# LIST

## of the medicines recommended for the registration by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Forcorium | mometasone (mometasone furoate), gentamicin (gentamicin sulphate). dexpanthenol, econazole (econazole nitrate) | cream | 0,5mg+1mg+50mg+10mg; aluminium tube 15g | Werteks JSC, 197350, Saint Petersburg, Doroga v Kamenku, 62, lit A | Russia | Werteks JSC, 197350, Saint Petersburg, Doroga v Kamenku, 62, lit A | Russia | PoM | 23052 16.05.2025 |
| 2 | GENFERON | interferon alfa-2b, benzocaine, taurine | suppositories vaginal and rectal | 500000IU+55mg+10mg; (10/2x5/) | PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460 | Russia | BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515 | Russia | PoM | 23053 16.05.2025 |
| 3 | GENFERON | interferon alfa-2b, benzocaine, taurine | suppositories vaginal and rectal | 1000000IU+55mg+10mg; (10/2x5/) | PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460 | Russia | BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515 | Russia | PoM | 23054 16.05.2025 |

# LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Velaxin | venlafaxine (venlafaxine hydrochloride) | capsules prolonged-release | 75mg; (28/2x14/) in blister, (30/3x10/) in blister, | Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38 | Hungary | PoM | 23029 (001230) 16.05.2025 |
| 2 | Velaxin | venlafaxine (venlafaxine hydrochloride) | capsules prolonged-release | 75mg; (28/2x14/) in blister, (30/3x10/) in blister | Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65- bulk manufacturer, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- packager, quality control | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38 | Hungary | PoM | 23030 (001230) 16.05.2025 |
| 3 | Velaxin | venlafaxine (venlafaxine hydrochloride) | capsules prolonged-release | 150mg; (28/2x14/) in blister, (30/3x10/) in blister | Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38 | Hungary | PoM | 23031 (001230) 16.05.2025 |
| 4 | Velaxin | venlafaxine (venlafaxine hydrochloride) | capsules prolonged-release | 150mg; (28/2x14/) in blister, (30/3x10/) in blister | Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65- bulk manufacturer, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- packager, quality control | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38 | Hungary | PoM | 23032 (001230) 16.05.2025 |
| 5 | Naklofen | diclofenac (diclofenac sodium) | solution for injection | 75mg/3ml; (5/1x5/) ampoules 3ml in blister, (5/1x5/) ampoules 3ml in plastic container | 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 | 23033 (002971) 16.05.2025 |

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|---|---|---|---|---|---|---|---|---|---|---|
| 6 | Sinthomycin | chloramphenicol | liniment | 100mg/g; 25g aluminium tube | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager | Russia | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7 | Russia | OTC | 23034 (012532) 16.05.2025 |
| 7 | Hexicon | chlorhexidine (chlorhexidine bigluconate) | suppositories vaginal | 16mg; (5/1x5/), (10/2x5/) | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager | Russia | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7 | Russia | OTC | 23035 (004799) 16.05.2025 |
| 8 | Suprastin | chloropyramine (chloropyramine hydrochloride) | solution for injection | 20mg/ml; (5/1x5/) ampoules 1ml in blister, (10/1x10/) ampoules 1ml in blister | Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38 | Hungary | PoM | 23036 (010738) 16.05.2025 |
| 9 | Suprastin | chloropyramine (chloropyramine hydrochloride) | solution for injection | 20mg/ml; (5/1x5/) ampoules 1ml in blister, (10/1x10/) ampoules 1ml in blister | Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Pharmaceutical Control and Development Laboratory LLC, Mexikoi ut 9., Budapest, 1149, Hungary- quality control (microbiological) | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38 | Hungary | PoM | 23037 (010738) 16.05.2025 |
| 10 | Bisoprolol | bisoprolol (bisoprolol fumarate) | tablets film-coated | 5mg; (30/1x30/) in blister, (50/5x10/) in blister, (100/10x10/) in blister | Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway | Russia | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7 | Russia | PoM | 23038 (002780) 16.05.2025 |
| 11 | Bisoprolol | bisoprolol (bisoprolol fumarate) | tablets film-coated | 10mg; (30/1x30/) in blister, (50/5x10/) in blister, (100/10x10/) in blister | Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway | Russia | Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7 | Russia | PoM | 23039 (002780) 16.05.2025 |
| 12 | Niperten | bisoprolol (bisoprolol fumarate) | tablets film-coated | 2,5mg; (30/3x10/) in blister | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | PoM | 23040 (005925) 16.05.2025 |
| 13 | Niperten | bisoprolol (bisoprolol fumarate) | tablets film-coated | 5mg; (30/3x10/) in blister | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | PoM | 23041 (005925) 16.05.2025 |

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| 14 | Niperten | bisoprolol (bisoprolol fumarate) | tablets film-coated | 10mg; (30/3x10/) in blister | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500 | Russia | PoM | 23042 (005925) 16.05.2025 |
| 15 | Avastin | bevacizumab | concentrate for solution for infusion | 25mg/ml; glass vial 4ml | F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control | Switzerland | F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, 4070, Basel | Switzerland | PoM | 23043 (006142) 16.05.2025 |
| 16 | Avastin | bevacizumab | concentrate for solution for infusion | 25mg/ml; glass vial 16ml | F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control | Switzerland | F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, 4070, Basel | Switzerland | PoM | 23044 (006142) 16.05.2025 |
| 17 | Co-Amlessa | perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide | tablets | 2mg+5mg+0,625mg; (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 | 23045 (006352) 16.05.2025 |
| 18 | Co-Amlessa | perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide | tablets | 4mg+5mg+1,25mg; (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 | 23046 (006352) 16.05.2025 |
| 19 | Co-Amlessa | perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide | tablets | 4mg+10mg+1,25mg; (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 | 23047 (006352) 16.05.2025 |
| 20 | Co-Amlessa | perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide | tablets | 8mg+5mg+2,5mg; (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 | 23048 (006352) 16.05.2025 |
| 21 | Co-Amlessa | perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide | tablets | 8mg+10mg+2,5mg; (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 | 23049 (006352) 16.05.2025 |

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| 22 | Thiogamma | thioctic acid | tablets film-coated | 600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister | Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological) | Germany | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 23050 (000546) 16.05.2025 |
| 23 | Thiogamma | thioctic acid | tablets film-coated | 600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister | Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewicza 58, Konstantynow Lodzki, 95-050- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MIKROLAB Spotka z ograniczona odpowiedzialnoscia, ul. Lubelska 5/7, 03-802 Warszawa, Poland- quality control (microbiological) | Germany | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 23051 (000546) 16.05.2025 |

# LIST

oof the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Solution Protargol 2% | silver proteinate | solution for topical use | 20mg/ml; 15ml plastic bottle-dropper, 15ml plastic container with pump dispenser | ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079 | Republic of Armenia | ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079 | Republic of Armenia | OTC | 21607/1/1 16.05.2025 |

# LIST

## of the medicines recommended for the re-registration by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Glucosamine Plus | glucosamine (glucosamine hydrochloride), chondroitin sulfate (chondroitin sulfate sodium) | tablets film-coated | 500mg+400mg; (30) in plastic container, (60) in plastic container, (100) in plastic container | IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo | Syria | IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo | Syria | OTC | 23025 16.05.2025 |
| 2 | Hexpanthen | dexpanthenol, chlorhexidine (chlorhexidine bigluconate) | suppositories vaginal | 100mg+16mg; (10/2x5/) | Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22 | Republic of Armenia | Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22 | Republic of Armenia | OTC | 23026 16.05.2025 |
| 3 | DESALLERGAN | desloratadine | solution oral | 0,5mg/ml; glass bottle 120ml | Vetprom AD, Otez Paissij str. 26, Radomir 2400 | Bulgaria | Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400 | Bulgaria | PoM | 23027 16.05.2025 |

# LIST

## of the medicines with extented of the regitration certificate term by the Center according to the meeting decision N 05-1/25 on May 16, 2025

| N | Trade name | Common name of the active substance | Pharmaceutical form | Strength and packaging, presen-tation | 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 | Strepsils Intensive | flurbiprofen | lozenges with honey and lemon flavour | 8,75mg; (24/3x8/) in blister | Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB | UK | Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB | UK | OTC | 23020 16.05.2025 |
| 2 | Strepsils | dichlorobenzyl alcoholl, amylmetacresol | lozenges with honey and lemon flavour | 1,2mg+0,6mg; (24/2x12/) in blister, (36/3x12/) in blister | Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB | UK | Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB | UK | OTC | 23021 16.05.2025 |
| 3 | Elidel | pimecrolimus | cream for external use | 10mg/g; aluminium tube 15g | MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac | France | MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg | Germany | PoM | 23022 16.05.2025 |
| 4 | Fluconazole | fluconazole | capsules | 150mg; (10/1x10/) in blister | Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | PoM | 23023 16.05.2025 |
| 5 | Linex | lyophilized viable lactic acid bacterias (Lactobacillus acidophilus, Bifidobacterium infantis, Enterococcus faecium) | capsules hard | 1,2x10^7CFU; (16/2x8/) in blister | Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana-quality control, batch releaser, Lek Pharmaceuticals d.d., Kolodvorska cesta 27, Menges, 1234, Slovenia-bulk manufacturer, packager | Slovenia | Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana | Slovenia | OTC | 23024 16.05.2025 |

# LIST

## of the variations requiring registration approved by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Gabagamma | gabapentin | capsules hard | 300mg; (20/2x10/), in blister, (50/5x10/), in blister | Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewicza 58, Konstantynow Lodzki, 95-050- packager, quality control (physicochemical), batch releaser, Zhejiang Jingxin Pharmaceutical Co., Ltd., No. 800 Xinchang East Road, Yulin subdistrict, Xinchang County, Zhejiang Province, China- bulk manufacturer, MIKROLAB Spotka z ograniczona odpowiedzialnoscia, ul. Lubelska 5/7, 03-802 Warszawa, Poland- quality control (microbiological) | Poland | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 23017 16.05.2025 |
| 2 | Gabagamma | gabapentin | capsules hard | 400mg; (20/2x10/), in blister, (50/5x10/), in blister | Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewicza 58, Konstantynow Lodzki, 95-050- packager, quality control (physicochemical), batch releaser, Zhejiang Jingxin Pharmaceutical Co., Ltd., No. 800 Xinchang East Road, Yulin subdistrict, Xinchang County, Zhejiang Province, China- bulk manufacturer, MIKROLAB Spotka z ograniczona odpowiedzialnoscia, ul. Lubelska 5/7, 03-802 Warszawa, Poland- quality control (microbiological) | Poland | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 23018 16.05.2025 |

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| 3 | KLARUKTAM | cefotaxim (cefotaxim sodium), sulbactam (sulbactam sodium) | powder for solution for i/m and i/v injection and infusion | 1000mg+500mg; glass vial 20ml | ALTEGRA JSC, Moscow region, Dubna district, Dubna, Science Avenue, building 33, 141983- batch releaser, quality control, secondary packager, "Ruzpharma" LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1, Russia- bulk manufacturer, primary packager | Russia | Alpharma LLC, ext. ter.city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow, 127247 | Russia | PoM | 23019 16.05.2025 |

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Mildronat 100mg/ml | meldonium | solution for injection | 100mg/ml; (10/2x5/) ampoules 5ml in blister | Grindeks JSC, Krustpils street 53, LV-1057, Riga- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680, Martin, Slovak Republic- bulk manufacturer, packager, quality control | Latvia | Grindeks JSC, Krustpils street 53, LV-1057, Riga | Latvia | PoM | 21535/1/1 16.05.2025 |
| 2 | ACC 200 | acetylcysteine | tablets effervescent | 200mg; (20) in plastic container | Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Hermes Pharma Ges.m.b.H, Schwimmschulweg 1a, Wolfsberg, 9400, Austria- bulk manufacturer, packager, quality control | Germany | Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana | Slovenia | OTC | 22457/1/1 16.05.2025 |
| 3 | KLARUKTAM | cefotaxim (cefotaxim sodium), sulbactam (sulbactam sodium) | powder for solution for i/m and i/v injection and infusion | 1000mg+500mg; glass vial 20ml | Ruzpharma LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1 | Russia | Alpharma LLC, ext. ter.city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow, 127247 | Russia | PoM | 20913/1/1 16.05.2025 |
| 4 | Eliquis | apixaban | tablets film-coated | 2,5mg; (20/1x20/) in blister, (60/3x20/) in blister | Pfizer Manufacturing Deutschlad GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer | Germany | Pfizer Inc., 66 Hudson Boulevard East, New York, New York 10001-2192 | USA | PoM | 19625/4/2 16.05.2025 |

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| 5 | Eliquis | apixaban | tablets film-coated | 5mg; (20/1x20/) in blister, (60/3x20/) in blister | Pfizer Manufacturing Deutschlad GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer | Germany | Pfizer Inc., 66 Hudson Boulevard East, New York, New York 10001-2192 | USA | PoM | 19626/4/2 16.05.2025 |
| 6 | Dimethyl Fumarate Delayed-Release Capsules 120mg | dimethyl fumarate | capsules delayed-release | 120mg; (14) plastic container | Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State | India | Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51 | Ireland | PoM | 22583/1/1 16.05.2025 |
| 7 | Dimethyl Fumarate Delayed-Release Capsules 240mg | dimethyl fumarate | capsules delayed-release | 240mg; (60) plastic container | Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State | India | Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51 | Ireland | PoM | 22584/1/1 16.05.2025 |

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## of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Kaporiza | rizatriptane (rizatriptane benzoate) | orodispersible tablets | 10mg; (2/1x2/) in blister, (6/1x6/) in blister | Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057 | India | "Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345 | Russia | PoM | ЛП-№001129-РГ-АМ 16.05.2025 |
| 2 | Kaporiza | rizatriptane (rizatriptane benzoate) | orodispersible tablets | 10mg; (2/1x2/) in blister, (6/1x6/) in blister, (6/3x2/) in blister | SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, " Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057, India- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager | Russia | "Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345 | Russia | PoM | ЛП-№001129-РГ-АМ 16.05.2025 |
| 3 | Zoloft | sertraline (sertraline hydrochloride) | tablets film-coated | 50mg; (14/1x14/) in blister; (28/2x14/) in blister | Pfizer Manufacturing Deutschlad GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | ЛП-№002851-ГП-АМ 16.05.2025 |
| 4 | Zoloft | sertraline (sertraline hydrochloride) | tablets film-coated | 100mg; (14/1x14/) in blister; (28/2x14/) in blister | Pfizer Manufacturing Deutschlad GmbH, Mooswaldallee 1, 79108 Freiburg Im Breisgau | Germany | VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505 | USA | PoM | ЛП-№002851-ГП-АМ 16.05.2025 |

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Glucosamine Plus | glucosamine (glucosamine hydrochloride), chondroitin sulfate (chondroitin sulfate sodium) | tablets film-coated | 500mg+400mg; (30) in plastic container, (60) in plastic container, (100) in plastic container | IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo | Syria | IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo | Syria | OTC | 19068/1 16.05.2025 |
| 2 | Gabagamma | gabapentin | capsules hard | 300mg; (20/2x10/) and (50/5x10/), in blister | Medis International a.s., Prumyslova 961/16, Bolatice, 74723- packager, batch releaser, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany- bulk manufacturer, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological) | Czech Republic | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 19925/2/1 16.05.2025 |

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| 3 | Gabagamma | gabapentin | capsules hard | 400mg; (20/2x10/) and (50/5x10/), in blister | Medis International a.s., Prumyslova 961/16, Bolatice, 74723- batch releaser, packager, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany- bulk manufacturer, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological) | Czech Republic | Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen | Germany | PoM | 19926/2/1 16.05.2025 |
| 4 | Tergynan | ternidazole, neomycin (neomycin sulfate), nystatin, prednisolone (prednisolone sodium metasulphobenzoate) | tablets vaginal | 200mg+65000IU+100000IU+3mg; (6/1x6/) in blister, (10/1x10/) in blister | Sophartex, 21 rue du Pressoir, 28500 Vernouillet- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Eurofins Amatsi Analytics, Zone ZA du Mardaric 04310 Peyruis, France- quality control (microbiological) | France | Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux | France | PoM | 21432/1 16.05.2025 |
| 5 | Rotarix | human rotavirus vaccine live | suspension oral | not less than 10^6CCID^50/dose; (50) plastic tube 1.5ml (1 dose) | GlaxoSmithKline Biologicals s.a., Rue de l` Institut, 89 B-1330 Rixensart- batch releaser, GlaxoSmithKline Biologicals SA, Parc de la Noire Epine Rue Fleming, 20,1300 Wavre, Belgium- bulk manufacturer, quality control, packager | Belgium | GlaxoSmithKline Biologicals s.a., Rue de l` Institut, 89 B-1330 Rixensart | Belgium | PoM | 20908/4 16.05.2025 |
| 6 | Fluconazole | fluconazole | capsules | 150mg; (10/1x10/) in blister | Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | PoM | 19180/1 16.05.2025 |
| 7 | Fucorcin | resorcin | solution for external use | 78mg/ml; 10ml glass bottle, 15ml glass bottle, 25ml glass bottle, 30ml glass bottle | Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7 | Republic of Armenia | Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7 | Republic of Armenia | OTC | 18599/1 16.05.2025 |
| 8 | Nasonex | mometasone (mometasone furoate) | spray nasal (suspension) | 50mcg/dose; 18g (140 dose) plastic bottle with spray pump 18g (140 dose) | Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220 | Belgium | Organon Central East GmbH, Weystrasse 20, 6006 Luzern | Switzerland | PoM | 22715/1 16.05.2025 |

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| 9 | Hexpanthen | dexpanthenol, chlorhexidine (chlorhexidine bigluconate) | suppositories vaginal | 100mg+16mg; (10/2x5/) | Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22 | Republic of Armenia | Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22 | Republic of Armenia | OTC | 19036/2 16.05.2025 |
| 10 | DESALLERGAN | desloratadine | solution oral | 0,5mg/ml; glass bottle 120ml | Vetprom AD, Otez Paissij str. 26, Radomir 2400 | Bulgaria | Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400 | Bulgaria | PoM | 19202/1 16.05.2025 |
| 11 | Ingavirin | pentanedioic acid (pentanedioic acid imidazolyl ethanamide) | capsules | 60mg; (7/1x7/) in blister | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2 | Russia | Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2 | Russia | OTC | 20119/2/1 16.05.2025 |
| 12 | Singulair | montelukast (montelukast sodium) | tablets film-coated | 10mg; (14/1x14/) in blister | Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser Organon Pharma (UK) Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU, United Kingdom - bulk manufacturer | the Netherlands | Organon Central East GmbH, Weystrasse 20, 6006 Luzern | Switzerland | PoM | 19607/3/2 16.05.2025 |
| 13 | Metronidazole Denta | metronidazole (metronidazole benzoate), chlorhexidine (chlorhexidine gluconate 20% solution) | gel for gums | 10mg/g+0,5mg/g; aluminium tube 20g | Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building | Republic of Armenia | OTC | 19054/1 16.05.2025 |

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## of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/25 on May 16, 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 | Flavamed cough solution | ambroxol (ambroxol hydrochloride) | solution oral | 15mg/5ml; glass bottle 100ml and measuring spoon | Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin | Germany | Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin | Germany | OTC | ЛП-№007190-РГ-АМ 16.05.2025 |
| 2 | Pronoran | piribedil | tablets prolonged-release coated | 50mg; (30/2x15/) in blister, (30/1x30/) in blister | Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy | France | Les Laboratoires Servier, 50, Rue Carnot, 92284 Suresnes Cedex | France | PoM | ЛП-№003873-ГП-АМ 16.05.2025 |
| 3 | Pronoran | piribedil | tablets prolonged-release coated | 50mg; (29/1x29/) in blister, (30/1x30/) 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 | ЛП-№003873-ГП-АМ 16.05.2025 |
| 4 | Pronoran | piribedil | tablets prolonged-release coated | 50mg; (29/1x29/) in blister, (30/1x30/) in blister | SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer | Russia | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex | France | PoM | ЛП-№003873-ГП-АМ 16.05.2025 |
| 5 | Oncaspar | Pegaspargase | lyophilizate for solution for i/m injection and infusion | 750IU/ml; glass vial 5ml | Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE),25 Commerce Drive, Bedford, New Hampshire (NH) 03110 , USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager | France | Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex | France | PoM | ЛП-№000545-ГП-АМ 16.05.2025 |

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| 6 | Trittico | trazodone (trazodone hydrochloride) | tablets prolonged-release | 150mg; (20/2x10/) in blister, (60/6x10/) in blister, (90/6x15/) in blister | 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 | PoM | ЛП-№001171-ГП-АМ 16.05.2025 |