

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-2/23 on April 28, 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	Haedensa	monochlorcarvacrol, menthol, ichtammol	ointment rectal	0,5mg+25mg+5mg; 20g aluminium tube	Merz Pharma GmbH & Co. KGaA, Ludwigstrasse 22, 64354 Reinheim	Germany	Alpen Pharma AG, Finkenhubelweg 16, 3012 Bern	Switzerland	OTC	21347 28.04.2023

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 04-2/23 on April 28,
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	Cavinton Comforte	vinpocetine	tablets orodispersible	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21345 (002614) 28.04.2023
2	Cavinton Comforte	vinpocetine	tablets orodispersible	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21346 (000988) 28.04.2023
3	Halixol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	21345 (002614) 28.04.2023
4	Azirex	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	21343 (003060) 28.04.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-2/23 on April 28, 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	Ketorolac	ketorolac (ketorolac tromethamine)	solution for i/m injection	30mg/ml; (10) ampoules 1ml, (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64, No10/1, 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	PoM	21348 28.04.2023
2	Termicon	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; 10g aluminium tube, 15g aluminium tube	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., b. 280-quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., b. 279, Russia- bulk manufacturer, packager	Russia	«OTCPharm» JSC, Testovskaya street, 10, flr. 12, apartment II, room. 29, Moscow 123112	Russia	OTC	21349 28.04.2023
3	Setal MR	trimetazidine (trimetazidine dihydrochloride)	tablets modified-release	35mg; (60/6x10/) in blister	Polfarmex S.A., Jozefow 9 Street, 99-300 Kutno	Poland	Polfarmex S.A., Jozefow 9 Street, 99-300 Kutno	Poland	PoM	21350 28.04.2023
4	Medrol	methylprednisolone	tablets	4mg; (30/3x10/) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21351 28.04.2023

5	RubiDol	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (5) glass vials 2ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21352 28.04.2023
6	Amelotex	meloxicam	tablets	15mg; (20/2x10/) in blister	SotexPharmFirm» CJSC, bld. 11, village Belikovo, Sergiev-Posad urban district, Moscow Region-quality control, batch releaser Replek Farm Ltd, Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, primary packager, «Sotex»PharmFirm» CJSC, bld. 12, village Belikovo, Sergiev-Posad urban district, Moscow Region, 141345, Russia- secondary packager	Russia	«Sotex»PharmFirm» CJSC, bld. 11, village Belikovo, Sergiev-Posad, Moscow Region, 141345	Russia	PoM	21353 28.04.2023
7	Azithromycin ABR	azithromycin (azithromycin dihydrate)	capsules hard	500mg; (3/1x3/) in blister	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	21354 28.04.2023
8	Betadine	povidone-iodine	suppositories vaginal	200mg; (7/1x7/), (14/2x7/)	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	21355 28.04.2023
9	Betadine	povidone-iodine	ointment	100mg/g; 20g aluminium tube	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	21356 28.04.2023
10	Ketogel	ketoprofen	gel for external use	25mg/g; 30g aluminium tube, 40g aluminium tube, 50g aluminium tube	Vetprom AD, Otets Paisiy str. 26, Radomir 2400	Bulgaria	Danhson-BG, Otets Paisiy str. 26, Radomir 2400	Bulgaria	PoM	21357 28.04.2023

11	Aquadetrim plus	vitamin A, vitamin D3	drops oral	20000IU/ml+10000IU/ml; 10ml glass bottle-dropper	Pharmaceutical Works POL- PHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POL- PHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Po- land- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelp- linska Str., 83-200 Starogard Gdanski	Poland	PoM	21358 28.04.2023
12	Orlip	orlistat	capsules	60mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	OTC	21359 28.04.2023
13	Sedalgin Plus	metamizole (metamizole sodium), caffeine, thiamine hydrochloride	tablets	500mg+50mg+38,75mg; (10/1x10/), (20/2x10/) and (50/5x10/) in blister	Balkanpharma-Dupnitsa AD, str.»Samokovsko Shosse» N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, str.»Samokovsko Shosse» N3, Dupnitsa 2600	Bulgaria	OTC	21360 28.04.2023

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/23
on April 28, 2023

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1	Tranexam	tranexamic acid	tablets film-coated	250mg; (10/1x10) in blister, (30/3x10) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physicochemical), batch releaser, Test center «FARMOBORO-NA» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18484/3/1 28.04.2023
2	Tranexam	tranexamic acid	tablets film-coated	500mg; (10/1x10) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physicochemical), batch releaser, Test center «FARMOBORO-NA» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18485/3/1 28.04.2023

3	Zinacef	cefuroxime (cefuroxime sodium)	powder for solution for injection	750mg; glass vial	ACS Dobfar S.p.A., Via A. Fleming, 2, Verona, 37135	Italy	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19000/3/3 28.04.2023
4	Pantoprazole Canon	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	OTC	18741/2/2 28.04.2023
5	Pantoprazole Canon	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	18740/2/2 28.04.2023
6	Ketorolac	ketorolac (ketorolac tromethamine)	solution for i/m injection	30mg/ml; (10) ampoules 1ml, (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella	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	17324/3/1 28.04.2023
7	Valerian extract	valerian thick extract	tablets coated	20mg; (50/5x10/) in blister, (50/2x25/) in blister, (25) in blister, (10) in blister, (50) glass bottle, (50/1x50/) glass bottle	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 24, Stroiteley str., 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	20508/1/1 28.04.2023
8	Orlip	orlistat	capsules	120mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	20699/1/1 28.04.2023

9	Amorolfine Lacquer	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 2,5ml glass vial, (10) spatulas, (30) nail files, (30) cleansing swabs	Chanelle Medical Unlimited Company, Dublin Road Loughrea, H62 FH90- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Complete Laboratory Solutions, Units 3A & 8, Small Business Park, Tuam Road, Galway, Ireland- quality control (microbiological)	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	20727/1/1 28.04.2023
10	Glurenorm	gliquidone	tablets	30mg; (60/6x10/) in blister	Boehringer Ingelheim Hellas Single Member S.A ., 5th km, Paiania-Markopoulo, 19441 Koropi Attiki- bulk manufacturer, packager, quality control (physicochemical), batch releaser, QACS Ltd., Antigonis str.1, Metamorfossi, 14451, Greece- quality control (microbiological)	Greece	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	17772/4/2 28.04.2023
11	Enzix Duo	I-enalapril (enalapril maleate), II-indapamide	tablets and tablets film-coated	I-10mg, II-2,5mg; (45/3x15// (10)-I tablets + (5)-II film-coated tablets/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	21112/1/1 28.04.2023
12	Enzix Duo Forte	I-enalapril (enalapril maleate), II-indapamide	tablets and tablets film-coated	I-20mg, II-2,5mg; (45/3x15// (10)-I tablets + (5)-II film coated tablets/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	21113/1/1 28.04.2023
13	No-spa	drotaverine (drotaverine hydrochloride)	solution for i/m and i/v injection	20mg/ml; (25/5x5/) ampoules 2ml	Chinoi Pharmaceutical and Chemical Works Private Co. Ltd., 3510 Miskolc, Csanyikvolgy	Hungary	Opella Healthcare Commercial Ltd., 1045 Budapest, To u. 1-5	Hungary	PoM	20553/1/1 28.04.2023

14	Zinnat	cefuroxime (cefuroxime axetil)	tablets film-coated	250mg; (10/1x10) in blister	Glaxo Operations UK Limited, Harmire Road, Barnard Castle, Durham, DL12 8DT	UK	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	17725/1/1 28.04.2023
15	Actemra	tocilizumab	concentrate for solution for i/v infusion	20mg/ml; (1) glass vial 4ml	F. Hoffmann-La Roche Ltd., 4303, Kaiseraugust-secondary packager, batch releaser, Chugai Pharma Manufacturing Co., Ltd., 16-3 Kiyohara Kogyodanchi,Utsunomiya-city,Tochigi, 321-3231, Japan-bulk manufacturer, primary packager, Roche Pharma AG, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany-quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	PoM	18922/2/1 28.04.2023
16	Actemra	tocilizumab	concentrate for solution for i/v infusion	20mg/ml; (1) glass vial 10ml	F. Hoffmann-La Roche Ltd., 4303, Kaiseraugust-secondary packager, batch releaser, Chugai Pharma Manufacturing Co., Ltd., 16-3 Kiyohara Kogyodanchi,Utsunomiya-city,Tochigi, 321-3231, Japan-bulk manufacturer, primary packager, Roche Pharma AG, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany-quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	PoM	18923/3/1 28.04.2023
17	Actemra	tocilizumab	concentrate for solution for i/v infusion	20mg/ml; glass vial 4ml	F. Hoffmann-La Roche Ltd., 4303, Kaiseraugust-secondary packager, batch releaser, Chugai Pharma Manufacturing Co., Ltd., 16-3 Kiyohara Kogyodanchi,Utsunomiya-city,Tochigi, 321-3231, Japan-bulk manufacturer, primary packager, Roche Pharma AG, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany-quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	PoM	20244/1/1 28.04.2023

18	Actemra	tocilizumab	concentrate for solution for i/v infusion	20mg/ml; glass vial 10ml	F. Hoffmann-La Roche Ltd., 4303, Kaiseraugust-secondary packager, batch releaser, Chugai Pharma Manufacturing Co., Ltd., 16-3 Kiyohara Kogyodanchi,Utsunomiya-city,Tochigi, 321-3231, Japan-bulk manufacturer, primary packager, Roche Pharma AG, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany-quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	PoM	20245/1/1 28.04.2023
19	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic bottle 15ml (150 dose) with metering pump	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb, Montenegro	Serbia	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	18377/4/1 28.04.2023
20	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic bottle 15ml (150 dose) with metering pump	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb, Montenegro	Serbia	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	18378/4/1 28.04.2023

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/23
on April 28, 2023

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1	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	5mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20251/3 28.04.2023
2	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	5mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20252/2 28.04.2023
3	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	10mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38, Hungary	Hungary	PoM	20253/2 28.04.2023
4	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	10mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20254/3 28.04.2023
5	Divigel	estradiol (estradiol hemihydrate)	gel	1mg/g; (28) sachets 1g	Orion Corporation, Orionintie 1, 02200 Espoo- batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager, quality control	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19718/2 28.04.2023

6	Sinecod	butamirate (butamirate citrate)	drops oral	5mg/ml; glass vial 20ml with dropper	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18372/3/1 28.04.2023
7	Efferalgan	paracetamol	tablets effervescent	500mg; (16/4x4/) in strip	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Mal- maison	France	OTC	20903/1 28.04.2023
8	Humalog Mix 25	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20820/2 28.04.2023
9	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20821/2 28.04.2023
10	Humalog	insulin lispro	solution for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20819/1 28.04.2023
11	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	18257/2 28.04.2023
12	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	18258/3 28.04.2023
13	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	18259/3 28.04.2023
14	Inestom	levocarnitine	solution oral	100mg/ml; (10) glass vial 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfosi, Attici	Greece	PoM	16829/3 28.04.2023
15	Inestom	levocarnitine	solution for injection	200mg/ml; (5) ampoules 5ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfosi, Attici	Greece	PoM	16830/3 28.04.2023

16	Floxaton	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg (10/1x10/) in blister	Medochemie Ltd., (Central Factory), 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	18249/2 28.04.2023
17	Clopidogrel-Asteria	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (28/4x7/) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	18701/4/2 28.04.2023
18	Aescusan	dry extract of horse chestnut seeds, thiamine hydrochloride	solution oral	47,25mg/g+5mg/g; 20ml glass bottle	Pharma Wernigerode GmbH, Dornbergsweg 35, 38855 Wernigerode	Germany	Pharma Wernigerode GmbH, Dornbergsweg 35, 38855 Wernigerode	Germany	OTC	17365/1 28.04.2023
19	Termicon	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; 10g and 15g aluminium tube	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	17329/3/1 28.04.2023
20	Pergoveris	follitropin alfa, lutropin alfa	powder lyophilized for solution for s/c injection	150IU+75IU; (1) glass vial and (1) solvent in vial 1ml, (3) glass vials and (3) solvent in vials 1ml, (10) glass vials and (10) solvent in vials 1ml	Merck Serono S.A., Succursale d' Aubonne, Zone Industrielle de l' Ourietta, 1170 Aubonne	Switzerland	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20411/1 28.04.2023
21	Ermucin	erdosteine	granules for oral suspension	225mg; (10) sachets 4,425mg	Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG)	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	18075/3 28.04.2023
22	Ermucin	erdosteine	capsules hard	300mg; (10/1x10/) and (20/2x10/) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131- 20037 Paderno Dugnano (MI)- batch releaser, bulk manufacturer, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy-packager	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	18076/3 28.04.2023
23	ERMUCIN	erdosteine	powder for oral suspension	175mg/5ml; glass vial 50g and measuring cap	ZETA FARMACEUTICI S.P.A, VIA GALVANI, 10-36066, SANDRIGO (VI)	Italy	UAB «MRA» Totoriu str. 20-9, LT-01121 Vilnius	Lithuania	PoM	19980/3 28.04.2023
24	Loranex	desloratadine	solution oral	0,5mg/ml; 150ml glass vial and measuring device	Laboratorios Basi-Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, lote 8,15,16, 3450-232 Mortagua	Portugal	GM Pharmaceuticals Ltd, 65,Phonichala str., Tbilisi	Georgia	PoM	20803/1 28.04.2023

25	Orlip	orlistat	capsules	60mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	OTC	17521/2 28.04.2023
26	Spitomin	bupirone	tablets	5mg (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19523/2 28.04.2023
27	Spitomin	bupirone	tablets	10mg (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19524/2 28.04.2023
28	Verapress MR 240 Tablets	verapamil (verapamil hydrochloride)	tablets modified-release	240mg; (28/2x14/) 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	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	17986/4 28.04.2023
29	Azithromycin ABR	azithromycin (azithromycin dihydrate)	capsules hard	500mg; (3/1x3/) in blister	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	17246/1 28.04.2023
30	Aquadetrim plus	vitamin A, vitamin D3	drops oral	20000IU/ml+10000IU/ml; 10ml glass bottle-dropper	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 Pelpinska Str., 83-200 Starogard Gdanski	Poland	PoM	17654/2/1 28.04.2023
31	Ketogel	ketoprofen	gel for external use	25mg/g; 30g aluminium tube, 40g aluminium tube, 50g aluminium tube	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Danson-BG, Otez Paissij str. 26, Radomir 2400	Bulgaria	PoM	17358/1/2 28.04.2023

32	Recormon	epoetin beta	solution for i/v and s/c injection	2000IU/0,3ml; (6) pre-filled syringes 0,3ml and (6) needles	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18566/5 28.04.2023
33	RubiDol	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (5) glass vial 2ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	17892/1 28.04.2023
34	Travolife Hedera	ivy leaves dry extract	syrup	7mg/ml; 100ml glass bottle with measuring cup	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, London	UK	OTC	20991/1 28.04.2023
35	Medrol	methylprednisolone	tablets	4mg; (30/3x10/) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	17574/3 28.04.2023
36	Sedalgin Plus	metamizole (metamizole sodium), caffeine, thiamine hydrochloride	tablets	500mg+50mg+38,75mg; (10/1x10/), (20/2x10/) and (50/5x10/) in blister	Balkanpharma-Dupnitsa AD, str.»Samokovsko Shosse» N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, str.»Samokovsko Shosse» N3, Dupnitsa 2600	Bulgaria	OTC	17764/1 28.04.2023
37	Diane-35	cyproterone (cyproterone acetate), ethinylestradiol	tablets coated	2mg+0,035mg; (21/1x21/) in blister	Bayer Weimar GmbH & Co. KG, Doebererstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 51373 Leverkusen	Germany	PoM	18774/3 28.04.2023