection | 125mg/ml; (5/1x5) ampoules 4ml in blister | SotexPharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex»Pharm-Firm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager | Russia | «Sotex»PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345 | Russia | PoM | 20255/3/1 15.12.2023 |
| 29 | Fervex | paracetamol, ascorbic acid, pheniramine (pheniramine maleate) | powder for oral solution with lemon flavor, sugar free | 500mg+200mg+25mg; (8) sachets 4,95g | UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage | France | UPSA SAS, 3, rue Joseph Monier-92500 Rueil- Malmaison | France | OTC | 17806/1 15.12.2023 |
| 30 | Rovastat | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 10mg; (28/4x7) in blister | Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager | Poland | Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow | Poland | PoM | 21307/1 15.12.2023 |
| 31 | Rovastat | rosuvastatin (rosuvastatin calcium) | tablets film-coated | 20mg; (28/4x7) in blister | Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager | Poland | Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow | Poland | PoM | 21308/1 15.12.2023 |
| 32 | Codelac Broncho with thyme | ambroxol (ambroxol hydrochloride), glycyrrhizic acid trisodium (sodium glycyrrhizinate), thyme extract | elixir | 10mg/5ml+30mg/5ml+500mg/5ml; 100ml glass bottle and measuring spoon, 200ml glass bottle and measuring spoon | 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 | 21335/1 15.12.2023 |
| 33 | Fenistil gel | dimetindene (dimetindene maleate) | gel | 1mg/g; aluminium tube 30g | GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon | Switzerland | OTC | 18391/3/2 15.12.2023 |

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| 34 | Nystatin | nystatin | film-coated tablets | 500000IU; (20/2x10) in blister | Open joint stock company «Borisovskiy zavod medicinskih preparatov», 24, No3/2, Stroiteley str., Borisov, Minsk region | Republic of Belarus | Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapayev str., Borisov, Minsk region | Republic of Belarus | PoM | 18313/2/1 15.12.2023 |
| 35 | Bromhexin | bromhexine (bromhexine hydrochloride) | tablets | 8mg; (20/1x20) in blister | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18 | Russia | Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18 | Russia | OTC | 17030/1 15.12.2023 |