

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 11-2/21 on November 26, 2021

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20278 26.11.2021
2	Simulect	basiliximab	powder lyophilized for solution for injection or infusion	20mg; glass vial and solvent in ampoule 5ml	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- powder bulk manufacturer, packager, quality control, batch releaser, Delpharm Dijon, 6, Boulevard de l'Europe 21800, France- solvent bulk manufacturer, primary packager, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20279 26.11.2021

3	Tecentriq	atezolizumab	concentrate for solution for infusion	60mg/ml; 20ml glass vial	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20280 26.11.2021
4	Slideron	methylprednisolone	tablets	4mg; (20/2x10/) in blister	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Spey Medical Ltd, Lynton house 7-12 Tavistock square, London, WC1H9LT	UK	PoM	20281 26.11.2021
5	Otisfen	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; glass bottle and dropper 20g	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Belarus	OTC	20282 26.11.2021
6	Dorsob	dorzolamide (dorzolamide hydrochloride)	drops eye	20mg/ml; plastic vial 5ml	Famar A.V.E. Alimos Plant 63, Ag. Dimitriou Str., Agiou Dimitriou 63, Alimos Attiki, 17456	Greece	Belinda Laboratories LLP, Astra house, Arklow road, SE14 6EB, London	UK	PoM	20285 26.11.2021
7	Sulfasalazin-EN	sulfasalazine	tablets gastro-resistant	500mg; (50/5x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, quality control, batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20286 26.11.2021

8	Meropenem	meropenem	powder for solution for i/v injection	500mg; (1) glass vial 10ml, (40) glass vials 10ml	Belmedpreparaty RUE, Grodinsky region, 231286, Lida, str. Kachana,19/8	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	20287 26.11.2021
9	Meropenem	meropenem	powder for solution for i/v injection	1000mg; (1) glass vial 20ml,, (12) glass vial 20ml, (40) glass vial 20ml, (1) glass vial 100ml,, (12) glass vial 100ml, (40) glass vial 100ml	Belmedpreparaty RUE, Grodinsky region, Lida, str. Kachana,19/8	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	20288 26.11.2021
10	Bactrim forte	sulfamethoxazole, trimethoprim	tablets film-coated	800mg+160mg; (10/1x10/) in blister	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel- batch releaser, Produtos Roche Quimicos e Farmaceuticos S/A, Estrada dos Bandeirantes 2020 Taquara, RJ, 22775-109, Brazil- bulk manufacturer, F. Hoffmann- La Roche AG, Wurmisweg CH-4303 Kaiseraugst, Switzerland- packager, DELPHARM MILANO S.R.L. VIA CARNEVALE, 1 - 20090 SEGRATE (MI), Italy- quality control	Switzerland	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	20289 26.11.2021

11	Cetrotide	cetrorelix (cetrorelix acetate)	powder lyophilized for solution for s/c injection	0,25mg; glass vial with powder, prefilled syringe with solvent 1ml, (2) needles and (2) alcohol swabs, (7) glass vials with powder, (7) prefilled syringes with solvent 1ml, (14) needles and (14) alcohol swabs	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt- batch releaser, Baxter Oncology GmbH, Kantstrasse 2, Halle/Westfalen, 33790, Germany- powder bulk manufacturer, primary packager, quality control, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- solvent bulk manufacturer, primary packager, quality control, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- secondary packager	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20290 26.11.2021
12	Piralgin	metamizole (metamizole sodium), naproxen, caffeine, phenobarbital, codeine	tablets	300mg+100mg+50mg+10mg+8mg; (10/1x10/) in blister, (20/2x10/) in blister, (1500/150x10/) 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	20291 26.11.2021

LIST

of the medicines recommended for the mutual recognition of the EAEU registration by the Center according to the meeting decision N 11-2/21 on November 26, 2021

President_____E. Amroya

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Alkazol	cilostazol	tablets	100mg; (30/1x30/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, J . Uriach & Compania, S.A. Av. Cami Reial, 51-57, 08184 Palau-Solita i Plegamans, Barcelona, Spain- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20292 (000841) 26.11.2021

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 11-2/21 on November 26, 2021

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Paralel	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (20/2x10/) 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	20293 26.11.2021
2	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20294 26.11.2021
3	Katarel	tenoxicam	powder lyophilized and solvent for solution for i/m/i/v injection	20mg; glass vial and solvent in ampoule 2ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	20295 26.11.2021

4	Furasol	furazidin (furazidin potassium)	powder for solution for external use	100mg; (5) sachets 1g, (15) sachets 1g	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	OTC	20296 26.11.2021
5	Cyclodol Grindeks	trihexyphenidyl (trihexyphenidyl hydrochloride)	tablets	2mg; (50/2x25/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	20297 26.11.2021
6	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml +25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; (10) glass vials 0,5ml	Sanofi Pasteur, Parc Industriel d'Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20298 26.11.2021
7	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml +25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; pre-filled syringe 0,5ml and (2) needles	Sanofi Pasteur, Parc Industriel d'Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20299 26.11.2021

8	Adenuric 80mg	febuxostat	tablets film-coated	80mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	PoM	20300 26.11.2021
9	Adenuric 120mg	febuxostat	tablets film-coated	120mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	PoM	20301 26.11.2021
10	EsCial Forte	essential phospholipids, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, nicotinamide, tocopherol acetate, cyanocobalamin	capsules	300mg+6mg+6mg+6mg +30mg+6mg+6mcg; (30/3x10/) in blister	Nabros Pharma Pvt. Ltd., Survey No110/A/2 Amit Farm, Jain Upasrya, N.H. No. 8 Kajipura, Kheda, 387411, Gujarat	India	Nabros Pharma Pvt. Ltd., 3rd Floor, Oriental House II, Law Garden, Ellis Bridge, Ahmedabad-380 006	India	OTC	20302 26.11.2021
11	Grippferon	interferon alfa-2b	drops nasal	10000IU/ml; 10ml plastic vial with dropper	FIRN M LLC, 4, Dzerzhinskogo str., p. Kokoshkino, d.p. Kokoshkino, Moscow, 108804	Russia	FIRN M LLC, 4, Dzerzhinskogo str., p. Kokoshkino, d.p. Kokoshkino, Moscow, 108804	Russia	OTC	20303 26.11.2021
12	Mildronat	meldonium (meldonium dihydrate)	solution for injection	100mg/ml; (10/2x5/) ampoules 5ml in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga-batch releaser, Santonika UAB, 134B Veiveriu street,Kaunas, LT-46353, Lithuania- bulk manufacturer, packager, quality control	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	20304 26.11.2021

13	Teotard	theophylline	capsules modified-release	200mg; (40/4x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Temmler Ireland Limited, Killorglin, County, Kerry, Ireland- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20305 26.11.2021
14	Teotard	theophylline	capsules modified-release	350mg; (40/4x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Temmler Ireland Limited, Killorglin, County, Kerry, Ireland- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20306 26.11.2021
15	Erolin	loratadine	tablets	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	20307 26.11.2021
16	Niclosamide	niclosamide	tablets chewable	500mg; (4) in plastic container	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	20308 26.11.2021
17	Genferon light	interferon alfa-2b, taurine	suppositories rectal	125000IU+5mg; (10/2x5/) Alu / Alu in strip, (10/2x15/) PVC / PVC in strip	BIOCAD CJSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Saint Petersburg, 198515	Russia	PoM	20309 26.11.2021

18	Genferon light	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/) Alu / Alu in strip, (10/2x15/) PVC / PVC in strip	BIOCAD CJSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Saint Petersburg, 198515	Russia	PoM	20310 26.11.2021
19	Dexamethasone	dexamethasone	drops eye, suspension	1mg/ml; 10ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	20311 26.11.2021
20	Timolol	timolol (timolol maleate)	drops eye	5mg/ml; 5ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	20312 26.11.2021
21	Somnol	zopiclone	tablets coated	7,5mg; (10/1x10/) in blister, (20/2x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	20313 26.11.2021
22	Amlonor	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	20314 26.11.2021

23	Amlonor	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	20315 26.11.2021
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LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decisionN N 11-2/21 on November 26, 2021

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Cholisal	choline salicylate, cetalkonium chloride	gel dental	87,1mg/g+0,1mg/g; 10g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	16274/1/1 26.11.2021
2	Skudexa	tramadol (tramadol hydrochloride), dexketoprofen	tablets film-coated	75mg+25mg; (15/1x15/) in blister PA/Aluminium/PVC, (15/1x15/) in blister PVC/PE/PVDC, (15/1x15/) in blister PVC/PVDC	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	19453/2/1 26.11.2021

3	Cevikap	ascorbic acid	drops oral	100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml	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	19437/1/1 26.11.2021
4	Kisqali	ribociclib(ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr -batch releaser, packager, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18535/4/1 26.11.2021
5	Tyverb	lapatinib (lapatinib ditosylate monohydrate)	tablets film-coated	250mg; (70) in plastic bottle	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Wellcome Operations, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17200/2/1 26.11.2021

6	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	18988/3/1 26.11.2021
7	Temodal	temozolomide	capsules	20mg; (5) sachets	Schering-Plough Labo N.V., Industriepark 30 B- 2220, Heist-op-den-Berg- batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland- bulk manufacturer	Belgium	Merck Sharp & Dohme IDEA GmbH, Tribtschenstrasse 60, 6005 Luzern	Switzerland	PoM	18300/2/2 26.11.2021
8	Temodal	temozolomide	capsules	100mg; (5) sachets	Schering-Plough Labo N.V., Industriepark 30 B- 2220, Heist-op-den-Berg- batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland- bulk manufacturer	Belgium	Merck Sharp & Dohme IDEA GmbH, Tribtschenstrasse 60, 6005 Luzern	Switzerland	PoM	18301/2/2 26.11.2021

9	Temodal	temozolomide	capsules	140mg; (5) in sachet	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg-batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland-bulk manufacturer	Belgium	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	17017/2/2 26.11.2021
10	Temodal	temozolomide	capsules	180mg; (5) in sachet	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg-batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland-bulk manufacturer	Belgium	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	17018/2/2 26.11.2021
11	Temodal	temozolomide	capsules	250mg; (5) sachets	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg-batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland-bulk manufacturer	Belgium	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	18301/2/2 26.11.2021
12	Somnol	zopiclone	tablets film-coated	7,5mg; (10/1x10/) and (20/2x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	16194/3/1 26.11.2021

13	Aluvia	lopinavir, ritonavir	tablets film-coated	100mg+25mg; (60) in plastic container	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafe	Germany	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	19526/1/1 26.11.2021
14	Aluvia	lopinavir, ritonavir	tablets film-coated	200mg+50mg; (120) in plastic container	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafe	Germany	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	16930/2/1 26.11.2021
15	Elocom	mometasone (mometasone furoate)	ointment	1mg/g; aluminum 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	18795/3/1 26.11.2021
16	Elocom	mometasone (mometasone furoate)	cream	1mg/g; 15g aluminium tube	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	16330/3/1 26.11.2021
17	Emend	fosaprepitant (fosaprepitant dimeglumine)	powder lyophilized for solution for infusion	150mg; (1) glass vial 10ml	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem - secondary packager, batch releaser Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Highway, Greenville, North Carolina 27834, USA - bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	16883/2/2 26.11.2021

18	AMBROLYTIN 15mg/5ml syrup	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml plastic bottle	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	19994/1/1 26.11.2021
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-2/21 on November 26, 2021

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Zindolin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg (10/1x10/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	18476/2 26.11.2021
2	Meloflex	meloxicam	solution for i/m injection	10mg/ml; (3) ampoules 1,5ml, (5) ampoules 1,5ml	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	20037/1 26.11.2021
3	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (25/5x5/) ampoules 2ml, in blister	Takeda Austria GmbH, St. Peter strasse 25, A-4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usacheva str 2, bld. 1, Moscow 119048	Russia	PoM	15994/2 26.11.2021

4	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 5ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	PoM	18634/2 26.11.2021
5	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 10ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	PoM	18635/2 26.11.2021
6	Furasol	furazidin (furazidin potassium)	powder for solution for external use	100mg; (5) sachets 1g, (15) sachets 1g	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	OTC	16001/2/1 26.11.2021
7	Katarel	tenoxicam	powder lyophilized and solvent for solution for i/m/i/v injection	20mg; (1) glass vial and solvent in ampoule 2ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Sximatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	15971/2/1 26.11.2021
8	Adenuric 80mg	febuxostat	tablets film-coated	80mg; (14/1x14/), (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	PoM	16377/2 26.11.2021

9	Adenuric 120mg	febuxostat	tablets film-coated	120mg; (14/1x14/), (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	16376/2 26.11.2021
10	Convulex	valproic acid (sodium valproate)	solution oral	300mg/ml; glass bottle 100ml and measuring syringe	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Gansterergasse 9-13, 1160 Vienna, Austria- bulk manufacturer, packager, 1. G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria, 2. G.L. Pharma GmbH, Gansterergasse 9-13, 1160 Vienna, Austria, 3. G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- quality control (physicochemical), G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control (microbiological)	Austria	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19632/1 26.11.2021

11	Convulex	valproic acid (sodium valproate)	syrup	50mg/ml; glass bottle 100ml and measuring syringe	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Gansterergasse 9-13, 1160 Vienna, Austria- bulk manufacturer, packager, 1. G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria, 2. G.L. Pharma GmbH, Gansterergasse 9-13, 1160 Vienna, Austria, 3. G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- quality control (physicochemical), G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control (microbiological)	Austria	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19631/1 26.11.2021
12	Cefalexin	cefalexin (cefalexin monohydrate)	capsules	500mg; (16/2x8/) in blister	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb- batch releaser, Hemomont D.O.O., Montenegro 81000, Podgorica, 8 marta 55a, Montenegro-bulk manufacturer, packager	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	15662/1 26.11.2021

13	Enbrel	etanercept	solution for s/c injection	50mg/ml; (4) pre-filled glass pen-syringes 1ml and (4) alcohol swabs	Wyeth Pharmaceuticals, New Lane, Havant, PO9 2NG - batch releaser, secondary packager, Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland-bulk manufacturer, Vetter Pharma-Fertigung, Eisenbahnstr. 2-4, Langenargen, Baden-Wuerttemberg, 88085, Germany- primary packager	UK	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	17028/3 26.11.2021
14	Urorec	silodosin	capsules hard	4mg; (30/3x10/) in blister	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	18079/1 26.11.2021
15	Urorec	silodosin	capsules hard	8mg; (30/3x10/) in blister, (90/9x10/) in blister	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	18078/1/1 26.11.2021
16	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	17635/5 26.11.2021

17	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	17633/5 26.11.2021
18	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+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	17634/5 26.11.2021
19	No-spa	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24/) blister, (100) plastic container	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	Sanofi-Aventis Private Co. Ltd., 1045 Budapest, To u. 1-5	Hungary	OTC	16868/2 26.11.2021
20	Cyclodol Grindeks	trihexyphenidyl (trihexyphenidyl hydrochloride)	tablets	2mg; (50/2x25/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	16218/3 26.11.2021

21	Femara	letrozole	tablets film-coated	2,5mg; (30/3x10/) in blister	Novartis Farma S.P.A.,131, Via Provinciale Schito, 80058 Torre Annunziata-packager, batch releaser, Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland bulk manufacturer, quality control	Italy	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19893/2 26.11.2021
22	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	5mg+160mg+12,5mg; (14/1x14/) and (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17440/6/1 26.11.2021
23	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+12,5mg ; (14/1x14/) and (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17441/6/1 26.11.2021
24	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	16373/6 26.11.2021
25	Furamag	furazidin (furazidin potassium)	capsules hard	25mg; (30/3x10/) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	16232/1 26.11.2021

26	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18320/4/1 26.11.2021
27	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18321/4/1 26.11.2021
28	Ketotifen Sopharma 1mg tablets	ketotifen (ketotifen hydrofumarate)	tablets	1mg; (30/3x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	16644/1 26.11.2021
29	Iodine 5% alcoholic solution	iodine	solution for external use	50mg/ml; 10ml, 15ml, 30ml and 250ml glass bottle	Alfa-Pharm CJSC, Khrimyan Hayrik 62, Gyumri	Republic of Armenia	Alfa-Pharm CJSC, Khrimyan Hayrik 62, Gyumri	Republic of Armenia	OTC	15931/1 26.11.2021
30	Grippferon	interferon alfa-2b	drops nasal	10000IU/ml; 10ml plastic vial with dropper	FIRN M LLC, 4, Dzerzhinskogo str., Kokoshkino Settlement, Moscow region, 108804	Russia	FIRN M LLC, 4, Dzerzhinskogo str., Kokoshkino Settlement, Moscow region, 108804	Russia	OTC	15898/2/1 26.11.2021

31	Mildronat	meldonium (meldonium dihydrate)	solution for injection	100mg/ml; (10/2x5/) ampoules 5ml, in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga- batch releaser, Santonika UAB, 134B Veiveriu street,Kaunas, LT-46353, Lithuania -bulk manufacturer, packager	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	16300/3/1 26.11.2021
32	Loratadine	loratadine	tablets	10mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64a No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	OTC	16628/2 26.11.2021
33	Rhophylac 300	immunoglobulin anti-D (Rh) human	solution for i/v and i/m injection	300mcg/2ml; pre-filled syringe 2ml and needle, in blister	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22- bulk manufacturer, quality control (phisicochemical), batch releaser, CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany- packager, quality control (microbiological)	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	19918/1 26.11.2021
34	Sutent	sunitinib (sunitinib malate)	capsules hard	12,5mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	PoM	18436/4 26.11.2021

35	Sutent	sunitinib (sunitinib malate)	capsules hard	25mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	PoM	18437/4 26.11.2021
36	Sutent	sunitinib (sunitinib malate)	capsules hard	50mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	PoM	18438/4 26.11.2021
37	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg; (50/5x10/) in blister, (60/3x20/) in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	OTC	16906/2/1 26.11.2021
38	Strepsils with Menthol and Eucalyptus	dichlorobenzyl alcohol, amylmetacresol, levomenthol	lozenges	1,2mg+0,6mg+8mg; (24/2x12/) in blister, (36/3x12/) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19461/1 26.11.2021

39	Clovate	clobetasol (clobetasol propionate)	cream for external use	0,5mg/g aluminium tube 25g	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19605/1 26.11.2021
40	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	19604/1 26.11.2021
41	Niclosamide	niclosamide	tablets chewable	500mg; (4) in plastic container	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	15953/1 26.11.2021
42	Elidel	pimecrolimus	cream for external use	10mg/g; aluminium tube 15g	MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac	France	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	19383/1 26.11.2021
43	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	16308/2/1 26.11.2021

44	Sertazol	sertaconazole (sertaconazole nitrate)	suppositories vaginal	300mg; (1)	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk- bulk manufacturer, packager, batch releaser, Rubicon" LLC, 62-2, M. Gorky street, 210002, Vitebsk, Belarus- quality control	Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Belarus	PoM	16181/2 26.11.2021
45	Maxitrol	dexamethasone, neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate)	drops eye (suspension)	1mg/ml+3500IU/ml+6000IU/ml; 5ml vial	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17916/2 26.11.2021
46	Omacor	omega-3 triglycerides	capsules soft	1000mg; (28) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt - batch releaser, Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, the Netherlands- bulk manufacturer, GMPack ApS, Plastvaenget 9, 9560 Hadsund, Denmark- packager	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	17500/2 26.11.2021
47	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	19166/1 26.11.2021

48	Timolol	timolol (timolol maleate)	drops eye	5mg/ml; 5ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	16247/2 26.11.2021
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