

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 11-1/22 on November 14, 2022

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	Dapoxetine Ibn Al Haytham	dapoxetine	tablets film-coated	30mg; (4/2x2/) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	PoM	20989 14.11.2022
2	Dapoxetine Ibn Al Haytham	dapoxetine	tablets film-coated	60mg; (4/2x2/) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	PoM	20990 14.11.2022
3	Travolife Hedera	ivy leaves dry extract	syrup	7mg/ml; 100ml glass bottle with measuring cup	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, London	UK	OTC	20991 14.11.2022

4	Zentel	albendazole	suspension oral	40mg/ml; plastic container 10ml	Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, Bad Oldesloe, Schleswig-Holstein, 23843	Germany	Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	20992 14.11.2022
5	Afobazol retard	fabomotizole (fabomotizole dihydrochloride)	tablets prolonged-release	30mg; (20/1x20/) in blister	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr. 12, apartment II, room. 29, Moscow 123112	Russia	OTC	20993 14.11.2022
6	Elsant D	desloratadine	tablets film-coated	5mg; (20/2x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, PrJSC "Pharmaceutical firm "Darnitsa", 13 Boryspilska Street, Kyiv, 02093, Ukraine- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	20994 14.11.2022
7	Fortox	clostridium botulinum toxin type A	powder for solution for injection	100IU; glass vial	Huons BioPharma Global Co., Ltd, 50 Bio valley 2-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	Huons BioPharma Global Co., Ltd, 50 Bio valley 2-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	PoM	20995 14.11.2022

8	Velpanat	sofosbuvir, velpatasvir	tablets film-coated	400mg+100mg; (28) plastic bottle	Natco Pharma Limited- Pharma Division, Kothur, Rangareddy District, Telangana, 509228	India	Natco Pharma Limited, Kothur, Rangareddy District, Telangana, 509228	India	PoM	20996 14.11.2022
9	BIOGEM 200	gemcitabine (gemcitabine hydrochloride)	powder lyophilized for solution for infusion	200mg; glass vial 10ml	United Biotech (P) Limited, Bagbania, Baddi- Nalagarh, Road, Distt. Solani (H.P.)-174101	India	Violeta Medical Center LLC, 2/33 Yerznkyan street, Arabkir, Yerevan	Republic of Armenia	PoM	20997 14.11.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 11-1/22 on November 14, 2022

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	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10) ampoules 5ml, (10/2x5/) ampoules 5ml in blister	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	PoM	20976 14.11.2022
2	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10) ampoules 10ml, (10/2x5/) ampoules 10ml in blister	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	PoM	20977 14.11.2022
3	Rennie	calcium carbonate, magnesium carbonate	tablets chewable with orange flavour	680mg+80mg; (24/2x12/) in blister	Delpharm Gaillard, 33, rue de l'industrie, 74240 Gaillard	France	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	20978 14.11.2022

4	Persen Day	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	tablets coated	35mg+17,5mg+17,5mg; (40/4x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- bulk manufacturer, quality control	Slovenia	Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy	Czech Republic	OTC	20979 14.11.2022
5	Triovit	beta-carotene, alfa-tocopherol acetate, ascorbic acid, selen	capsules	10mg+40mg+100mg+50 mcg; (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	OTC	20980 14.11.2022
6	Chymotrypsin	chymotrypsin	powder lyophilized for solution for injection, local and external use	10mg; (5) glass vials; (10) glass vials	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	PoM	20981 14.11.2022
7	Enterofuryl	nifuroxazide	capsules	100mg; (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20982 14.11.2022
8	Enterofuryl	nifuroxazide	capsules	200mg; (16/2x8/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20983 14.11.2022

9	Dicynone	etamsylate	tablets	250mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- bulk manufacturer, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20984 14.11.2022
10	Tempalgin	metamizole (metamizole sodium), triacetoneamine 4-toluensulfonate	tablets film-coated	500mg+20mg; (20/2x10/) in blister	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	20985 14.11.2022
11	Essentiale forte N	phospholipids (essential)-EPL	capsules	300mg; (30/3x10/) in blister	A. Nattermann & Cie. GmbH, Nattermannallee 1, D-50829 Cologne	Germany	A. Nattermann & Cie. GmbH, Nattermannallee 1, D-50829 Cologne	Germany	OTC	20986 14.11.2022
12	Kestine	ebastine	tablets film-coated	20mg; (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	PoM	20987 14.11.2022

13	Actilyse	alteplase	powder lyophilized for solution for infusion with solvent	50mg; glass vial and glass vial with solvent 50ml	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer str. 65, 88397 Biberach a.d.R.	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	20988 14.11.2022
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LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/22 on November 14, 2022

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	Drotaverine	drotaverine (drotaverine hydrochloride)	solution for i/v & i/m injection	20mg/ml; (10) ampoules 2ml, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	17519/2/1 14.11.2022
2	Trypsin crystalline	trypsin	powder lyophilized for solution for injection and for topical use	10mg; (5) glass vial, (10) glass vial	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	PoM	20618/1/1 14.11.2022
3	Sea Buckthorn Oil	hippopheae oil	suppositories rectal	500mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18117/2/1 14.11.2022

4	Talliton	carvedilol	tablets	6,25mg; (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	19431/2/1 14.11.2022
5	Talliton	carvedilol	tablets	12,5mg; (14/1x14/) in blister, (28/2x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19432/2/1 14.11.2022
6	Talliton	carvedilol	tablets	25mg; (14/1x14/) in blister, (28/2x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19433/2/1 14.11.2022
7	Promedols	trimeperidine (trimeperidine hydrochloride)	solution for injection	20mg/ml; (10/2x5/) ampoules in plastic liner, (100/20x5/) ampoules 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	18833/3/1 14.11.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/22 on November 14, 2022

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	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17885/2 14.11.2022
2	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17886/2 14.11.2022
3	Diclac ID 75	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified-release	12,5mg+ 62,5mg; (20/2x10/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19071/1 14.11.2022

4	Diclac ID 150	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified-release	25mg+125mg; (100/10x10/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19072/1 14.11.2022
5	Meteospasmyl	alverine (alverine citrate), simeticone	capsules	60mg+300mg (20/2x10/) in blister, (30/3x10/) in blister	Laboratoires MAYOLY SPINDLER, 6 avenue de l'Europe, 78400 Chatou-packager, quality control (physicochemical), batch releaser, Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie-Les-Lys, France- bulk manufacturer, quality control (microbiological)	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l'Europe, 78400 Chatou	France	OTC	19602/1 14.11.2022
6	Upsarin Ursa	acetylsalicylic acid	tablets effervescent	500mg; (16/4x4/) in strip	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	16994/2 14.11.2022
7	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	2,5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	19379/2 14.11.2022

8	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	19380/2 14.11.2022
9	Broncho-munal P	lyophilized bacterial lysate	capsules hard	3,5mg; (10/1x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19713/3 14.11.2022
10	Broncho-munal	lyophilized bacterial lysate	capsules hard	7mg; (10/1x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19712/3 14.11.2022
11	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with strawberry flavour, sugar free	1,2mg+0,6mg; (16/2x8/) 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	19427/2 14.11.2022

12	Tenoxin	tenoxicam	powder lyophilized for solution for injection	20mg; (1) glass vial 3ml and (1) solvent in ampoule 2ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009	Greece	Anfarm Hellas S.A., 4 Achaia str. & Trizinias, Kifissia, Attiki	Greece	PoM	20437/2 14.11.2022
13	Vitamin D3 Krka	coleciferol (vitamin D3)	tablets	1000IU; (30/3x10/) in blister, (60/6x10/) in blister, (90/9x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto - packager, quality control, batch releaser, KRKA d.d., Novo mesto Ulica Rada Pusenjaka 10, 9240 Ljutomer, Slovenia - bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19976/1 14.11.2022
14	Galvus	vildagliptin	tablets	50mg; (28/2x14/) in blister, (56/4x14/) 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	19791/3/1 14.11.2022
15	Pabi-Dexamethason	dexamethasone	tablets	500mcg; (20) in glass bottle and (20/1x20/) in blister	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	PoM	16444/2 14.11.2022

16	Tavin	tenofovir disoproxil fumarate	tablets film-coated	300mg; (30) in plastic container	Emcure Pharmaceuticals Ltd., Lane No. 3, Phase II, SIDCO Industrial Complex, Bari-Brahmana, Jammu (J&K)-181 133	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026	India	PoM	16622/1 14.11.2022
17	Pollezin	levocetirizine (levocetirizine dihydrochloride)	tablets film-coated	5mg; (7/1x7/) in blister, (14/2x7/) in blister, (10/1x10/) in blister, (20/2x10/) 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	PoM	18275/2 14.11.2022
18	Turbo micron G	diosmin, hesperidin	tablets film-coated	450mg+50mg; (60/6x10/) in blister	KERN PHARMA, S.L., Poligon Industrial Colon II. C/ Venus, 72 08228 TERRASSA (Barcelona)	Spain	GM Pharmaceuticals Ltd, Phonichala 65, Tbilisi	Georgia	OTC	17401/2 14.11.2022
19	Dermovate	clobetasol (clobetasol propionate)	cream	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	18211/3 14.11.2022
20	Dermovate	clobetasol (clobetasol propionate)	ointment	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	182112/3 14.11.2022

21	Oxolin	oxolin	ointment nasal	2,5mg/g; 10g aluminium tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17033/3 14.11.2022
22	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride	spray dosed for topical use	0.03mg+0.1mg; aluminum bottle 112 dose with dosing device	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control, batch release, Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, the Netherlands- bulk manufacturer, primary packager	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20732/1 14.11.2022
23	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	20290/1 14.11.2022

24	Cetrotide	cetrorelix (cetrorelix acetate)	powder lyophilized for solution for s/c injection	0,25mg; N7 glass vials with powder, N7 prefilled syringes with solvent 1ml, N14 needles, N14 alcohol swabs; N1 glass vials with powder, N1 prefilled syringes with solvent 1ml, N 2 needles, N 2 alcohol swabs	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt- batch releaser, FAREVA PAU 2, 50 chemin de Mazerolles, 64320 Idron, France- powder bulk manufacturer, primary packager, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- solvent bulk manufacturer, primary packager, quality control, FAREVA PAU 1, Avenue du Bearn, 64320 Idron, France- powder 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	20360/1 14.11.2022
25	Indapamide MB STADA	indapamide	tablets prolonged-release film-coated	1,5mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye shosse	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18876/2 14.11.2022
26	Pancreatin	pancreatin (amylase, protease, lipase)	tablets gastro-resistant	125mg (not less than 2800IU, not less than 180IU, not less than 3000IU); (50/5x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	16814/1 14.11.2022

27	Azarga	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; 5ml vial	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17919/3 14.11.2022
28	Triovit	beta-carotene, alfa- tocopherol acetate, ascorbic acid, selen	capsules	10mg+40mg+100mg+ 50mcg; (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	OTC	17027/3 14.11.2022
29	Catafast	diclofenac (diclofenac potassium)	powder for oral solution	50mg; (3) and (21) sachets	Mipharm S.p.A., VIA Bernardo Quaranta, 12, 20141 Milano (MI)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18035/3 14.11.2022
30	Cosentyx	secukinumab	solution for injection in syringe	150mg/ml; (1) pre- filled syringes, (2) pre- filled syringes	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20894 /1 14.11.2022
31	Cosentyx	secukinumab	solution for injection	150mg/ml; (1) pre- filled pen, (2) pre- filled pen	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20893 /1 14.11.2022
32	Cosentyx	secukinumab	lyophilisate for solution for subcutaneous injection	150mg; glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20892 /1 14.11.2022

33	Spirolon	spironolactone	tablets film-coated	25mg (50/5x10/) in blister	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	PoM	17658/2 14.11.2022
34	Acyclovir Denk 5% Cream	aciclovir	cream for topical use	50mg/g; aluminium tube 7g	RubiePharm Arzneimittel GmbH, Bruder-Grimm-Str. 62, 36396 Steinau an der Strasse- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor L+S AG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20095/1 14.11.2022
35	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant	75mg; (30/3x10/) 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	19359/2 14.11.2022
36	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant	150mg; (30/3x10/) 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	19360/2 14.11.2022

37	Fortrans	macrogol (macrogol 4000), sodium sulfate anhydrous, sodium hydrogen carbonate, sodium chloride, potassium chloride	powder for oral solution	64.0g+5.70g+1.68g+1.46g+0.75g ; (4) sachets 73,69g	Beaufour Ipsen Industrie, rue Ethe Virton, 28100 Dreux	France	Ipsen Consumer Healthcare, 65 quai Georges Gorse, 92100 Boulogne-Billancourt	France	OTC	20733/2 14.11.2022
38	Omnitus	butamirate (butamirate citrate)	tablets modified-release film-coated	50mg; (10/1x10/) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	OTC	18292/3 14.11.2022
39	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 LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	20734/1 14.11.2022
40	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	20298/3 14.11.2022

41	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	20299/3 14.11.2022
42	Diclofenac	diclofenac (diclofenac sodium)	gel for external use	10mg/g; 40g aluminium tube	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb-batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	OTC	20775/1 14.11.2022
43	Sandostatin LAR	octreotide (octreotide acetate)	powder for suspension for injection.	20mg; glass vial, 2ml solvent in pre-filled syringe, adapter and needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- secondary packager, batch releaser, Sandoz GmbH, Biochemiestrasse 10, 6336 Langkampfen, Austria- bulk manufacturer, primary packager, ABBOTT Biologicals B.V., Veerweg 12, 8121, AA Olst, the Netherlands- solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18641/3/2 14.11.2022

44	Sandostatin LAR	octreotide (octreotide acetate)	powder for suspension for injection	30mg; glass vial, 2ml solvent in pre-filled syringe, adapter and needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- secondary packager, batch releaser, Sandoz GmbH, Biochemiestrasse 10, 6336 Langkampfen, Austria- bulk manufacturer, primary packager, ABBOTT Biologicals B.V., Veerweg 12, 8121, AA Olst, the Netherlands- solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18642/3/2 14.11.2022
45	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	20278/1 14.11.2022
46	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	18535/6/1 14.11.2022

47	Enterol 250	lyophilized cells of saccharomyces boulardii	powder for oral suspension	250mg; (10) sachets	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	OTC	17504/3 14.11.2022
48	AmoxiClav-Denk 500/62,5	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+62,5mg; (16/2x8/) in blister	PenCef Pharma GmbH, Breitenbachstrasse 13-14, 13509 Berlin- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed Pharbil Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20171/1 14.11.2022
49	Rufixalo	rivaroxaban	tablets film-coated	2,5mg; (56/4x14/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20753/1 14.11.2022

50	Rufixalo	rivaroxaban	tablets film-coated	10mg; (10/1x10/) in blister, (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20754/1 14.11.2022
51	Rufixalo	rivaroxaban	tablets film-coated	15mg; (28/2x14/) in blister, (42/3x14/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20755/1 14.11.2022
52	Rufixalo	rivaroxaban	tablets film-coated	20mg; (28/2x14/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20756/1 14.11.2022

53	Meloxicam	meloxicam	solution for i/m injection	10mg/ml; (5) ampoules 1.5ml	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20765/1 14.11.2022
54	Zolomaks	alprazolam	tablets	0,25mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga-batch releaser, packager, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany- bulk manufacturer	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17927/1 14.11.2022
55	Zolomaks	alprazolam	tablets	0,5mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga-batch releaser, packager, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany- bulk manufacturer	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17926/1 14.11.2022

56	Zolomaks	alprazolam	tablets	1mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga- batch releaser, packager, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany- bulk manufacturer	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17925/1 14.11.2022
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