

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 03-2/23 on March 31, 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	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	10mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo 7, Sermoneta, 04013	Italy	Pfizer Inc.,Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21267 31.03.2023
2	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	50mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo 7, Sermoneta, 04013	Italy	Pfizer Inc.,Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21268 31.03.2023
3	Bactrim forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel- batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, packager, quality control	Switzerland	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	21269 31.03.2023

4	Para-Denk 500	paracetamol	tablets	500mg; (20/2x10/) in blister	<p>bene-Arzneimittel GmbH Herterichstrasse 1-3, Muenchen, Bayern, 81479- bulk manufacturer, packager, batch releaser, bene-Arzneimittel GmbH Bayerwaldstrasse 7-9, Geretsried, Bayern, 82538, Germany- quality control (physicochemical), Labor fur analytische und pharmazeutische Chemie Dr. Graner & Partner GmbH, Lochhausener Str. 205 81249 Muenchen, Germany- quality control (microbiological)</p>	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	OTC	21270 31.03.2023
5	Mastodynon	<p>vitex agnus-castus A\square caulophyllum thalictroides D4, cyclamen purpurascens D4, strychnos ignatii D6, iris versicolor D2, lilium tigrinum D3</p>	tablets	162mg+81mg+81mg+81 mg+162mg+81mg; (60/3x20/) in blister	<p>Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt- packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany-bulk manufacturer</p>	Germany	Bionorica SE, Kerschensteinerstr . 11-15, 92318 Neumarkt	Germany	OTC	21271 31.03.2023

6	Tadalafil Genericon	tadalafil	tablets film-coated	20mg; (4/1x4/) in blister	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria- quality control (phiscochemical), batch releaser, Pharmactive Ilac San. Ve Tic A.S., Cerkezkoy Organize Sanayi Bolgesi Karaagac, Mah. Fatih Bulv. N32, Kapakli, Tekirdag, 59510, Turkey- bulk manufacturer, packager, AGES Graz IMED, Beethovenstrasse 6, Graz, 8010, Austria- quality control (microbiological)	Austria	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria	Austria	PoM	21272 31.03.2023
7	DuTamsul	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules hard	0,5mg+0+4mg; (30) plastic container	Laboratorios Leon Farma S.A., Poligono Industrial Navatejera, C/ La Vallina s/n, Villaquilambre, 24008 Leon- bulk manufacturer, packager, quality control (phiscochemical), batch releaser, LABORATORIO ECHEVARNE, S.A.,C/ Provenca, No 312, Bajos, Barcelona, 08037, Spain- quality control (microbiological)	Spain	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria	Austria	PoM	21273 31.03.2023

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 03-2/23 on March 31, 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	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21262 (000575) 31.03.2023
2	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21263 (000575) 31.03.2023
3	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21264 (000575) 31.03.2023

4	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21265 (000575) 31.03.2023
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LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 02-1/23 on February 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	Plavix	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/1x14/) in blister, (28/2x14/) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	20848/1 31.03.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 03-2/23 on March 31, 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	Proculin	naphazoline (naphazoline hydrochloride)	drops eye (solution)	0,3mg/ml; plastic container 10ml	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Mefar Ilac Sanayii A.S., Ramazanoglu, Mah. Ensar-Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	21274 31.03.2023
2	Zanotazon	coleciferol	capsules soft	50000IU; (20/1x20/) in blister	Zahravi Pharmaceutical Company, Alinasab Industrial Town, Serum Darou St., Opp. Agricultural Training Center, 19th Km. Tehran Road, Tabriz	Iran	Giga Farm LLC, Gogunc str.3/5, Gyumri	Republic of Armenia	PoM	21275 31.03.2023
3	Amaryl	glimepiride	tablets	2mg; (30/2x15/) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	21276 31.03.2023

4	Amaryl	glimepiride	tablets	4mg; (30/2x15/) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	21277 31.03.2023
5	Arbidol	umifenovir (umifenovir hydrochloride)	tablets film-coated	50mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	21278 31.03.2023
6	Mydoptic	phenylephrine (phenylephrine hydrochloride)	drops eye	25mg/ml; (1) plastic vial-dropper 10ml, (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21279 31.03.2023
7	Mesalazol	mesalazine	suppositories rectal	250mg; (14/2x7/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	21280 31.03.2023
8	Mesalazol	mesalazine	suppositories rectal	500mg; (14/2x7/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	21281 31.03.2023

9	Teturam	disulfiram	tablets	150mg; (30/3x10/) in blister, (30/2x15/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	21282 31.03.2023
10	Tinctura iodine 5%	iodine	tincture	50mg/ml; 10ml and 30ml glass bottle	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	21283 31.03.2023
11	Glimepiride Denk 2	glimepiride	tablets	2mg; (30/3x10/) 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	21284 31.03.2023
12	Glimepiride Denk 3	glimepiride	tablets	3mg; (30/3x10/) 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	21285 31.03.2023

13	Milurit	allopurinol	tablets	100mg; (30) in glass bottle, (40) in glass bottle, (50) in glass bottle, (60) in glass bottle, (70) in glass bottle, (80) in glass bottle, (90) in glass bottle, (100) in glass bottle, (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	21286 31.03.2023
14	Milurit	allopurinol	tablets	300mg; (30) in glass bottle, (40) in glass bottle, (50) in glass bottle, (60) in glass bottle, (70) in glass bottle, (80) in glass bottle, (90) in glass bottle, (100) in glass bottle, (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21287 31.03.2023
15	Bisacodyl	bisacodyl	suppositories rectal	10mg; (10/2x5/)	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	21288 31.03.2023
16	Kefentech plaster	ketoprofen	plaster transdermal	30mg; (7) in pack	Jeil Health Science Inc, (Building B) 7 Cheonggangchang-ro, Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do	Republic of Korea	Jeil Health Science Inc, 343, Sapyeong-daero, Seocho-gu, Seoul	Republic of Korea	PoM	21289 31.03.2023

17	Skopryl plus	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (20/2x10/) in blister, (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	21290 31.03.2023
18	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10/) in blister, (50/5x10/) in blister	Mauermann-Arzneimittel KG, Heinrich-Knote-Strasse 2, Poecking, Bayern, 82343- bulk manufacturer, quality control, batch releaser, Mauermann-Arzneimittel KG, Sankt-Sebastian-Strasse 13, Aschering, 82343, Germany- packager	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	OTC	21291 31.03.2023
19	Nitromint	nitroglycerin	spray sublingual dosed	0,4mg/dose; 10g (180 doses) aluminium container, 10g (180 doses) COC container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	21292 31.03.2023
20	Lidocaine-Liqvo	lidocaine (lidocaine hydrochloride)	solution for injection	10mg/ml; (1) glass vial 20ml, (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	21293 31.03.2023
21	Lidocaine-Liqvo	lidocaine (lidocaine hydrochloride)	solution for injection	20mg/ml; (1) glass vial 20ml, (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	21294 31.03.2023

22	Prozerin-Darnitsa	neostigmine (neostigmine methylsulfate)	solution for injection	0,5mg/ml; (10/2x5/) ampoules 1ml in blister	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21295 31.03.2023
23	Captopril	captopril	tablets	25mg; (40/4x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, 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	21296 31.03.2023
24	Recreol	dexpanthenol	cream	50mg/g; 30g aluminium tube, 50g aluminium tube	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	21297 31.03.2023
25	Recreol	dexpanthenol	ointment	50mg/g; 30g aluminium tube, 50g aluminium tube	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	21298 31.03.2023
26	Alteyka Arterium	althaeae radix dry extract	syrup	7,5mg/5ml; 100ml plastic or glass bottle and measuring spoon, 100ml plastic or glass container and measuring spoon, 200ml plastic or glass bottle and measuring spoon	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	21299 31.03.2023

27	Glaveral	omeprazole	capsules gastro-resistant hard	20mg; (14) in plastic container, (28) in plastic container	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attici	Greece	PoM	21300 31.03.2023
28	Aevit	retinol palmitate (vitamin A), alfa-tocopherol acetate (vitamin E)	capsules	55,036mg (100000IU)+100mg; (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	PoM	21301 31.03.2023
29	Protamine sulphate	protamine sulfate	solution for injection	10mg/ml; (5) glass vial 5ml	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	21302 31.03.2023
30	Protamine sulphate	protamine sulfate	solution for injection	10mg/ml; glass vial 10ml	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	21303 31.03.2023

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-2/23 on March 31, 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	Choline alphoscerate	choline alfoscerate	solution for i/v and i/m injection	250mg/ml; (5) ampoules 4ml	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	18246/1/1 31.03.2023
2	AVEGRA BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 4ml	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17910/3/3 31.03.2023

3	AVEGRA BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 16ml	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17911/3/3 31.03.2023
4	Xefocam Rapid	lornoxicam	tablets film-coated	8mg; (12/2x6/) in blister	Takeda GmbH, Betriebsstatte Oranienburg, Lehnitzstrasse 70-98, 16515 Oranienburg	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	19354/2/2 31.03.2023
5	Papaverin	papaverine (papaverine hydrochloride)	suppositories rectal	20mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20664/1/1 31.03.2023
6	Bisacodyl	bisacodyl	tablets gastro-resistant film-coated	5mg; (30/3x10/) 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	OTC	18091/1/1 31.03.2023

7	Eliquis	apixaban	tablets film-coated	2,5mg; (20/2x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer	Germany	Pfizer Inc., 235, East 42nd street, New York 10017	USA	PoM	19625/3/1 31.03.2023
8	Eliquis	apixaban	tablets film-coated	5mg; (20/2x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer	Germany	Pfizer Inc., 235, East 42nd street, New York 10017	USA	PoM	19626/3/1 31.03.2023
9	Nurofen for children	ibuprofen	suspension oral with orange flavour	100mg/5ml; 150ml plastic container and measuring syringe, 200ml plastic container and measuring syringe	Reckitt Benckiser Healthcare India Private Limited, Khasra No. 701/534, Village Sandholi, Baddi-Nalagarh Road, District Solan, Baddi, Himachal Pradesh, IN-173 205	India	Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, NG90 2DB	UK	OTC	17842/3/1 31.03.2023

10	Trinitrina	nitroglycerin	concentrate for solution for infusion	5mg/1,5ml; (10) ampoules 1.5ml	FISIOPHARMA S.R.L., Nucleo Industriale, Palomonte, 84020	Italy	ACARPIA FARMACEUTICI S.R.L., Viale L. Majno 18 â€”0129, Milan	Italy	PoM	17860/1/1 31.03.2023
11	Normomed	inosine pranobex	tablets	500mg; (20/2x10/) in blister, (30/3x10/) in blister, (50/5x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, Kaluga region, Obninsk city, Obninsk urban district, str. Kiev highway, bld. 3a/3- quality control (physicalochemical) and batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, Kaluga region, Obninsk, str. Kiev highway, 107, Russia- bulk manufacturer, packager, Testing Center "PHARMOBORONA" LLC, Moscow region, Schelkovsky district, Schelkovo, ter. Recreation center Serkovo, str. 1, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19563/2/1 31.03.2023

12	Valerian-Belmed	valerianae rhizomes with roots (as powder)	tablets coated	200mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (50/5x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1, Republic of Belarus-quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5 No6, Republic of Belarus- bulk manufacturer, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/22 No6, Republic of Belarus-packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	OTC	20689/1/1 31.03.2023
13	Edarbi	azilsartan medoxomil	tablets	40mg; (28/2x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Almac Sciences Ireland Ltd, IDA Business & Technology Park, Garrycastle, Athlone, Co. Westmeath, Ireland-quality control (microbiological)	Ireland	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia		PoM	18955/2/2 31.03.2023

14	Edarbi	azilsartan medoxomil	tablets	80mg; (28/2x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Almac Sciences Ireland Ltd, IDA Business & Technology Park, Garrycastle, Athlone, Co. Westmeath, Ireland- quality control (microbiological)	Ireland	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18956/2/2 31.03.2023
15	MabThera	rituximab	concentrate for solution for infusion	100mg/10ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst-secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany-bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	PoM	18901/4/1 31.03.2023
16	DetriTon	colecalfiferol	capsules	5000IU; (30/3x10/) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21003/1/1 31.03.2023
17	Coal Tar	coal tar	shampoo	20mg/ml; 90ml plastic bottle	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18851/1/1 31.03.2023

18	Influcein	oseltamivir (oseltamivir phosphate)	capsules hard	75mg; (10/1x10/) in blister	CJSC Canonpharma production, 105B, bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	18062/2/2 31.03.2023
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-2/23 on March 31, 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	Myramistin	benzyltrimethyl (3-(myristoilamine) propyl) ammonium chloride monohydrate	solution for topical application	0,1mg/ml; 50ml plastic container with urological applicator, 50ml plastic container with urological applicator and pump dispenser, 50ml plastic container with urological applicator and gynecological device, 150ml plastic container with pump dispenser	INFAMED K LLC, ul. Kommunalnaya., build.12, g. Bagrationovsk, Bagrationovsky dist., Kaliningrad region, 238420	Russia	INFAMED LLC., Promzona ter., bulid. 473, g.Vidnoe, Leninsky dist., Moscow region, 142704	Russia	OTC	17466/3/1 31.03.2023
2	Lindynette 20	gestodene, ethinylestradiol	tablets coated	0,02mg+0,075mg; (21/1x21/) and (63/3x21/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	17723/2 31.03.2023

3	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany- bulk manufacturer, Berlin-Chemie AG, TempelhoferWeg 83, D-12347 Berlin,Germany / Berlin-Chemie AG, GlienickerWeg 125, D-12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19176/4 31.03.2023
4	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin- packager, quality control, batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19190/4 31.03.2023
5	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, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18445/5/1 31.03.2023

6	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	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	21143/1 31.03.2023
7	Parlazin	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg (10/1x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	19516/2 31.03.2023
8	Flavamed cough solution	ambroxol (ambroxol hydrochloride)	solution oral	15mg/5ml; glass bottle 100ml and measuring spoon	Berlin-Chemie AG.,Glienicker Weg 125, D-12489 Berlin	Germany	Berlin-Chemie AG.,Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19166/3 31.03.2023
9	Bisacodyl	bisacodyl	suppositories rectal	10mg; (10/2x5/) in blister	Lekhim-Kharkiv JSC, 36,Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv JSC, 36,Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	17045/1 31.03.2023
10	Kefentech plaster	ketoprofen	plaster transdermal	30mg; (7) in pack	Jeil Health Science Inc, (Building B) 7 Cheonggangchang-ro, Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do	Korea South	Jeil Health Science Inc, 343, Sapyeong-daero, Seocho-gu, Seoul	Korea South	PoM	16904/2/1 31.03.2023

11	Mesalazol	mesalazine	suppositories rectal	250mg; (14/2x7/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD- 4829	Moldova	PoM	17463/1 31.03.2023
12	Mesalazol	mesalazine	suppositories rectal	500mg; (14/2x7/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD- 4829	Moldova	PoM	17462/1 31.03.2023
13	Mydoptic	phenylephrine (phenylephrine hydrochloride)	drops eye	25mg/ml; (1) and (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	17612/2 31.03.2023
14	Proculin	naphazoline (naphazoline hydrochloride)	drops eye (solution)	0,3mg/ml; 10ml plastic container	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Mefar Ilac Sanayii A.S., Ramazanoglu, Mah. Ensar- Cad. No:20, 34906 Kurtkoy- Pendik, Istanbul, Turkey- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	17357/3/1 31.03.2023

15	Captopril	captopril	tablets	25mg; (40/4x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17650/1 31.03.2023
16	Enterogermina Forte	spores of polyantibiotic-resistant Bacillus clausii	suspension oral	4x10 ⁹ /5ml; (10) plastic vial 5ml	Sanofi S.R.L., Viale Europa,11, 21040 Origgio	Italy	Sanofi S.R.L., Viale Europa,11, 21040 Origgio	Italy	OTC	17306/3/1 31.03.2023
17	Amaryl	glimepiride	tablets	2mg; (30/2x15/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	16923/2 31.03.2023
18	Amaryl	glimepiride	tablets	4mg; (30/2x15/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	16922/2 31.03.2023

19	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10/) in blister, (50/5x10/) in blister	Mauermann-Arzneimittel KG, Heinrich-Knote-Strasse 2, Poecking, Bayern, 82343- bulk manufacturer, batch releaser, Mauermann-Arzneimittel KG, Sankt-Sebastian-Strasse 13, Aschering, 82343, Germany- packager	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	OTC	17669/3/1 31.03.2023
20	Lansoptol	lansoprazole	capsules	30mg; (14/2x7/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	17411/2 31.03.2023
21	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18423/6 31.03.2023
22	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18424/6 31.03.2023
23	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex,	France	PoM	18425/6 31.03.2023

24	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18426/6 31.03.2023
25	Reklin	meloxicam	solution for injection	15mg/1.5ml; (5) ampoules 1,5ml	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Vegapharm LLP, Unit 18, Norman road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	20524/1 31.03.2023
26	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) blisters, (28/4x7/) blisters	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18821/3 31.03.2023
27	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	19348/3/1 31.03.2023
28	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d'Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21089/1 31.03.2023

29	Tinctura iodine 5%	iodine	tincture for external use	50mg/ml; 10ml glass bottle, 30ml glass bottle	ESCO-PHARM LLC, Nor- Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	17253/1 31.03.2023
30	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film- coated	5mg+160mg+12,5mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	18911/4/2 31.03.2023
31	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film- coated	10mg+160mg+12,5mg ; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	18912/4/2 31.03.2023
32	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film- coated	10mg+160mg+25mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	18913/4/2 31.03.2023
33	Ketonal	ketoprofen	capsules	50mg; (25) glass container	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	18826/5 31.03.2023

34	Skopryl plus	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (20/2x10/) and (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	17412/3/1 31.03.2023
35	Amoxicillin 250mg	amoxicillin (amoxicillin trihydrate)	capsules	250mg; (100/10x10/) in blister	Medopharm Private Limited, No. 50 Kayarambedu Village, Guduvanchery, Chennai-603202	India	Troge Scientific Research I.PVT.LTD., Unit no.412, 4 th floor, Plot no.D-6 Wave Silver Tower, sector-18 Noida-201301, Gautam Buddha nagar,Uttar Pradesh	India	PoM	21031/1 31.03.2023
36	Amoxicillin 500mg	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (10/1x10/) in blister, (100/10x10/) in blister	Medopharm Private Limited, No. 50 Kayarambedu Village, Guduvanchery, Chennai-603202	India	Troge Scientific Research I.PVT.LTD., Unit no.412, 4 th floor, Plot no.D-6 Wave Silver Tower, sector-18 Noida-201301, Gautam Buddha nagar,Uttar Pradesh	India	PoM	21032/2/1 31.03.2023
37	Azaleptol	clozapine	tablets	100mg; (50/5x10/) in blister	PJSC "Technolog", Manuylskogo str. 8, 20300 Uman,Cherkassy region	Ukraine	PJSC "Technolog", Manuylskogo str. 8, 20300 Uman,Cherkassy region	Ukraine	PoM	17955/1 31.03.2023

38	Essentiale forte N	phospholipids (essential)-EPL	capsules	300mg; (30/3x10/) in blister	A. Nattermann & Cie. GmbH, Nattermannallee 1, D-50829 Cologne	Germany	A. Nattermann & Cie. GmbH, Nattermannallee 1, D-50829 Cologne	Germany	OTC	20986/1 31.03.2023
39	Arbidol	umifenovir (umifenovir hydrochloride)	tablets film-coated	50mg; (10/1x10/), (20/2x10/), (30/3x10/) and (40/4x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	17548/2/1 31.03.2023
40	Aevit	retinol palmitate (vitamin A), alfa-tocopherol acetate (vitamin E)	capsules	55,036mg (100000IU)+100mg; (15/1x15/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC	17184/2/1 31.03.2023
41	Glaveral	omeprazole	capsules gastro-resistant hard	20mg; (14) and (28) in plastic container	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	17108/2 31.03.2023
42	Mekinist	trametinib (trametinib dimthyl sulfoxide)	tablets film-coated	2mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, GlaxoSmithKline Manufacturing S.p.A., Strada Provinciale Asolana, 90, 43056 San Polo di Torrile, Parma, Italy- bulk manufacturer, quality control	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18988/4/1 31.03.2023

43	Povidone iodine	povidone iodine	solution for external use	100mg/ml; 20ml, 30ml, 60ml, 500ml and N1000ml plastic bottle, 50ml and 100ml glass or plastic bottle	Alfa-Pharm CJSC, Khrimyan Hayrik 62, Gyumri	Republic of Armenia	Alfa-Pharm CJSC, Shirak 1/68, Yerevan	Republic of Armenia	OTC	17312/2/2 31.03.2023
44	Upsarin Ursa	acetylsalicylic acid	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-Malmaison	France	OTC	21010/1 31.03.2023
45	Upsarin Ursa with vitamin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	330mg+200mg; (10) in plastic container	UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	19408 /1 31.03.2023
46	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	20242/4 31.03.2023
47	Izigel M	ibuprofen, levomenthol	gel for external use	50mg/g;+30mg/g; aluminium tube 40g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	GM Pharmaceuticals Ltd, Phonichala 65	Georgia	OTC	18813/2 31.03.2023

48	Ketonal Forte	ketoprofen	tablets film-coated	100mg; (20) in glass container	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	18639/5 31.03.2023
49	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	20970/2 31.03.2023
50	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	17881/2 31.03.2023
51	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	17882/2 31.03.2023

52	Ceftriaxone for injection	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; (10) glass vial	Reyoung Pharmaceutical Co. Ltd., No 6 Erlangshan Road, Yiyuan County, Shandong Province	China	Reyoung Pharmaceutical Co. Ltd., No 6 Erlangshan Road, Yiyuan County, Shandong Province	China	PoM	17143/1 31.03.2023
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LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-2/23 on March 31, 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	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 31.03.2023