

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/22 on December 15, 2022

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	Ferretab comp	ferrous fumarate, folic acid	capsules hard	152,1mg+0,5mg; (30/3x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Industriestrasse 1, A-8502 Lannach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, AGES GmbH IMED, Beethovenstrass 6, Graz, 8010, Austria- quality control (microbiological)	Austria	Acino Pharma AG, Birsweg 2, 4253 Liesberg	Switzerland	OTC	21062 15.12.2022
2	Quadriparin- SOLOpharm	enoxaparin (enoxaparin sodium)	solution for injection	4000anti-XaME/0,4ml; (10/5x2/) glass pre-filled syringes 0,4ml in blister	Grotex LLC, Industrialniy av. 71, bld. 2, lit. A, Saint Petersburg, 195279	Russia	Grotex LLC, Industrialniy av. 71, bld. 2, lit. A, Saint Petersburg, 195279	Russia	PoM	21063 15.12.2022

LIST

of the medicines recommended for the mutual recognition of the EAEU registration by the Center according to the meeting decision N 12-1/22 on December 15, 2022

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	Sodium bicarbonate	sodium bicarbonate	solution for infusion	84mg/ml; (10) glass vials 20ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21064 (003214) 15.12.2022
2	Glucose	glucose (glucose monohydrate)	solution for infusion	50mg/ml; 50ml plastic pack, 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 500ml plastic pack, 3000ml plastic pack	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21065 (002791) 15.12.2022
3	Artemelok	meloxicam	tablets	15mg; (20/2x10/) in PVC/Alu blister, (20/2x10/) in hard PVC/Alu blister	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	21066 (002479) 15.12.2022
4	Breviprost plus	travoprost, timolol maleate	drops eye	0,04mg/ml+5mg/ml; 5ml plastic vial-dropper	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21067 (001337) 15.12.2022

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/22 on December 15, 2022

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	Legalon 140	silibinin	capsules	140mg; (20/2x10/) in blister, (30/3x10/) in blister, (60/6x10/) in blister	Madaus GmbH, Luetticher Strasse 5, Troisdorf, 53842	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	OTC	21041 15.12.2022
2	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21042 15.12.2022
3	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21043 15.12.2022
4	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21044 15.12.2022

5	Xefocam	lornoxepam	powder lyophilized for solution for i/v and i/m injection	8mg; (5) glass vials	Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz- secondary packager, quality control, batch releaser, Wasserburger Arzneimittelwerk GmbH, Herderstrasse 2, D-83512 Wasserburg, Germany- bulk manufacturer, primary packager	Austria	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21045 15.12.2022
6	Caffetin COLD	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), dextromethorphan (dextromethorphan hydrobromide), ascorbic acid	tablets film-coated	500mg+30mg+15mg+60mg; (10/1x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	21046 15.12.2022
7	Avamigran	propyphenazone, caffeine, camylofin (camylofin hydrochloride), meclozamine (meclozamine citrate), ergotamine (ergotamine tartrate)	tablets film-coated	200mg+80mg+25mg+20mg+0,75mg; (10) in plastic container	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	21047 15.12.2022
8	Otipax	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; 15ml(16g) glass vial and dropper	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	OTC	21048 15.12.2022

9	Viferon	interferon alfa-2b	suppositories rectal	150000IU; (10/2x5)	Feron Ltd, 123098, Moscow, Gamaley str. 18	Russia	Feron LLC, 125424, Moscow, Volokolamsky highway 73-1, flor 6, room 46, of. 602	Russia	PoM	21049 15.12.2022
10	Viferon	interferon alfa-2b	suppositories rectal	1000000IU; (10/2x5)	Feron Ltd, 123098, Moscow, Gamaley str. 18	Russia	Feron LLC, 125424, Moscow, Volokolamsky highway 73-1, flor 6, room 46, of. 602	Russia	PoM	21050 15.12.2022
11	Viferon	interferon alfa-2b	suppositories rectal	500000IU; (10/2x5)	Feron Ltd, 123098, Moscow, Gamaley str. 18	Russia	Feron LLC, 125424, Moscow, Volokolamsky highway 73-1, flor 6, room 46, of. 602	Russia	PoM	21051 15.12.2022
12	Viferon	interferon alfa-2b	suppositories rectal	3000000IU; (10/2x5)	Feron Ltd, 123098, Moscow, Gamaley str. 18	Russia	Feron LLC, 125424, Moscow, Volokolamsky highway 73-1, flor 6, room 46, of. 602	Russia	PoM	21052 15.12.2022

13	Magrilan	fluoxetine (fluoxetine hydrochloride)	capsules	20mg; (30/3x10/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	21053 15.12.2022
14	Hemomycin	azithromycin (azithromycin dihydrate)	powder lyophilized for solution for infusion	500mg; (1) glass vial	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	21054 15.12.2022
15	Vitamin E	alfa-tocopherol acetate	capsules	100IU; (15/1x15/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21055 15.12.2022
16	Phezam	piracetam, cinnarizine	capsules hard	400mg+25mg; (60/6x10/) in blister	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, (ACTAVIS GROUP), str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	PoM	21056 15.12.2022
17	Caffetin SC	paracetamol, propyphenazone, caffeine	tablets	250mg+210mg+50mg; (6/1x6/) in strip, (12/2x6/) in strip	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	21057 15.12.2022

18	Hydrochlorothiazide	hydrochlorothiazide	tablets	25mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21058 15.12.2022
19	Nystatin	nystatin	tablets film-coated	500000IU; (20/2x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1-quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, N6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21059 15.12.2022
20	Drotaverine	drotaverine (drotaverine hydrochloride)	solution for i/v and i/m injection	20mg/ml; (10) ampoules 2ml, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21060 15.12.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/22 on December 15, 2022

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	Glucose 5% and Sodium chloride 0,45% solution for injection	glucose (glucose monohydrate), sodium chloride	solution for infusion	50mg/ml+4,5mg/ml; 500ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	17381/1/1 15.12.2022
2	Nolpaza control	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (7/1x7) in blister, (14/2x7) in blister, (14/1x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	OTC	18120/1/1 15.12.2022

3	Prevenar 13	pneumococcal polysaccharide conjugate vaccine (pneumococcal polysaccharide serotype 1, pneumococcal polysaccharide serotype 3, pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6A, pneumococcal polysaccharide serotype 6B, pneumococcal polysaccharide serotype 7F, pneumococcal polysaccharide serotype 9V, pneumococcal polysaccharide serotype 14, pneumococcal polysaccharide serotype 18C, pneumococcal polysaccharide serotype 19A, pneumococcal polysaccharide serotype 19F, pneumococcal polysaccharide serotype 23F)	suspension for injection	2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+ 2.2mcg/dose+2.2mcg/dose+4.4mcg/dose+ 2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+ 2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose; (1) pre-filled syringe 0,5ml, (10) pre-filled syringes 0,5ml	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, 2870- secondary packager, batch releaser, Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland- bulk manufacturer, primary packager, quality control	Belgium	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ	UK	PoM	19089/3/1 15.12.2022
4	Inspra	eplerenone	tablets film-coated	25mg; (30/3x10/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	France	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	19164/1/1 15.12.2022

5	Inspra	eplerenone	tablets film-coated	50mg; (30/3x10/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	France	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	19165/1/1 15.12.2022
6	Polyoxidonium	azoximer bromide	tablets	12mg; (10/1x10/) in blister, (10/1x10/) in blister, (20/2x10/) in blister, (20/2x10/) in blister	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143- secondary packager, quality control and batch releaser, NPO Petrovax Pharm LLC, 1 Sosnovaya str., Bld.. 1, Pokrov village, Podolsk, Moscow region, 142143, Russia- bulk manufacturer, primary packager	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	OTC	19975/1/1 15.12.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/22 on December 15, 2022

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	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17165/2 15.12.2022
2	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17164/2 15.12.2022
3	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17163/2 15.12.2022

4	Dynapar AQ	diclofenac (diclofenac sodium)	solution for injection	75mg/ml; (5) ampoules 1ml	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	PoM	17451/1 15.12.2022
5	Avelox	moxifloxacin	tablets coated	400mg; (5/1x5/) in blister	Bayer Healthcare Manufacturing S.r.l., Via delle Groane, 126 20024, Garbagnate Milanese	Italy	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	20410/2 15.12.2022
6	Nurofen Forte	ibuprofen	tablets coated	400mg; (12/1x12/) 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	18614/4 15.12.2022
7	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	20321/1 15.12.2022

8	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	20322/1 15.12.2022
9	Noliprel Bi-Forte	perindopril (perindopril arginine), indapamide	tablets film-coated	10mg+2,5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	20271/1 15.12.2022
10	Norditropin NordiFlex	somatropin	solution for s/c injection	6,7mg/ml; pre-filled pen 1,5ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd-batch releaser, Novo Nordisk A/S, Hagedornsvej 1, DK-2820 Gentofte, Denmark- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S Kirke Vaerloesevej 30, Vaerloese, 3500, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20413/2 15.12.2022
11	Vitaprost Forte	samprost (dry extract of calf prostate)	suppositories rectal	100mg; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17128/3 15.12.2022

12	Sandimmun Neoral	ciclosporin	capsules soft	25mg; (50/10x5/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18340/2 15.12.2022
13	Sandimmun Neoral	ciclosporin	capsules soft	50mg; (50/10x5/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18341/2 15.12.2022
14	Sandimmun Neoral	ciclosporin	capsules soft	100mg; (50/10x5/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18342/2 15.12.2022

15	Diflucan	fluconazole	solution for i/v infusion	2mg/ml; glass vial 50ml	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18203/3 15.12.2022
16	Xefocam	lornoxicam	powder lyophilized for solution for i/v and i/m injection	8mg; (5) glass vial	Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz- batch releaser, packager, Wasserburger Arzneimittelwerk GmbH, Herderstrasse 2, D-83512 Wasserburg, Germany- bulk manufacturer	Austria	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17046/3/1 15.12.2022
17	Omarens	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (30/3x10/) in blister	Synthon Hispania, S.L./C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Spey Medical Ltd, Lynton house 7-12 Tavistock square, London, WC1H9LT	UK	PoM	20084/1 15.12.2022
18	Karnilev	levocarnitine	solution for injection	1g/5ml; (5/1x5/) ampoules 5ml in plastic container	Help S.A. Pedini Ioanninon, Ioannina, 45500	Greece	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	United Kingdom	PoM	20470/1 15.12.2022

19	Karnilev	levocarnitine	solution oral	1g/10ml; glass bottle 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Spey Medical Ltd, Lynton House 7- 12 Tavistock square, WC1H 9LT, London	UK	PoM	20355/1 15.12.2022
20	Dexdor	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml (5) ampoules 2ml, (25) ampoules 2ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19463/3 15.12.2022
21	Caffetin COLD	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), dextromethorphan (dextromethorphan hydrobromide), ascorbic acid	tablets film- coated	500mg+30mg+15mg+ 60mg; (10/1x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	17218/3/1 15.12.2022
22	Pyrazinamide	pyrazinamide	tablets	400mg; (100/10x10/) and (672/24x28/) in blister	Macleods Pharmaceuticals Ltd., Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210 (UT)	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai- 400 059	India	PoM	16014/1 15.12.2022

23	Validol	menthol solution in menthyl isovalerate	capsules	100mg; N10 and (15/1x15/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC	17148/3/2 15.12.2022
24	Hydrochlorothiazide	hydrochlorothiazide	tablets	25mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	17181/2 15.12.2022
25	Campto	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 2ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18308/4 15.12.2022
26	Campto CS	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 5ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18309/3 15.12.2022
27	Campto CS	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 15ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18310/3 15.12.2022

28	Vitamin E	alfa-tocopherol acetate	capsules	100IU; (15/1x15/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC	17068/2/1 15.12.2022
29	Lysobact Spray with Peppermint flavour	lysozyme (lysozyme hydrochloride), cetylpyridinium chloride	spray	20mg/ml+1,5mg/ml; 30ml glass bottle with spraying pump and spray applicator	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17939/1 15.12.2022
30	Natalsid	sodium alginate	suppositories rectal	250mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20436/1 15.12.2022
31	Axetine 750mg	cefuroxime (cefuroxime sodium)	powder for solution for injection or infusion	750mg (10) glass vial	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	17599/1 15.12.2022
32	Axetine 1,5g	cefuroxime (cefuroxime sodium)	powder for solution for injection or infusion	1500mg (10) glass vial	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	17598/1 15.12.2022

33	Riidor	cefepime (cefepime dihydrochloride monohydrate)	powder for solution for injection/ infusion	1000mg; (1) glass vial	AbiPharm LLC, Mtskheta district, village Tsilkani, 3319	Georgia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	16879/2/1 15.12.2022
34	Peo	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; glass vial	Laboratorio Reig Jofre, S.A., Jarama 111 Poligono Industrial, Toledo, 45007 Toledo	Spain	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	19081/1 15.12.2022
35	Caffetin SC	paracetamol, propyphenazone, caffeine	tablets	250mg+210mg+50mg; (6/1x6/) and (12/2x6/) in strip	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	OTC	17217/2 15.12.2022
36	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) glass cartridges 3ml	Lilly France S.A.S., 2, rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991, RA Houten	the Netherlands	PoM	18646/2 15.12.2022
37	A-cnotren	isotretinoin	capsules soft	10mg; (30/3x10/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, 69300 Rodopi-packager, quality control, batch releaser, G.A. Pharmaceuticals S.A., (GAP S.A), 46, Agisilaou str., 17341 Agios Dimitrios Attiki, Greece- bulk manufacturer	Greece	Pharmathen Investments Group Limited, 32, Kritis str., Papachristoforou Bulding, 4th floor, 3087, Limassol	Cyprus	PoM	19663/3/1 15.12.2022

38	A-cnotren	isotretinoin	capsules soft	20mg; (30/3x10/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, 69300 Rodopi-packager, quality control, batch releaser, G.A. Pharmaceuticals S.A., (GAP S.A), 46, Agisilaou str., 17341 Agios Dimitrios Attiki, Greece- bulk manufacturer	Greece	Pharmathen Investments Group Limited, 32, Kritis str., Papachristoforou Bulding, 4th floor, 3087, Limassol	Cyprus	PoM	17645/3/1 15.12.2022
39	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	10mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20439/2 15.12.2022
40	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	20mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20440/2 15.12.2022
41	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	40mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20441/2 15.12.2022

42	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film- coated	80mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20441/2 15.12.2022
43	Vegtasone	mometasone (mometasone furoate)	cream	1mg/g; aluminium tube 15g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Vegapharm LLP, Unit 18, Normon road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	20066/2 15.12.2022

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 12-1/22 on December 15, 2022

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	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	000545 15.12.2022