

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-1/22 on October 28, 2022

President _____ E. Amroyan

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	Atazor-R	atazanavir sulphate, ritonavir	tablets film-coated	300mg+100mg; (30) in plastic container	Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057, Maharashtra State	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026, Maharashtra State	India	PoM	20965 28.10.2022
2	Tavin-EM	tenofovir (tenofovir disoproxil fumarate), emtricitabine	tablets film-coated	300mg+200mg; (30) in plastic container	Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057, Maharashtra State	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026, Maharashtra State	India	PoM	20966 28.10.2022
3	Covifor	remdesivir	powder lyophilized for solution for infusion	100mg; (6/6x1/) glass vials	M/s. Aspiro Pharma Limited, Sy.No. 321, Biotech Park, Phase-III, c/o, karkapatla (V), Markook (M), Siddipet (D), Telegana State	India	Hetero Labs Limited, M/s. Hetero corporate, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad, Telangana	India	PoM	20967 28.10.2022

4	Racium	valerianae rhizomes with roots (as powder),melissae folium,folium menthae piperite	capsules	100mg+50mg+50mg; (42/2x21/) in blister	Republican unitary production enterprise Academpharm,UI. Akademika Kuprevicha, d5, k.3, 220141 Minsk	Belarus	Republican unitary production enterprise Academpharm,UI. Akademika Kuprevicha, d5, k.3, 220141 Minsk	Belarus	OTC	20968 28.10.2022
5	Allergodil	azelastine (azelastine hydrochloride)	spray nasal	1mg/1ml; 10ml glass vial with pump dispenser	Madaus GmbH, Luetticher Strasse 5,Troisdorf, 53842	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	OTC	20969 28.10.2022
6	Exoderil	naftifine hydrochloride	cream for external use	10mg/g; aluminium tube 15g	Salutas Pharma GmbH, Betriebsstaette Osterweddingen, Lange Goehren 3,Suelzetal, OT Osterweddingen,Sachsen-Anhalt, 39171- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Salutas Pharma GmbH, Otto-von-Guericke Alle-1, 39179 Barleben, Sachsen-Anhalt, Germany-quality control (microbiological)	Germany	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	20970 28.10.2022

7	Chophytol	cynara scolymus extract	tablets coated	200mg; (60/2x30/) in blister, (180/6x30/) in blister	Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie- Les-Lys	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l` Europe, 78400 Chatou	France	OTC	20971 28.10.2022
8	Bonspri	ofatumumab	solution for subcutaneous injection	20mg/0,4ml; glass pre- filled syringe 0,4ml in blister	Novartis Pharma Stein, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20972 28.10.2022
9	Chophytol	cynara scolymus extract	solution oral	200mg/ml; 120ml glass bottle	Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie- Les-Lys	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l` Europe, 78400 Chatou	France	OTC	20973 28.10.2022

10	Brinzolamide Moosmann	brinzolamide	drops eye (suspension)	10mg/ml; plastic vial 5ml	Lusomedicamenta Sociedade Tecnica Farmaceutica, S.A, Rua Norberto de Oliveira, No 1/5, Povia Sto. Adriaio, 2620-111- bulk manufacturer, packager, quality control (microbiological), batch releaser, Lusomedicamenta Sociedade Tecnica, Farmaceutica, S.A. Estrada Consiglieri Pedroso, 66, 69- B, Queluz de Baixo, 2730- 055 Barcarena, Portugal- quality control (physicochemical)	Portugal	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Kotayk Marz 2413	Republic of Armenia	PoM	20974 28.10.2022
11	Brinzolamide Timolol Moosmann	brinzolamide, timolol (timolol maleate)	drops eye (suspension)	10mg/ml+5mg/ml; plastic vial-dropper 5ml	Lusomedicamenta Sociedade Tecnica Farmaceutica, S.A, Rua Norberto de Oliveira, No 1/5, Povia Sto. Adriaio, 2620-111- bulk manufacturer, packager, quality control (microbiological), batch releaser, Lusomedicamenta Sociedade Tecnica, Farmaceutica, S.A. Estrada Consiglieri Pedroso, 66, 69- B, Queluz de Baixo, 2730- 055 Barcarena, Portugal- quality control (physicochemical)	Portugal	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Kotayk Marz 2413	Republic of Armenia	PoM	20975 28.10.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 10-1/22 on October 28, 2022

President _____ E. Amroyan

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	Denk-Air Junior 4mg	montelukast (montelukast sodium)	tablets chewable	4mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20936 28.10.2022
2	Denk-Air Junior 5mg	montelukast (montelukast sodium)	tablets chewable	5mg; (28/2x14/) In blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20937 28.10.2022

3	Denk-Air 10mg	montelukast (montelukast sodium)	tablets film-coated	10mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20938 28.10.2022
4	CalciD-Denk	calcium (calcium carbonate), colecalciferol	tablets effervescent	1000mg+22mcg(880IU); (20) in plastic container	Losan Pharma GmbH, Otto-Hahn-Strasse 13, 79395 Neuenburg- 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20939 28.10.2022
5	Eslidin	lipoid PPL-400 (phospholipids), methionine	capsules	300mg+100mg; (30/3x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20940 28.10.2022

6	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) in blister, (36/3x12/) in blister, (60/4x15/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	20941 28.10.2022
7	Lamisil	terbinafine (terbinafine hydrochloride)	cream	10mg/g; 15g aluminium tube, 15g laminated tube	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	20942 28.10.2022
8	Ipigrix 5mg/ml	ipidacrine (ipidacrine hydrochloride)	solution for injection	5mg/ml; (10/2x5/) ampoules 1ml	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	20943 28.10.2022
9	Ipigrix 15mg/ml	ipidacrine (ipidacrine hydrochloride)	solution for injection	15mg/ml; (10/2x5/) ampoules 1ml	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	20944 28.10.2022

10	Valocordin	ethylbromisovalerate, phenobarbital	drops oral (solution)	18,4mg/ml+18,4mg/ml; 20ml glass bottle, 50ml glass bottle	Krewel Meuselbach GmbH, Xavier-Vorbruggen str. 6, 98694 Ilmenau	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	20945 28.10.2022
11	Corvalol- Pharmstandard	alfa-bromisovaleric acid ethyl ester, phenobarbital, peppermint oil	drops oral	20mg/ml+18,26mg/ml+ 1,42mg/ml; 25ml glass bottle-dropper	Pharmstandard- Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard- Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	20946 28.10.2022
12	Epiduo	adapalene, benzoyl peroxide	gel	1mg/g+25mg/g; 5g plastic tube, 15g plastic tube, 30g plastic tube, 15g plastic multidose container with airless pump, 30g plastic multidose container with airless pump	Laboratoires Galderma Z.I. Montdesir, 74540 Alby-sur- Cheran	France	Galderma SA, Zahlerweg 10, 6300 Zug	Switzerland	PoM	20947 28.10.2022
13	Alfa Normix	rifaximin	tablets film- coated	200mg; (12/1x12/) in blister	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del' 99, 5-40133 Bologna (BO)	Italy	PoM	20948 28.10.2022

14	Metronidazole	metronidazole	tablets	250mg; (10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20949 28.10.2022
15	Ferrum LEK	iron (III) hydroxide with polymaltose complex	tablets chewable	100mg; (30/3x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20950 28.10.2022
16	Glycerin	glycerol	suppositories rectal	1,24g; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20951 28.10.2022
17	Glycerin	glycerol	suppositories rectal	2,11g; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20952 28.10.2022
18	Metoclopramide	metoclopramide (metoclopramide hydrochloride)	solution for injection	5mg/ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella, (10) ampoules 2ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20953 28.10.2022

19	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; 53g powder in 100ml glass bottle and 5ml measuring spoon	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20954 28.10.2022
20	Pancef	cefixime (cefixime trihydrate)	tablets film-coated	400mg; (5/1x5/) in blister, (7/1x7/) in blister, (10/2x5/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20955 28.10.2022
21	Survanta	beractant (phospholipids)	suspension intratracheal	25mg/ml; glass vial 4ml	AbbVie Inc., 1401 Sheridan Road, North Chicago, Illinois 60064- bulk manufacturer, primary packager, quality control, batch releaser, AbbVie Inc., 1 North Waukegan Road, North Chicago, Illinois 60064, USA- secondary packager	USA	AbbVie Biopharmaceuticals GmbH, Alte Steinhauserstrasse 14, 6330 Cham	Switzerland	PoM	20956 28.10.2022

22	Bisacodyl	bisacodyl	tablets gastro-resistant	5mg; (30/3x10/) in blister	Balkanpharma-Razgrad AD, 68, Aprilsko vastanie Blvd, 7200 Razgrad	Bulgaria	Balkanpharma-Dupnitsa AD, (ACTAVIS GROUP), str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	OTC	20957 28.10.2022
23	Diazolin-Darnitsa	mebhydrolin	tablets	100mg; (10/1x10/) in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	OTC	20958 28.10.2022
24	Vitamin B complex	thiamine (thiamine nitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), nicotinamide	film-coated tablets	5mg+1mg+4mg+50mg; (20/1x20/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	20959 28.10.2022
25	Nuroton	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	20960 28.10.2022
26	Indovasin	indometacin, troxerutin	gel for external use	30mg/g+20mg/g; aluminium tube 45g	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	20961 28.10.2022

27	Elonva	corifollitropin alfa	solution for injection	100mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, 1.Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany, 2.N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands- quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20962 28.10.2022
28	Elonva	corifollitropin alfa	solution for injection	150mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, 1.Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany, 2.N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands- quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20963 28.10.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-1/22 on October 28, 2022

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1	Noradrenaline	noradrenaline tartrate	concentrate for solution for infusion	1mg/ml; (5/1x5/) ampoules 4ml in plastic liner, (10/2x5/) ampoules 4ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2.Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19569/2/2 28.10.2022
2	Rexocef	cefpodoxime (cefpodoxime proxetil)	powder for oral suspension	40mg/5ml; 64.8g powder in 100ml plastic vial with, measuring cup and dosing syringe	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Lupin Limited, 198-202, New Industrial Estate Area No.2 Mandideep-462046 district-Raisen M.P, India- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia		PoM	18167/3/1 28.10.2022

3	Aciclovir-Belmed	aciclovir	tablets	200mg; (10/1x10/), (20/2x10/) and (30/3x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, No6, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	17647/1/1 28.10.2022
4	Atracurium Besylate 10mg/ml Solution for Injection/Infusion	atracurium (atracurium besylate)	solution for injection/infusion	10mg/ml; (5) ampoules 2,5ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	18361/3/1 28.10.2022
5	Atracurium Besylate 10mg/ml Solution for Injection/Infusion	atracurium (atracurium besylate)	solution for injection/infusion	10mg/ml; (5) ampoules 5ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	18362/3/1 28.10.2022
6	Trifas	torasemide	solution for injection	10mg/2ml; (5) ampoules 2ml	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Florence	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	20870/1/1 28.10.2022

7	Zinacef	cefuroxime (cefuroxime sodium)	powder for solution for injection	750mg; glass vial	ACS Dobfar S.p.A., Via A. Fleming, 2, Verona, 37135	Italy	GlaxoSmithKline SpA, Viale dell Agricoltura, 7, Verona, 37135	Italy	PoM	19000/2/2 28.10.2022
8	Relief	phenylephrine (phenylephrine hydrochloride)	ointment rectal	2,5mg/g 28.4g laminated tube and applicator	Famar S.A., National Road Athens-Lamia, Km 49, 19011 Avlona	Greece	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	17204/3/1 28.10.2022
9	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	20119/1/1 28.10.2022
10	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (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	20120/1/1 28.10.2022
11	Holosas	rosae fructus extract	syrup	400mg/g; 95ml glass bottle, 215ml glass bottle	Altayvitamini JSC, 659325, The Altay territory, Biysk, 69 Zavodskaya Str.	Russia	Altayvitamini JSC, 659325, The Altay territory, Biysk, 69 Zavodskaya Str.	Russia	OTC	18914/1/1 28.10.2022

12	Essentiale N	phospholipids (essential)-EPL	solution for i/v injection	50mg/ml; (5) ampoules 5ml	Famar Health Care Services Madrid, S.A.U., Avenida de Leganes, 62, 28923 Alcorcon (Madrid)	Spain	Opella Healthcare LLC, Tverskaya str. 22, Moscow	Russia	PoM	17459/2/2 28.10.2022
13	Depantol	dexpanthenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18209/4/1 28.10.2022
14	Ducressa	dexamethasone (dexamethasone sodium phosphate), levofloxacin (levofloxacin hemihydrate)	drops eye	1mg/ml+5mg/ml; 5ml plastic vial-droper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	20402/1/1 28.10.2022
15	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	1,5mg+1mg; (18/2x9/) 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	19855/3/1 28.10.2022
16	Depakine enteric 300	valproate sodium (valproic acid)	tablets gastro-resistant	300mg; (100/10x10/) in blister	Sanofi-Aventis S.A., Ctra. C35 La Batlloria a Hostalric, km 63.09,17404 Riells I Viabrea (Girona)	Spain	Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	20628/1/1 28.10.2022

17	Strepsils Intensive	flurbiprofen	spray dosed for topical use with cherry and mint flavour	8,75mg; (1) plastic container with dosing device, 15ml (at least 15 dose)	Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd, 65 Lardkrabang-Bangplee Road Moo 12, Bangplee, Samutprakarn, 10540	Thailand	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	20726/2/1 28.10.2022
18	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; glass vial 20ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MPL Mikrobiologisches Pruflabor GmbH, Grabenweg 68, 6020 Innsbruck, Austria- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	20430/2/1 28.10.2022

19	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; glass vial 100ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MPL Mikrobiologisches Pruflabor GmbH, Grabenweg 68, 6020 Innsbruck, Austria- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	20431/2/1 28.10.2022
20	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (30/2x15/) in blister, (60/4x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19451/1/1 28.10.2022
21	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (60/6x10/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy- packager, batch releaser, Merck Healthcare KGaA, Frankfurter Strasse 250, 64 293 Darmstadt, Germany- bulk manufacturer, quality control	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19452/1/1 28.10.2022

22	Regulax Picosulphate	sodium picosulfate (sodium picosulfate monohydrate)	drops oral	7,5mg/ml; glass bottle 20ml	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf- batch releaser, Krewel Meuselbach GmbH, Xavier-Vorbruggen-Strasse 6, 98694 Ilmenau, Germany- bulk manufacturer, packager, quality control (physicochemical and microbiological)	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	18814/1/1 28.10.2022
23	Kapsikam	dimethyl sulfoxide, camphor racemic, turpentine oil, benzyl nicotinate, nonivamide	ointment for external use	50mg/g+30mg/g+30mg/g+20mg/g+2mg/g; aluminium tube 30g and applicator, aluminium tube 50g and applicator	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	18480/3/1 28.10.2022
24	Vsiqq	Brolucizumab	solution for intraocular injection	120mg/ml; glass vial and filter needle	Novartis Pharma Stein AG Technical Operations Schweiz, Stein Steriles, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19953/3/2 28.10.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-1/22 on October 28, 2022

President _____ E. Amroyan

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	Noradrenaline	noradrenaline (noradrenaline tartrate)	concentrate for solution for infusion	1mg/ml; (5/1x5/) ampoules 2ml in plastic liner, (10/2x5/) ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2. Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19568/2/1 28.10.2022
2	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, DK-3400 Hillerod, Denmark- seconadary packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20594/1 28.10.2022

3	Levemir FlexPen	insulin detemir (recombinant)	solution for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17819/3 28.10.2022
4	Clovate	clobetasol (clobetasol propionate)	ointment for external use	0,5mg/g aluminium tube 25g	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BauschHealth LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19604/2 28.10.2022
5	Denk-Air Junior 5mg	montelukast (montelukast sodium)	tablets chewable	5mg; (28/2x14/) In blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16798/4 28.10.2022
6	Auxilen	dexketoprofen (dexketoprofen trometamol)	solution for injection/ infusion	50mg/2ml; (5/1x5/) ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	18965/4/2 28.10.2022

7	Denk-Air Junior 4mg	montelukast (montelukast sodium)	tablets chewable	4mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16799/4 28.10.2022
8	Denk-Air 10mg	montelukast (montelukast sodium)	tablets film- coated	10mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16800/3 28.10.2022

9	Moviprep	sachet A-macrogol (macrogol 3350), sodium sulfate, sodium chloride, potassium chloride; sachet B-ascorbic acid, sodium ascorbate	powder for oral solution	sachet A-100g+7.5g+2.691g+1.015g; sachet B-4.7g+5.9g; (4/(2) sachetA(111.896 g) + (2) sachetB(10.6 g)/)	Norgine Limited, New Road, Tir-Y-Berth, Hengoed, Mid Glamorgan, CF82 8SJ- bulk manufacturer, packager, quality control (physicochemical), batch releaser, READING SCIENTIFIC SERVICES LIMITED, READING SCIENCE CENTRE, WHITEKNIGHTS CAMPUS, PEPPER LANE, READING, RG6 6LA, UK- quality control (microbiological)	UK	Norgine B.V., Antonio Vivaldistraat 150, 1083HP Amsterdam	the Netherlands	OTC	19299/4 28.10.2022
10	Terbisil	terbinafine (terbinafine hydrochloride)	tablets	250mg; (14/1x14/) in blister, (28/2x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19853/1 28.10.2022
11	Spasmopriv Forte	fenoverine	capsules	200mg; (10/1x10/) in blister, (20/2x10/) in blister	Laboratorios Legrand S.A., Calle 19 No. 68 B-50, Bogota, D.C.	Colombia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	18440/2 28.10.2022
12	Carsil 22,5mg coated tablets	silymarin	tablets coated	22,5mg; (80/8x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	20796/1 28.10.2022

13	Tricor	fenofibrate	tablets film-coated	145mg; (30/3x10/) in blister	Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine les Dijon- batch releaser, packager, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	17395/2/1 28.10.2022
14	Nanotropil novo	fonturacetam	tablets	100mg; (10/1x10/) in blister, (30/3x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physical/chemical), Federal State Budgetary Healthcare Institution "Center for Hygiene and Epidemiology No. 8 of the Federal Medical and Biological Agency", Kaluga region, Obninsk, pr-kt. Lenin, 85, 249030, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo city, Fabrichnaya St., 2	Russia	PoM	20086/3/1 28.10.2022

15	Bobotic	simeticone	drops oral	66,66mg/ml; 30ml glass bottle	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	OTC	17849/2/1 28.10.2022
16	Tyverb	lapatinib (lapatinib ditosylate monohydrate)	tablets film-coated	250mg; (70) in plastic bottle	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20159/1 28.10.2022
17	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	250mg+125mg; (20/2x10/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	17635/6 28.10.2022
18	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	17633/7 28.10.2022

19	Bronchobos	carbocisteine	syrup	125mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19988/3 28.10.2022
20	Bronchobos	carbocisteine	syrup	250mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19989/3 28.10.2022
21	Betadine	povidone-iodine	suppositories vaginal	200mg; (7) and (14/2x7/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	17582/2 28.10.2022
22	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	250mg; (1) Act-O-Vial (250mg powder and 4ml solvent)	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19887/1 28.10.2022
23	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	500mg; (1) glass vial with powder and (1) glass vial with solvent 7,8ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19888/1 28.10.2022

24	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	1000mg; (1) glass vial with powder and (1) glass vial with solvent 15,6ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19889/1 28.10.2022
25	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/), (36/3x12/) and (60/4x15/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex,	France	OTC	17194/3 28.10.2022
26	Doxy-Denk 100	doxycycline (doxycycline hyclate)	tablets	100mg; (20/2x10/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17812/2 28.10.2022
27	CalciD-Denk	calcium (calcium carbonate), colecalciferol	tablets effervescent	1000mg+22mcg (880IU); (20) in plastic container	Losan Pharma GmbH, Otto-Hahn-Strasse 13, 79395 Neuenburg- 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	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16831/6/1 28.10.2022

28	Rehydron	sodium chloride, potassium chloride, sodium citrate, glucose anhydrous	powder dose	3,5g+2,5g+2,9g+10g; (20) sachet 18,9g	Recipharm Parets S.L.U, C/Ramon and Cajal 2 , 08150 Parets del Valles (Barcelona)	Spain	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	17096/4/1 28.10.2022
29	Rehydron	sodium chloride, potassium chloride, sodium citrate, glucose anhydrous	powder dose	3,5g+2,5g+2,9g+10g; (20) sachet 18,9g	Recipharm Parets S.L.U, C/Ramon and Cajal 2 , 08150 Parets del Valles (Barcelona)	Spain	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	20825/1 28.10.2022
30	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	cream	0,5mg/g+10mg/g+1mg /g; aluminium tube 15g	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	18445/5/1 28.10.2022
31	Zimfil-ODF 20	tadalafil	films orodispersible	20mg; (4/1x4), (10/1x10), (10x4x1), (10x10x1) sachets	Zim Laboratories Ltd., B- 21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur, Maharashtra	India	Zim Laboratories Ltd., Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur-440 013	India	PoM	16128/2/1 28.10.2022
32	Chymotrypsin	chymotrypsin	powder lyophilized for solution for injection, local and external use	10mg; (5) glass vials; (10) glass vials	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	PoM	15738/2/4 28.10.2022

33	Zocardis 7,5	zofenopril (zofenopril calcium)	tablets film-coated	7,5mg; (28/2x14/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L` Aquila (AQ)- bulk manufacturer, packager, batch releaser, Dompe Farmaceutici S.P.A., Via Campo Di Pile, 67100 L` Aquila, Italy-quality control	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	19909/1 28.10.2022
34	Zocardis 30	zofenopril (zofenopril calcium)	tablets film-coated	30mg; (28/2x14/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L` Aquila (AQ)- bulk manufacturer, packager, batch releaser, Dompe Farmaceutici S.P.A., Via Campo Di Pile, 67100 L` Aquila, Italy-quality control	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	19910/1 28.10.2022

35	Oftan Dexamethason	dexamethasone (dexamethasone sodium phosphate)	drops eye	1mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19337/1 28.10.2022
36	Epiduo	adapalene, benzoyl peroxide	gel	1mg/g+25mg/g; 5g, 15g and 30g plastic tube, 15g and 30g plastic multidose container with airless pump	Laboratoires Galderma Z.I. Montdesir, 74540 Alby-sur- Cheran	France	Galderma SA, Zahlerweg 10, 6300 Zug	Switzerland	PoM	16656/2 28.10.2022
37	Depakine Chrono	valproic acid (valproate sodium)	tablets coated prolonged- release	300mg; (100/2x50/) in plastic container	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis (Suisse) SA, 11, rue de Veyrot 1217 Meyrin	Switzerland	PoM	17701/2 28.10.2022
38	Depakine Chrono	valproic acid (valproate sodium)	tablets coated prolonged- release	500mg; (30) in plastic container	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17700/2 28.10.2022

39	Glycine	glycine	tablets sublingual	100mg; (50/1x50/) in blister	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	OTC	17013/2/1 28.10.2022
40	Sedistress	dry extract of passiflora, ethyl ester of alpha- bromisovaleric acid	tablets	300mg+10.2mg, (30/3x10/) in blister, (60/6x10/)in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	19037/2 28.10.2022
41	Spasmovax	phloroglucinol	solution for i/m and i/v injection	10mg/ml; (10) ampoules 4ml	Doppel Farmaceutici S.r.l., Via Volturno 48, Quinto De Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	PoM	20092/1 28.10.2022
42	Bilobil	ginkgo biloba folies dry extract	capsules	40mg; (20/2x10/) and (60/6x10/) 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	OTC	17594/2 28.10.2022
43	Polcortolon TC	tetracycline (tetracycline hydrochloride), triamcinolone (triamcinolone acetonide)	aerosol for external use (suspension)	23,12mg/g+ 0,58mg/g; 17,3g aluminium container	Tarchomin Pharmaceutical Works "Polfa" S.A., 2,A. Fleminga str., 03-176 Warsaw	Poland	Tarchomin Pharmaceutical Works "Polfa" S.A., 2,A. Fleminga str., 03- 176 Warsaw	Poland	PoM	17843/2 28.10.2022

44	Jeanine	ethinylestradiol, dienogest	tablets coated	0.03mg+2mg; (21/1x21/) in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser- Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	19345/2 28.10.2022
45	Vizoptin	tetryzoline (tetryzoline hydrochloride)	drops eye (solution)	0,5mg/ml; 15ml plastic vial-dropper	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	LLC Rompharm Company Georgia, Vake-Saburtalo District, G. Saakadze downhill, N8, office N7a, Tbilisi	Georgia	OTC	17067/2 28.10.2022
46	Tresiba FlexTouch	insulin degludec	solution for injection	100U/ml; (5) pre- filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerod,3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK- 2880 Bagsvaerd	Denmark	PoM	20828/1 28.10.2022
47	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	Switzerland	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18919/5/1 28.10.2022

48	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	18322/3 28.10.2022
49	Efferalgan	paracetamol	suppositories rectal	150mg; (10/2x5/)	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN, France	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	18323/3 28.10.2022
50	Efferalgan	paracetamol	suppositories rectal	300mg; (10/2x5/)	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN, France	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	18324/4 28.10.2022
51	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/d ose+40mcg/dose+ 20mcg/dose; 0,5ml/dose glass vial	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, quality control, batch releaser, Merck Sharp & Dohme Corp., 770 Sumneytown Pike, West Point, 19486, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20189/2/1 28.10.2022

52	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/dose+40mcg/dose+20mcg/dose; 0,5ml/dose pre-filled syringe and (1) needle, 0,5ml/dose pre-filled syringe and (2) needles	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, quality control, batch releaser, Merck Sharp & Dohme Corp., 770 Sumneytown Pike, West Point, 19486, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	20190/2/1 28.10.2022
53	Enterogermina	spores of polyantibiotic-resistant Bacillus clausii	suspension oral	2x10 ⁹ /5ml; (10) plastic vials 5ml	Sanofi S.P.A., Viale Europa, 11, 21040 Origgio	Italy	Sanofi S.P.A., Viale Europa, 11, 21040 Origgio	Italy	OTC	19188/2 28.10.2022
54	Ursocam	ursodeoxycholic acid	tablets	250mg; (25) and (100) in plastic container, (25/1x25/) and (100/4x25/) in blister	Polfarmex S.A., Jozefow 9 Street, 99-300 Kutno	Poland	Polfarmex S.A., Jozefow 9 Street, 99-300 Kutno	Poland	PoM	17569/2/1 28.10.2022
55	Valocordin	ethylbromisovalerate, phenobarbital	drops oral (solution)	18,4mg/ml+ 18,4mg/ml; 20ml and 50ml glass bottle	Krewel Meuselbach GmbH, Xavier-Vorbruggen str. 6, 98694 Ilmenau	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	16776/2/1 28.10.2022

56	Guttalax	sodium picosulfate	drops oral	7,5mg/ml; 15ml plastic bottle, 30ml plastic bottle	Istituto de Angeli S.R.L. Loc. Prulli, 103/C 50066 Reggello, Firenze	Italy	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926, Frankfurt am Main	Germany	OTC	20530/2/1 28.10.2022
57	Pancef	cefixime (cefixime trihydrate)	tablets film-coated	400mg; (5/1x5/), (7/1x7/) and (10/2x5/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Alkaloid AD-Skopje, Blvd. Partizanski odredi 98A,1000 Skopje, Macedonia- bulk manufacturer, packager	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	PoM	17081/3 28.10.2022
58	Bepanthen	dexpanthenol	ointment	50mg/g; aluminium tube 30g, aluminium tube 100g	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach- Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	18643/6/1 28.10.2022
59	Fortrans	macrogol (macrogol 4000), sodium sulfate anhydrous, sodium hydrogen carbonate, sodium chloride, potassium chloride	powder for oral solution	64.0g+5.70g+1.68g+1.4 6g+0.75g ; (4) sachets 73,69g	Beaufour Ipsen Industrie, rue Ethe Virton, 28100 Dreux	France	Ipsen Consumer Healthcare, 65 quai Georges Gorse, 92100 Boulogne- Billancourt	France	OTC	20733/1 28.10.2022

60	Berlipril plus	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg (30/3x10/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	19588/1 28.10.2022
61	Papaverine hydrochloride	papaverine (papaverine hydrochloride)	solution for injection	20mg/ml; (10) ampoules 2ml CAMA, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20338/1 28.10.2022
62	GalvusMET	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+500mg; (30/3x10/) and (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18037/4 28.10.2022
63	GalvusMET	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10/) and (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18039/7 28.10.2022

64	GalvusMET	vildagliptin, metformin (metformin hydrochloride)	tablets film- coated	50mg+1000mg; (30/3x10/) and (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18038/8 28.10.2022
65	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film- coated	50mg+850mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,No 2, Pendik,Istanbul 34912- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461, Singapore- bulk manufacturer, quality control	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19535/4 28.10.2022
66	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film- coated	50mg+1000mg; (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,No 2, Pendik,Istanbul 34912- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461, Singapore- bulk manufacturer, quality control for	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19536/4 28.10.2022

67	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film- coated	50mg+850mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,No 2, Pendik,Istanbul 34912- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg, Germany- bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland quality control (microbiological)	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19537/4 28.10.2022
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68	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak, No 2, Pendik, Istanbul 34912- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg, Germany- bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland- quality control (microbiological)	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19538/4 28.10.2022
69	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10/) in blister, (60/6x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20714/1 28.10.2022

70	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (60/6x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20715/1 28.10.2022
71	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche AG, Viaduktstrasse 33, Basel, 4051- batch releaser, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20090, Italy- bulk manufacturer, packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20242/2 28.10.2022
72	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche Ltd.,4303, Kaiseraugust- packager, batch releaser, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20090, Italy-bulk manufacturer, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18692/3 28.10.2022

73	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	18119/3 28.10.2022
74	Ketonal DUO	ketoprofen	capsules modified-release	150mg; (20/2x10/) in blister, (30/3x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19541/4 28.10.2022
75	Albunorm Octapharma 5%	albumin human	solution for i/v infusion	50mg/ml; 100ml glass bottle, 250ml glass bottle, 500ml glass bottle	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	PoM	19439/1 28.10.2022
76	Albunorm Octapharma 20%	albumin human	solution for i/v infusion	200mg/ml; 50ml glass bottle, 100ml glass bottle	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	PoM	19441/1 28.10.2022

77	Zimfil-ODF 20	tadalafil	films orodispersible	20mg; (4/1x4), (10/1x10), (10x4x1), (10x10x1) sachets	Zim Laboratories Ltd., B- 21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur, Maharashtra	India	Zim Laboratories Ltd., Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur-440 013	India	PoM	16128/2/1 28.10.2022
78	Meteospasmyl	alverine (alverine citrate), simeticone	capsules	60mg+300mg (20/2x10/) in blister, (30/3x10/) in blister	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou- packager, quality control (physicochemical), batch releaser, Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie- Les-Lys, France- bulk manufacturer, quality control (microbiological)	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou	France	OTC	19602/1 28.10.2022
79	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche Ltd.,4303, Kaiseraugust- packager, batch releaser, Delpharm Milano S.R.L., Via Carnevale,1, Segrate (MI), 20090, Italy-bulk manufacturer, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrass e, 124, CH-4070, Basel	Switzerland	PoM	18692/4 28.10.2022

80	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche AG, Viaduktstrasse 33, Basel, 4051- batch releaser, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20090, Italy- bulk manufacturer, packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20242/3 28.10.2022
81	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	19166/2 28.10.2022
82	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; 53g powder in 100ml glass bottle and 5ml measuring spoon	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Alkaloid AD-Skopje, Blvd. Partizanski odredi 98A,1000 Skopje, Macedonia- bulk manufacturer, packager	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	PoM	17082/3 28.10.2022
83	Vitamin B complex	thiamine (thiamine nitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), nicotinamide	film-coated tablets	5mg+1mg+4mg+50mg; (20/1x20/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	16917/2 28.10.2022

84	Amaryl M	glimepiride, metformin (metformin hydrochloride)	tablets film-coated	2mg+500mg; (30/3x10/) in blister	Handok Inc., 78 Daepungsandan-ro, Daeso- myeon, Eumseong-gun, Chungcheongbuk-do	Korea South	Sanofi-aventis group, 54, rue La Boetie, 75008 Paris	France	PoM	19275/2 28.10.2022
85	Levocom	levodopa, carbidopa	tablets	250mg+25mg; (30/3x10/) in blister, (100/10x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18602/3/1 28.10.2022
86	Trittico	trazodone	tablets prolonged- release	150mg; (20/2x10) in blister	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Via Vecchia del Pinocchio, 22-60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Viale Amelia, 70, 00181, Rome	Italy	PoM	18798/4/1 28.10.2022
87	Antiflu Kids	paracetamol, ascorbic acid, chlorpheniramine (chlorpheniramine maleate)	powder for oral solution with raspberry flavour	160mg+50mg+1mg; (5) sachets	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788- packager, quality qontrol, batch releaser, Contract Pharmacal Corporation, 150 Commerce Drive Hauppauge, New York 11788, USA- bulk manufacturer	USA	JSC BAYER, 3rd Rybinskaya St., 18, build. 2, 107113 Moscow	Russia	OTC	20056/2 28.10.2022

88	Donormyl	doxylamine (doxylamine succinate)	tablets coated	15mg; (10) in plastic container, (30) in plastic container	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	PoM	18512/2 28.10.2022
89	Egilok	metoprolol (metoprolol tartrate)	tablets	25mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	18268/3 28.10.2022
90	Egilok	metoprolol (metoprolol tartrate)	tablets	50mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	18269/3 28.10.2022
91	Egilok	metoprolol (metoprolol tartrate)	tablets	100mg; (30) in glass container, (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	18270/3 28.10.2022

92	Sedative drops	valerian tincture, hawthorn tincture, motherwort tincture	drops oral	17ml/50ml+ 16,5ml/50ml+ 16,5ml/50ml; 50ml glass bottle	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No2, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	OTC	18021/1 28.10.2022
93	Indovasin	indometacin, troxerutin	gel for external use	30mg/g+20mg/g; 45g aluminium tube	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma- Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	16834/3 28.10.2022
94	Valerianae tincture	valerianae extract	tincture	200mg/ml; glass vial 30ml	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	19644/1 28.10.2022
95	Valused	valerian root dry extract, hop strobiles dry extract, passion flower dry extract	capsules soft	60mg+40mg+40mg; (30/2x15/) in blister	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	PoM	17093/3 28.10.2022

96	Corvalol- Pharmstandard	alfa-bromisovaleric acid ethyl ester, phenobarbital, peppermint oil	drops oral	20mg/ml+18,26mg/ml +1,42mg/ml; 25ml glass bottle-dropper	Pharmstandard- Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard- Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	17111/1/1 28.10.2022
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LIST

of the variations not requiring reformulation of certificate for the mutual recognition of the EAEU registration approved by the Center according to the meeting decision N 10-1/22 on
October 28, 2022

President _____ E. Amroyan

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	SIMBRINZA	brinzolamide, brimonidine (brimonidine tartrate)	drops eye, suspension	10mg/ml+2mg/ml, 5ml plastic vial-dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	000013 28.10.2022