

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	Perinam Denk 8/5	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	8mg+5mg; (30/2x15) in blister	Actavis Ltd., BLB015, BLB016, Bulebel Industrial Estate, Zejtun, Z1N 3000	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr.79, 81675 Muenchen	Germany	PoM	22618 27.12.2024
2	Tiodin	thiamine (thiamine bromide), sodium iodide	solution for i/m injection	12,5mg/ml+10mg/ml; (10) ampoules 5ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Scientific Technological Center of Organic and Pharmaceutical Chemistry, A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA, Yerevan, Azatutyun avenue 26	Republic of Armenia	PoM	22619 27.12.2024
3	Cefxim EXPRESS-Pharmstandard	cefixime (cefixime trihydrate)	tablets dispersible	400mg; (7/1x7) in blister, (14/2x7) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 277, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 278	Russia	PoM	22620 27.12.2024
4	Soral	tenoxicam	powder lyophilized for solution for injection	20mg; (3) glass vials and (3) ampoules with solvent 2ml	Global Pharmaceutical Industries SAE, 5th Industrial Zone, Plot No. 2A, 6th of October City, Giza, 12573	Egypt	Global Napi Pharmaceuticals, 2nd Industrial Zone, No. 40, St. 18, 6th October City	Egypt	PoM	22621 27.12.2024

5	Acyclovir Vision	aciclovir	ointment eye	30mg/g; aluminium tube 5g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	22622 27.12.2024
6	Zometa	zoledronic acid (zoledronic acid monohydrate)	concentrate solution for infusion	4mg/5ml; glass vial 5ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- secondary packager, batch releaser, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria- bulk manufac- turer, primary packager, Novartis Pharma Stein AG, Schaffhauser- strasse, 4332 Stein, Switzerland- qual- ity control (physicochemical), AGES GmbH IMED, Beethovenstrasse 6, Graz, 8010, Austria- quality control (microbiological)	Slovenia	Novartis Pharma AG, Licht- strasse 35, 4056 Basel	Switzerland	PoM	22623 27.12.2024
7	Dexmedetomidine EVER Pharma	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml	EVER Pharma Jena GmbH, Otto- Schott-Strasse 15, 07745 Jena	Germany	EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	22624 27.12.2024
8	DEMISEPT	flurbiprofen	compressed lozenges	8,75mg; (20/2x10) in blister	FORTEX NUTRACEUTICALS LTD. 10, Prohladen kat street, 1362 Sofia	Bulgaria	DEMI PHARM LLC, Griboye- dovi 12, ap. 25, Sevan 1501	Republic of Armenia	OTC	22625 27.12.2024
9	Novosept	benzyltrimethyl [3-(myristoil- amine) propyl] ammonium chloride monohydrate	solution for topical and external use	0,1mg/ml; 50ml plastic con- tainer (pump dispenser and applicator), 150ml (dispenser), 200ml plastic container (maisorinng aplicator)	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	IE Sergey Sergeevich Patvakan- ov, Apartment 44, Building 10, Antarayin 1-st District, Tsaghkadzor	Republic of Armenia	OTC	22626 27.12.2024

## LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	Lodigrel	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/2x7) in blister, (28/4x7) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22630 (013086) 27.12.2024
2	Septolete total	benzylamine (benzylamine hydrochloride), cetylpyridinium (cetylpyridinium chloride)	spray for topical use	1,5mg/ml+5mg/ml; plastic container with pump dispenser 30ml (250 dose)	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	22631 (000940) 27.12.2024
3	Progestogel	progesterone	gel for external use	10 mg/g; 80g aluminium tube and dosator	Besins Manufacturing Belgium, Groot-Bijgaardenstraat, 128-1620, Drogenbos- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Quali Controle, 9 rue Francois Truffaut, Meru, 60110, France- quality control (microbiological)	Belgium	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	22632 (008837) 27.12.2024
4	Progestogel	progesterone	gel for external use	10 mg/g; 80g aluminium tube and dosator	Laboratoires Besins International, 13, Rue Perier, 92120 Montrouge- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Quali Controle, 9 rue Francois Truffaut, Meru, 60110, France, for Besins Healthcare SA, Rue Washington 80, Ixelles 1050, Belgium- quality control (microbiological)	France	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	22633 (008837) 27.12.2024

5	Flucaps	oseltamivir	capsules	30mg; (10/1x10) 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	22634 (105124) 27.12.2024
6	Flucaps	oseltamivir	capsules	45mg; (10/1x10) 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	22635 (105124) 27.12.2024
7	Flucaps	oseltamivir	capsules	75mg; (10/1x10) 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	22636 (105124) 27.12.2024
8	Airtal	aceclofenac	tablets film-coated	100mg; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister, (60/6x10) in blister, (90/9x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22637 (004910) 27.12.2024
9	Airtal	aceclofenac	tablets film-coated	100mg; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister, (60/6x10) in blister, (90/9x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22638 (004910) 27.12.2024

10	Airtal	aceclofenac	tablets film-coated	100mg; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister, (60/6x10) in blister, (90/9x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia-packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia-quality control (microbiological)	Russia	Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22639 (004910) 27.12.2024
11	Pergoveris	follitropin alfa, lutropin alfa	powder lyophilized for solution for s/c injection	150IU+75IU; (1) glass vial and (1) solvent in vial 1ml, (3) glass vials and (3) solvent in vials 1ml, (10) glass vials and (10) solvent in vials 1ml	Merck Serono S.A., Succursale d' Aubonne, Zone Industrielle de l' Ourietzaz, 1170 Aubonne	Switzerland	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	22640 (007873) 27.12.2024
12	Brimica Genuair	acridinium (acridinium bromide), formoterol fumarate dihydrate	powder for inhalation	340mcg/dose+12mcg/dose; (1) inhaler with 60 unit doses, (3) inhalers with 180(3x60) unit doses	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Berlin-Chemie AG, Glienicke-er Weg 125, 12489 Berlin	Germany	PoM	22627 (013538) 27.12.2024
13	Metronidazole	metronidazole	solution for i/v infusion	5mg/ml; plastic pack 100ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22628 (013538) 27.12.2024

## LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	Zondan	ondansetron (ondansetron hydrochloride dihydrate)	tablets film-coated	8mg; (30/3x10) in blister	Incepta Pharmaceuticals Limited, Dewan Idris Road, Zirabo, Savar, Dhaka	Bangladesh	Incepta Pharmaceuticals Limited, Dewan Idris Road, Zirabo, Savar, Dhaka	Bangladesh	PoM	22641 27.12.2024
2	Biokson	ceftriaxone (ceftriaxone sodium triseskvihydrate)	powder for solution for i/m and i/v injection	1000mg; glass vial	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	PoM	22642 27.12.2024
3	Helmintox	pyrantel (pyrantel embonate)	suspension oral	125mg/2,5ml; 15ml glass bottle and measuring spoon 2,5ml	INNOTHERA CHOUZY, rue Rene Chantereau, Chouzy-sur-Cisse, VALLOIRE-SUR-CISSE, 41150 - quality control, batch releaser, THEPENIER PHARMA & COSMETICS Route Departementale 912, SAINT LANGIS LES MORTAGNE, 61400, France- bulk manufacturer, packager	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	PoM	22643 27.12.2024
4	Fluditec	carbocisteine	syrup	20mg/ml; 125ml glass bottle and 20ml measuring cup	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150-batch releaser, Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d' En Sigal, 31770, Colomiers, France-bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	22644 27.12.2024

5	Fluditec	carbocisteine	syrup	50mg/ml; 125ml glass bottle and 20ml measuring cup	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150- batch releaser, Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d' En Sigal, 31770, Colomiers, France- bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	22645 27.12.2024
6	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14) in blister, (28/4x7) 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	22646 27.12.2024
7	Panthenol Pharm-standard	dexpanthenol	foam for external use	50mg/g; aluminium container 58g	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22647 27.12.2024
8	Polygynax	neomycin sulfate, polymyxin B sulfate, nystatin	capsules vaginal	35000IU+35000IU+100000IU; (6/1x6) in blister, (12/2x6) in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150-packager, quality control, batch releaser, Catalent France Beenheim SA-Beenheim, 74 rue principale, Beenheim, 67930, France-bulk manufacturer	France	Laboratoire Innotech International, 22 Avenue Aristide Briand 94110 Arcueil	France	PoM	22648 27.12.2024
9	Polygynax	neomycin sulfate, polymyxin B sulfate, nystatin	capsules vaginal	35000IU+35000IU+100000IU; (6/1x6) in blister, (12/2x6) in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150-packager, quality control, batch releaser, Swiss caps AG, Husestrasse 35, 9533 Kirchberg, Switzerland-bulk manufacturer	France	Laboratoire Innotech International, 22 Avenue Aristide Briand 94110 Arcueil	France	PoM	22649 27.12.2024
10	Rabies Vaccine Inactivated (freeze dried)	purified rabies antigen	powder lyophilized for solution for injection and solvent	2,5IU/ml; (1) glass vial and (1) solvent in ampoule 1ml, (5) glass vials and (5) solvent in ampoules 1ml, (50) glass vials, (50) solvent in ampoules 1ml	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028 Dist-PUNE ZONE3- bulk manufacturer, packager, quality control, batch releaser, SOVEREIGN PHARMA PRIVATE LIMITED, Survey No. 46/1-4, Village Kadaiya, Daman-396210, India- solvent manufacturer	India	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028	India	PoM	22650 27.12.2024
11	Levomycetin Tatchempharm	chloramphenicol	tablets	500mg; (10/1x10) in blister	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	22651 27.12.2024

12	HEDESPAN	ivy leaves dry extract	syrup	7mg/ml; 100ml glass bottle with measuring cup	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	22652 27.12.2024
----	----------	------------------------	-------	--	---	----------	---	----------	-----	---------------------



## LIST

of the medicines recommended for the re-registration under the EAEU procedure by the Center according to the meeting decision N 12-2/24 on  
December 27, 2024

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	Anaferon	affinity purified antibodies to human interferon gamma	tablets to be sucked	10000UMA; (20/1x20) in blister	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	22629 (018547) 27.12.2024

## LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	FLAZON	metronidazole (metronidazole benzoate)	suspension oral	25mg/ml; glass bottle 100ml and measuring cup	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	22654 27.12.2024
2	Permethrin	permethrin	cream	50mg/g; aluminium tube 50g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22655 27.12.2024
3	Betamethasone	betamethasone (betamethasone valerate)	cream for external use	1mg/g; aluminium tube 15g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22656 27.12.2024

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/24 on December 27,  
2024

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	Cytosar	cytarabine	powder lyophilized for solution for injection	100mg; glass vial	Latina Pharma S.p.A, Via Murillo7, Sermoneta, 04013	Italy	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	20394/3/3 27.12.2024
2	Cytosar	cytarabine	powder lyophilized for solution for injection	500mg; glass vial	Latina Pharma S.p.A, Via Murillo7, Sermoneta, 04013	Italy	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	20395/3/3 27.12.2024

3	Survanta	beractant (phospholipids)	suspension endotracheal	25mg/ml; glass vial 4ml	AbbVie Inc., 1401 Sheridan Road, North Chicago, Illinois 60064- bulk manufacturer, primary packager, quality control, batch releaser, AbbVie Inc., 1 North Waukegan Road, North Chicago, Illinois 60064, USA- secondary packager	USA	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	20956/2/1 27.12.2024
4	Furasol	furazidin (furazidin potassium)	powder for solution for external use	100mg; (5) sachets 1g, (15) sachets 1g	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	OTC	20296/1/1 27.12.2024
5	Neiromidin	ipidacrine (ipidacrine hydrochloride)	tablets	20mg; (50/5x10), in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	19930/2/1 27.12.2024
6	Neiromidin	ipidacrine (ipidacrine hydrochloride)	solution for i/m and s/c injection	15mg/ml; (10) ampoules 1ml	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114- quality control, batch releaser, Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia, Bulgaria- bulk manufacturer, packager	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20020/2/1 27.12.2024

7	Vazonat	meldonium (meldonium dihydrate)	capsules	250mg; (20/2x10) in blister, (40/4x10) in blister, (60/6x10) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20801/1/1 27.12.2024
8	Furamag	furazidin (furazidin potassium)	capsules	25mg; (30/3x10) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20510/2/1 27.12.2024
9	Furamag	furazidin (furazidin potassium)	capsules	50mg; (30/3x10) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20511/1/1 27.12.2024
10	Otofa	rifamycin (rifamycin sodium)	drops ear	26mg (20000IU)/ml; 10ml glass bottle with dropper	Pharmaster, Zone Industrielle de Krafft, 67150 Erstein- bulk manufacturer, packager, batch releaser, QUALI CONTROLE, 29 rue Paul Vaillant Couturier, 60110 MERU, France- quality control (physico-chemical), SOLVIAS FRANCE-HOMBOURG, Zone Industrielle, rue du Canal d' Alsace, 68490 HOMBORG, France- quality control (microbiological)	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	PoM	20832/2/1 27.12.2024
11	HEDESPAN	ivy leaves dry extract	syrup	7mg/ml; 100ml glass bottle with measuring cup	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	19049/1/1 27.12.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	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 ECHEVARRNE, 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	21273/3 27.12.2024
2	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	21463/2 27.12.2024
3	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	21464/2 27.12.2024
4	Tinctura menthae piperitae	folium menthae piperite, oil menthae piperitae	tincture	50mg/ml+ 50mg/ml; glass bottle 30ml	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	18726/1 27.12.2024
5	CLOTRIMAZOLE	clotrimazole	cream	10mg/g; aluminium tube 15g	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	OTC	18709/1 27.12.2024

6	Flazon	metronidazole (metronidazole benzoate)	suspension oral	25mg/ml; glass bottle 100ml and measuring cup	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18890/1 27.12.2024
7	Inestom	levocarnitine	solution oral	100mg/ml; (10) glass vials 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki	Greece	PoM	21320/1 27.12.2024
8	Betamethasone	betamethasone (betamethasone valerate)	cream for external use	1mg/g; aluminium tube 15g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-Dis- trict, 19 Building	Republic of Armenia	PoM	19059/1 27.12.2024
9	Permethrin	permethrin	cream	50mg/g; alumi- num tube 50g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-Dis- trict, 19 Building	Republic of Armenia	OTC	18984/1 27.12.2024
10	Bixitor 60mg	etoricoxib	tablets film- coated	60mg; (30/3x10/ in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gadd- apotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiolog- ical)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21068/2/1 27.12.2024
11	Bixitor 90mg	etoricoxib	tablets film- coated	90mg; (30/3x10/ in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gadd- apotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiolog- ical)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21069/2/1 27.12.2024

12	Bixitor 120mg	etoricoxib	tablets film-coated	120mg; (10/1x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gaddapotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21070/2/1 27.12.2024
13	Panthenol Pharmstandard	dexpanthenol	foam for external use	50mg/g; aluminium container 58g	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19070/3/2 27.12.2024
14	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	18821/5 27.12.2024
15	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd., 9 HaShalom Road, Neshar, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	21674/2 27.12.2024
16	Relief	phenylephrine (phenylephrine hydrochloride)	ointment rectal	2,5mg/g; 28,4g laminated tube and applicator	Famar A.V.E., National Road Athens-Lamia, Km 49, 19011 Avlona	Greece	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	21729/1 27.12.2024
17	Rovastat Duo	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets	10mg+10mg; (30/3x10) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego st., 95-200 Pabianice, Lodzkie	Poland	Adamed Pharma S.A., 6A, Pienkowi, Mariana Adamkiewicza st., 05-152 Czosnow, Mazowieckie	Poland	PoM	20467/2 27.12.2024



## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/24 on December 27, 2024

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	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/1x30) in blister, (60/2x30) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 27.12.2024
2	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (60/4x15) in blister	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	000531 27.12.2024
3	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (30/1x30) in blister, (60/2x30) in blister, (60/4x15) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 27.12.2024
4	Terbisil	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; aluminium tube 15g	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	002081 27.12.2024