

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-2/25 on April 30, 2025

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	MOMETASONE-ASTERIA	mometasone (mometasone furoate)	spray nasal	0,5mg/ml; plastic bottle with metering pump 18ml (140 dose)	ILDONG PHARMACEUTICAL CO., LTD, 25, Gongdan 1-ro, Anseong-si, Gyeonggi-do- batch releaser, SAMCHUNDANG PHARM. CO., LTD, 71, Jeyakgongdan 2-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do- bulk manufacturer, packager, quality control	Republic of Korea	ASTERIA LLC, 72/3 Nairi Zaryan street, 0051 Yerevan	Republic of Armenia	PoM	22993 30.04.2025
2	Tafinlar	dabrafenib	capsules hard	75mg; (120) in plastic container	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22994 30.04.2025
3	Domosedan	detomidine (detomidine hydrochloride)	solution for injection	10mg/ml; (1) glass vial 5ml, (1) glass vial 20ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	22995 30.04.2025
4	Grani-Denk 1mg/ml	granisetron (granisetron hydrochloride)	concentrate for solution for injection/ infusion	1mg/ml; (5) ampoules 1ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen Hassia, 34212- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22996 30.04.2025

5	Grani-Denk 1mg/ml	granisetron (granisetron hydrochloride)	concentrate for solution for injection/infusion	1mg/ml; (5) ampoules 3ml	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen Hassia, 34212- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22997 30.04.2025
6	Vitaprost Plus	prostate extract (water-soluble peptide), lomefloxacin (lomefloxacin hydrochloride)	suppositories rectal	20mg+400mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22998 30.04.2025
7	Dutasteride/ Tamsulosin	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,5mg+0+4mg; (30) plastic container	Sag Manufacturing S.L., Carretera Nacional 1, Km 36, 28750, San-Agustin-Del-Guadalix	Spain	Laboratorio STADA, S.L, Frederic Mompou, 5, 08960 Sant-Just-Desvern (Barcelona)	Spain	PoM	22999 30.04.2025

LIST

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2025

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1	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant	75mg; (30/3x10) in blister, (50/5x10) in blister, (60/6x10) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	OTC	23002 (002328) 30.04.2025
2	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant	150mg; (30/3x10) in blister, (50/5x10) in blister, (60/6x10) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	OTC	23003 (002328) 30.04.2025
3	Tribestan	tribulus terrestris herb dry extract	tablets film-coated	250mg; (60/6x10) in blister, (180/18x10) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	23004 (011496) 30.04.2025
4	AMIODARONE	amiodarone (amiodarone hydrochloride)	concentrate for solution for infusion	50mg/ml; (10) ampoules 3ml label banderol, (10) ampoules 3ml dividella, (10) ampoules 3ml CAMA	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No10/1, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23005 (011474) 30.04.2025
5	Heparin ointment	heparin (heparin sodium), benzocaine, benzyl nicotinate	ointment for external use	100IU/g+40mg/g+0.8mg/g; 25g aluminium tube, 25g laminated tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager, quality control	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	23006 (007666) 30.04.2025
6	Vabysmo	faricimab	solution for intraocular injection	120mg/ml; glass vial and filter needle	F. Hoffmann-La Roche Ltd., Wurmisweg 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, 4070, Basel	Switzerland	PoM	23007 (002181) 30.04.2025

7	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; 53g powder in 100ml glass bottle, 32g powder in 60ml glass bottle and 5ml measuring spoon	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Mcedonia	PoM	23008 (000662) 30.04.2025
8	AZARGA	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; plastic vial- dropper 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23009 (009342) 30.04.2025

LIST

oof the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 04-2/25 on April 30, 2025

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	Brilliant green	brilliant green	solution for external use	10mg/ml; glass bottle 10ml, pen-brush 3,5ml	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	22399/1/1 30.04.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-2/25 on April 30, 2025

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	Akcipro-500	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No. D-10, D-11, M.I.D.C. Indl. Estate, Nira Road, Jejuri, Tal. Purandar (Saswad), Dist. Pune-412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., 117, Block No. 2, Emerald Plaza, Hiranandani Meadows, Barrister Nath Pai Road, Thane (West) 400 610	India	PoM	23010 30.04.2025
2	Cadigrel	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (30/3x10) in blister, (30/3x10) in strip	CADILA PHARMACEUTICALS LTD., 1389 TRASAD ROAD, DHOLKA-382225, Ahmedabad, Gujarat state	India	CADILA PHARMACEUTICALS LTD., 1389 TRASAD ROAD, DHOLKA-382225, Ahmedabad, Gujarat state	India	PoM	23011 30.04.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 04-2/25 on April 30, 2025

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1	METRONIDAZOLE- ASTERIA	metronidazole	tablets	500mg; (30/3x10') in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeon-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	23012 30.04.2025
2	Betaiodine	povidone-iodine	cream	100mg/g; aluminium tube 15g, aluminium tube 20g	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	OTC	23013 30.04.2025
3	Co-Prelessa	perindopril (perindopril erbumine), indapamide	tablets	8mg+2,5mg; (30/3x10') 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	23014 30.04.2025
4	Fluimucil	acetylcysteine	tablets effervescent	600mg; (10/5x2') in blister	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	OTC	23015 30.04.2025
5	Monural	fosfomicin (fosfomicin trometamol)	granules for oral solution	3g; (1) sachet 8g, (2) sachets 8g	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	PoM	23016 30.04.2025

LIST

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1	Tobradex	tobramycin, dexamethasone	drops eye (suspension)	3mg/ml+1mg/ml; 5ml plastic vial	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21668/1/1 30.04.2025
2	Lorinden A	flumetasone (flumetasone pivalate), salicylic acid	ointment for external use	0,2mg/g+30mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BAUSCH HEALTH IRELAND LIMITED, 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3	Ireland	PoM	20427/2/1 30.04.2025
3	Lorinden C	flumetasone (flumetasone pivalate), clioquinol	ointment for external use	0,2mg/g+30mg/g; aluminium tube 15g	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BAUSCH HEALTH IRELAND LIMITED, 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3	Ireland	PoM	20514/2/1 30.04.2025
4	Omnadren 250	testosterone (testosterone propionate), testosterone (testosterone phenylpropionate), testosterone (testosterone isocaproate), testosterone (testosterone decanoate)	oily solution for i/m injection	30mg/ml+60mg/ml+60mg/ml+100mg/ml; (5) ampoules 1ml	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BAUSCH HEALTH IRELAND LIMITED, 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3	Ireland	PoM	20734/3/1 30.04.2025

LIST

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decision N 04-2/25 on April 30, 2025

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1	Etoriax	etoricoxib	tablets film-coated	30mg; (30/3x10) 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	JITI-N°000248-ITI-AM 30.04.2025
2	Etoriax	etoricoxib	tablets film-coated	60mg; (30/3x10) 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	JITI-N°000248-ITI-AM 30.04.2025
3	Etoriax	etoricoxib	tablets film-coated	90mg; (30/3x10) 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	JITI-N°000248-ITI-AM 30.04.2025
4	Etoriax	etoricoxib	tablets film-coated	120mg; (30/3x10) 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	JITI-N°000248-ITI-AM 30.04.2025
5	Etoriax	etoricoxib	tablets film-coated	30mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuc, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025

6	Etoriax	etoricoxib	tablets film-coated	60mg; (30/3x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025
7	Etoriax	etoricoxib	tablets film-coated	90mg; (30/3x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025
8	Etoriax	etoricoxib	tablets film-coated	120mg; (30/3x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025
9	Etoriax	etoricoxib	tablets film-coated	30mg; (30/3x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403 511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025
10	Etoriax	etoricoxib	tablets film-coated	60mg; (30/3x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403 511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025

11	Etorix	etoricoxib	tablets film-coated	90mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403 511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025
12	Etorix	etoricoxib	tablets film-coated	120mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403 511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000248-ITI-AM 30.04.2025

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/25 on April 30, 2025

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1	Lorista H 100	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (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	21333/1 30.04.2025
2	Deep Heat	methyl salicylate, menthol (racemic), eucalyptus oil, turpentine oil	cream for external use	128mg/g+59,1mg/g+19,7mg/g+14,7mg/g; 15g aluminium tube, 67g aluminium tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	22331/1 30.04.2025
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	22643/1 30.04.2025
4	Co-Prenessa	perindopril (perindopril erbumine), indapamide	tablets	8mg+2,5mg; (30/3x10/) 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	19115/2 30.04.2025
5	Betaiodine	povidone-iodine	cream	100mg/g; aluminium tube 15g, aluminium tube 20g	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	OTC	18973/1 30.04.2025

6	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	Switzerland	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	22682/1 30.04.2025
7	Urdoxa	ursodeoxycholic acid	capsules	250mg; (50/5x10) in blister, (100/5x20) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow reg.- quality control, batch releaser, Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region, Russia- bulk manufacturer, packager	Russia	Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region	Russia	PoM	20647/1 30.04.2025
8	Nebilet Plus 5/12,5	nebivolol (nebivolol hydrochloride), hydrochlorothiazide	tablets film-coated	5mg+12,5mg; (28/2x14) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (phiscochemical), Berlin- Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (microbiological)	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	20199/3 30.04.2025
9	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister, (10) in strip	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	18487/2 30.04.2025
10	Akcipro-500	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No D-10, D-11, M.I.D.C. Indl. Estate., Nira Road, Jejuri, Tal. Purandhar (Saswad), Dist. Pune-412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., 117, Block No2, Emerald Plaza, Hiranandani Meadows, Barrister Nath Pai Road, Thane (W) 400 610	India	PoM	18534/1 30.04.2025

LIST

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1	Flavamed effervescent tablets	ambroxol (ambroxol hydrochloride)	tablets effervescent	60mg; (10) plastic container	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- batch releaser, Hermes Pharma GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	ЛПТ-№008364-PT-AM 30.04.2025
2	Pronoran	piribedil	tablets prolonged-release coated	50mg; (30/2x15/) in blister, (30/1x30/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, Rue Carnot, 92284 Suresnes Cedex	France	PoM	ЛПТ-№00387-ITI-AM 30.04.2025
3	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29/) in blister, (30/1x30/) 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	ЛПТ-№00387-ITI-AM 30.04.2025
4	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29/) in blister, (30/1x30/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	ЛПТ-№00387-ITI-AM 30.04.2025
5	Sulid	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	AVVA RUS JSC, Kirov region, Kirov city, Luganskaya Str. 53A	Russia	TOO "AVVA Kazakhstan", 050008, city Almaty, Almaly region, Abaya avenue, 109B room 501,	Republic of Kazakhstan	PoM	ЛПТ-№004593-ITI-AM 30.04.2025