

**LIST**

of the medicines recommended for the registration by the Center according to the meeting decision N 07-2/22 on July 28, 2022

President \_\_\_\_\_ E. Amroyan

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Humalog	insulin lispro	solution for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20819 28.07.2022
2	Humalog Mix 25	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20820 28.07.2022
3	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20821 28.07.2022

4	Influvac tetra	A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909), A/HongKong/2671/2019 (H3N2)-like strain (A/HongKong/2671/2019, IVR-208), B/Washington/02/2019-like strain (B/Washington/02/2019, wild type), B/Phuket/3073/2013,wild type)	suspension for injection	15mcg haemagglutinin/dose+ 15mcg haemagglutinin/dose+ 15mcg haemagglutinin/dose+ 15 mcg haemagglutinin/dose; (1) pre-filled syringe 0,5ml with needle	ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst-pakager, batch releaser, Abbott Biologicals B.V., C.J. van Houtenlaan 36, WEESP, 1381CP, the Netherlands- bulk manufacturer, quality control (physicochemical)	the Netherlands	ABBOTT Biologicals B.V. C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	20822 28.07.2022
5	Levofloxacin	levofloxacin (levofloxacin hemihydrate)	solution for infusion	5mg/ ml; vial 100ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	20823 28.07.2022

## LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 07-2/22 on July 28, 2022

President \_\_\_\_\_ E. Amroyan

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Perufen	ibuprofen	suspension oral	20mg/ml; 100ml glass vial and measuring device, 200ml glass vial and measuring device	Laboratorios Basi-Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lote 8, 15, 16, Mortagua, 3450-232	Portugal	GM Pharmaceuticals Ltd, 65, Phonichala, Tbilisi	Georgia	OTC	20824 28.07.2022
2	Rehydron	sodium chloride, potassium chloride, sodium citrate, glucose anhydrous	powder dose	3,5g+2,5g+2,9g+10g; (20) sachet 18,9g	Recipharm Parets S.L.U, C/Ramon and Cajal 2 , 08150 Parets del Valles (Barcelona)	Spain	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	20825 28.07.2022
3	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg; (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	20826 28.07.2022

4	Ascophen-Darnitsa	acetylsalicylic acid, paracetamol, caffeine	tablets	200mg+200mg+40mg; (6/1x6/) in blister, (10/1x10/) in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	OTC	20827 28.07.2022
5	Tresiba FlexTouch	insulin degludec	solution for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerod,3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20828 28.07.2022
6	Flucinar N	fluocinolone acetonide, neomycin (neomycin sulphate)	ointment for external use	0,25mg/g+5mg/g; 15g 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	PoM	20829 28.07.2022
7	Vazonat	meldonium (meldonium dihydrate)	solution for i/v injection	100mg/ml; (10) ampoules 5ml	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114- batch releaser, Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia, Bulgaria- bulk manufacturer, packager	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaime, LV-2114	Latvia	PoM	20830 28.07.2022

8	Nemotan	nimodipine	tablets film-coated	30mg; (30/3x10/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	20831 28.07.2022
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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-2/22 on July 28, 2022

President \_\_\_\_\_ E. Amroyan

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Hedelix	ivy leaves extract	drops oral	40mg/ml; 50ml glass bottle	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf- batch releaser, Krewel Meuselbach GmbH, Xavier-Vorbruggen str. 6, 98694 Ilmenau, Germany - bulk manufacturer, packager	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	17719/1/1 28.07.2022
2	Docetaxel Ebewe	docetaxel	concentrate for solution for infusion	10mg/ml; glass vial 2ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- 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)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach	Austria	PoM	20546/1/1 28.07.2022

3	Docetaxel Ebewe	docetaxel	concentrate for solution for infusion	10mg/ml; glass vial 8ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee-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)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach	Austria	PoM	20545/1/1 28.07.2022
4	Eneas	enalapril (enalapril maleate), nitrendipine	tablets	10mg+20mg; (30/3x10/) in blister	Ferrer Internacional, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	20210/1/1 28.07.2022
5	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with lemon flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	19020/1/1 28.07.2022
6	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	17068/1/1 28.07.2022

7	Auxilen	dexketoprofen (dexketoprofen trometamol)	solution for injection/infusion	50mg/2ml; (5/1x5/ ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	18965/3/2 28.07.2022
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-2/22 on July 28, 2022

President \_\_\_\_\_ E. Amroyan

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Perufen	ibuprofen	suspension oral	20mg/ml; 100ml and 200ml glass vial and measuring device	Laboratorios Basi -Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lote 8, 15, 16, Mortagua, 3450-232	Portugal	GM Pharmaceuticals Ltd, 65, Phonichala, Tbilisi	Georgia	OTC	16408/3/1 28.07.2022
2	Propafenon Alkaloid	propafenone (propafenone hydrochloride)	tablets film-coated	150mg; (40/4x10/) 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	20260/1 28.07.2022
3	Trimedat	trimebutine	tablets	100mg; (10/1x10) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19737/2 28.07.2022

4	Trimedat	trimebutine	tablets	200mg; (30/3x10) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19738/2 28.07.2022
5	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	1,5mg+1mg; (18/2x9/) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19855/2 28.07.2022
6	Grammidin neo	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+1mg; (18/2x9/) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20067/2 28.07.2022
7	Fluconazole-Inta	fluconazole	capsules	50mg; (30/3x10/) in blister	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	PoM	14470/1 28.07.2022

8	Fluconazole-Inta	fluconazole	capsules	150mg; (10/1x10/) in blister	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	PoM	14471/1 28.07.2022
9	Aremed	anastrozole	tablets film-coated	1mg (28/2x14/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	19301/1 28.07.2022
10	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 (phiscochemical), 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	19918/2 28.07.2022

11	Nurofen	ibuprofen	tablets coated	200mg (8/1x8/) in blister, (10/1x10/) in blister, (20/2x10/) in blister	Reckitt Benckiser Healthcare International LTD, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International LTD, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19548/3 28.07.2022
12	Levicitam	levetiracetam	tablets film-coated	250mg (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18675/2/1 28.07.2022
13	Levicitam	levetiracetam	tablets film-coated	500mg (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18676/2/1 28.07.2022
14	Prestance 5mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+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	17894/4 28.07.2022
15	Prestance 5mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (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	17895/4 28.07.2022

16	Prestance 10mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+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	17897/4 28.07.2022
17	Prestance 10mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (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	17896/4 28.07.2022
18	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	5mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18393/2 28.07.2022
19	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	10mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18394/2 28.07.2022
20	Betadine	povidone-iodine	ointment	100mg/g; 20g aluminium tube	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	17583/2 28.07.2022

21	KOXIKEA	etoricoxib	tablets film-coated	60mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20346/1 28.07.2022
22	KOXIKEA	etoricoxib	tablets film-coated	90mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20347/1 28.07.2022
23	KOXIKEA	etoricoxib	tablets film-coated	120mg; (7/1x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20348/1 28.07.2022
24	Tresiba FlexTouch	insulin degludec	solution for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd-batch releaser, bulk manufacturer, primary packager, Novo Nordisk A/S, Brennum Park, Hillerod,3400, Denmark-secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	16744/2 28.07.2022

25	Doloforte Denk	tramadol (tramadol hydrochloride), paracetamol	tablets film-coated	37,5mg+325mg; (20/2x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning - bulk manufacturer, packager, quality control (physicochemica), 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 Munchen	Germany	PoM	16694/2/1 28.07.2022
26	Relief	phenylephrine (phenylephrine hydrochloride)	ointment rectal	2,5mg/g 28.4g laminated tube and applicator	Famar S.A., National Road Athens-Lamia, Km 49, 19011 Avlona	Greece	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	17204/2 28.07.2022
27	Deavit Neo	colecalfiferol	drops oral (solution)	0,5mg/ml; 10ml glass bottle	Sopharma JSC, Industrial zone Sandanski 2800	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20607/1 28.07.2022