

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-2/22 on April 21, 2022

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Clomentin	escitalopram (escitalopram oxalate)	tablets film-coated	10mg; (28/2x14/) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia-secondary packaging, batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, primary packaging, quality control	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia	Cyprus	PoM	21.04.2022
2	Befeton	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (10) ampoules 3ml	Divine Laboratories Pvt. Ltd. Block N471, Dabhasa, Tal-Padra, Dist. Vadodara-391440	India	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	

3	Ambroxol-Hemofarm	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml glass bottle and 5ml measuring spoon	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb-batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb	Serbia	OTC	21.04.2022
4	Instgra	dolutegravir (dolutegravir sodium)	tablets film-coated	50mg; N30in plastic container, N90in plastic container, N180 in plastic container	Emcure Pharmaceuticals Ltd.,Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026	India	PoM	21.04.2022
5	Carsil Forte	silymarin	capsules hard	90mg; (30/5x6/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	21.04.2022
6	Angiseptin	chlorhexidine (chlorhexidine diacetate), tetracaine (tetracaine hydrochloride), ascorbic acid	lozenges	2mg, 0.2mg, 50mg; (18/6x3/) in blister	Rubicon LLC, 62-B, M. Gorky street, Vitebsk- bulk manufacturer, packager, batch releaser, "Rubicon" LLC, 62-2, M. Gorky street, Vitebsk, Belarus-quality control (physicochemical and microbiological)	Belarus	Rubicon LLC, 62B, M. Gorky street, Vitebsk	Belarus	OTC	21.04.2022
7	Migralgin	sumatriptan (sumatriptan succinate)	tablets film-coated	50mg; (10/1x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21.04.2022

8	Migralgin	sumatriptan (sumatriptan succinate)	tablets film-coated	100mg; (10/1x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21.04.2022
9	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	21.04.2022
10	Bupivacaine hydrochloride 5mg/ml	bupivacaine (bupivacaine hydrochloride)	solution for injection	5mg/ml; (5) ampoules 4ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality Pharmaceuticals Limited, Village Nag Kalan, Majitha Road, Majitha, Amritsar, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	21.04.2022

11	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; 30mg/5ml, glass vial 5ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi	Georgia	PoM	21.04.2022
12	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; 100mg/16.7ml, glass vial 20ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi	Georgia	PoM	21.04.2022
13	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; 150mg/25ml, glass vial 25ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi	Georgia	PoM	21.04.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-2/22 on April 21, 2022

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	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	21.04.2022
2	Dexalfen	dexketoprofen (dexketoprofen trometamol)	solution for i/m and i/v injection	25mg/ml; (5/1x5/) ampoules 2ml in blister, N5(1x5) 2ml ampoules in PVC/polimer film blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region-quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	21.04.2022

3	Drotaverine hydrochloride	drotaverine (drotaverine hydrochloride)	tablets	40mg; (20/2x10/) in blister	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	OTC	21.04.2022
4	Oxytocin Grindeks	oxytocin	solution for injection	5IU/ml; (10/2x5/) ampoules 1ml in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, packager	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21.04.2022
5	Indometacin Sopharma 25mg gastro-resistant tablets	indometacin	tablets gastro-resistant	25mg; (30/1x30/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	21.04.2022
6	Sodium chloride	sodium chloride	solution for topical application	50mg/ml; (1) plastic vial-dropper 10ml, (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	OTC	21.04.2022
7	Cefecon D	paracetamol	suppositories rectal	50mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21.04.2022

8	Cefecon D	paracetamol	suppositories rectal	100mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21.04.2022
9	Cefecon D	paracetamol	suppositories rectal	250mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21.04.2022
10	Benzylpenicillin	benzylpenicillin (benzylpenicillin sodium)	powder for solution for injection	1000000IU; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	21.04.2022
11	Depakine enteric 300	valproate sodium (valproic acid)	tablets gastro- resistant	300mg; (100/10x10/) in blister	Sanofi-Aventis S.A., Ctra. C35 La Batlloria a Hostalric, km 63.09,17404 Riells I Viabrea (Girona)	Spain	Sanofi Winthrop Industrie, 1, rue de la Vierge- Ambares et Lagreve, 33565 Carbon Blanc- Cedex	France	PoM	21.04.2022
12	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	solution for infusion	2mg/ml; 200ml plastic pack	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21.04.2022

13	Pikovit	vitamin A, vitamin D3, vitamin C, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin PP, folic acid, vitamin B5, calcium phosphate	pastilles	0.35mg+0.08mg+10mg+0.25mg+0.3mg+0.3mg+0.2mg+3mg+0.04mg+1.2mg+43mg; (30/2x15/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- batch releaser, quality control (microbiological), KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- bulk manufacturer, packager, 1. KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia 2.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21.04.2022
14	Zyrtec	cetirizine (cetirizine dihydrochloride)	drops oral	10mg/ml; 10ml glass bottle	Aesica Pharmaceuticals S.r.l., Via Praglia, 15-10044 Pianezza (TO)	Italy	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9S	UK	OTC	21.04.2022
15	Essliver Forte	essential phospholipids, thiamine (thiamine mononitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), alpha-tocopherol acetate, nicotinamide, cyanocobalamin	capsules	300mg+6mg+6mg+6mg+6mg+30mg+6mcg; (30/3x10/) in blister, (50/5x10/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7- secondary packager, quality control, batch releaser, Nabros Pharma Pvt. Ltd., Survey No110/A/2 Amit Farm, Jain Upasrya, N.H. No. 8 Kajipura, Kheda, 387411, Gujarat, India- bulk manufacturer, primary packager	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21.04.2022

16	Hemomycin	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; 60ml glass bottle with 10g powder and measuring spoon 5ml	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	PoM	21.04.2022
17	Vegarpi	sildenafil (sildenafil citrate)	tablets coated	50mg; (10/1x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21.04.2022
18	Dapsone	dapsone	tablets	100mg; (50/5x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21.04.2022
19	CoLosar-Denk 50/12,5	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, SYNLAB Analytics & Services Germany GmbH, Hauptstrasse 105, 04416 Markkleeberg, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	21.04.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/22 on April 21, 2022

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Riboxin	inosine	tablets coated	200mg; (50/5x10/) blisters	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1-quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5 No6, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	16915/1/1
2	Warfarin STADA	warfarin (warfarin sodium)	tablets	2,5mg; (50) and (100) in plastic container, (50/1x50/) and (100/1x100/) in plastic container	Takeda Pharma Sp.z o.o., 12 Ksiestwa Lowickiego st., 99-420 Lyszkowice	Poland	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	16936/2/1

3	Emsibel	methylethylpyridinol hydrochloride	drops eye (solution)	10mg/ml; 5ml vial-dropper	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/1, No 5, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	17289/1/1
4	RotaTeq	rotavirus type G1, rotavirus type G2, rotavirus type G3, rotavirus type G4, rotavirus type P1A	solution oral	not less than 2,2x10 ⁶ IU+not less than 2,8x10 ⁶ IU+not less than 2,2x10 ⁶ IU+not less than 2x10 ⁶ IU+not less than 2,3x10 ⁶ IU; (1) plastic tube 2ml and (10) plastic tube 2ml	Merck Sharp & Dohme B.V. Waarderweg 39, Haarlem 2031 BN- batch releaser, Merck Sharp & Dohme Corp., 770 Sumneytown Pike, West Point, Pennsylvania(PA) 19486, USA- bulk manufacturer, packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	17626/2/2
5	CoPlavix	clopidogrel, acetylsalicylic acid	tablets film-coated	75mg+100mg; (30/3x10/) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	17195/2/2
6	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	20mg; (14/1x14/) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	OTC	18684/2/1

7	Levetiracetam Canon	levetiracetam	tablets film-coated	500mg; (30/3x10/) in blister, (60/6x10/) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	18288/3/1
8	Ibuprofen Medana	ibuprofen	suspension oral with strawberry flavour	20mg/ml; plastic container 100ml and measuring syringe, plastic container 120ml and measuring syringe	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St., 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej St., 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	OTC	19094/1/1
9	Januvia	sitagliptin (sitagliptin phosphate hydrate)	tablets film-coated	100mg; (28/2x14/) in blister	Organon Pharma (UK) Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU	UK	Merck Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18855/2/2

10	Gabapentin	gabapentin	capsules hard	300mg; (30/3x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20211/1
11	Pneumovax 23	pneumococcal polysaccharide vaccine	solution for injection	25mcg/0,5ml; 0,5ml glass vial	Merck Sharp & Dohme B.V. Waarderweg 39,2031 BN Haarlem- batch releaser, secondary packager, Merck Sharp & Dohme Corp., Sumneytown Pike P.O. Box West Point, Pennsylvania 19486-0004, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	16908/2/2
12	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 1209 Orange street, Wilmington DE 19801	USA	PoM	19129/3/1

13	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 1209 Orange street, Wilmington DE 19801	USA	PoM	19130/3/1
14	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, Glienicker Weg 125, 12489 Berlin	Germany	PoM	19870/1/1
15	Soolantra	ivermectin	cream	10mg/g; 2g plastic tube, 15g plastic tube, 30g plastic tube, 45g plastic tube, 60g plastic tube	Laboratoires Galderma Z.I. Montdesir, 74540 Alby-sur-Cheran	France	Galderma SA, Zahlerweg 10, 6300 Zug	Switzerland	PoM	20121/1/1

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/22 on April 21, 2022

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Dibase 10,000I.U./ml oral drops, solution	colecalciferol (vitamin D3)	drops oral, solution	10000IU/ml; glass bottle 10ml and dropper	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	18334/2
2	Dibase 25,000I.U./2.5ml oral solution	colecalciferol (vitamin D3)	solution oral	25000IU/2.5ml; glass bottle 2.5ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	18335/2
3	Dibase 50,000I.U./2.5ml oral solution	colecalciferol (vitamin D3)	solution oral	50000IU/2.5ml; glass bottle 2.5ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	18336/3

4	Drotaverine hydrochloride	drotaverine (drotaverine hydrochloride)	tablets	40mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	OTC	16852/1
5	Dexalfen	dexketoprofen (dexketoprofen trometamol)	solution for i/m and i/v injection	25mg/ml; (5/1x5/) ampoules 2ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region, - quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad district, Moscow Region, 141345	Russia	PoM	16600/3/1

6	Nebilet Plus 5/12,5	nebivolol (nebivolol hydrochloride), hydrochlorothiazide	tablets film-coated	5mg+12,5mg; (28/2x14/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical), Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (microbiological)	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	20199/1
7	Bronchobos	carbocisteine	syrup	125mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19988/2
8	Bronchobos	carbocisteine	syrup	250mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19989/2

9	Allergosan	chloropyramine (chloropyramine hydrochloride)	cream for external use	10mg/g; aluminium tube 18g	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	19401/1
10	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18320/5/1
11	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18321/5/1
12	Pikovit	vitamin A, vitamin D3, vitamin C, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin PP, folic acid, vitamin B5, calcium phosphate	pastilles	0.35mg+0.08mg+10mg+0.25mg+0.3mg+0.3mg+0.2mg+3mg+0.04mg+1.2mg+43mg; (30/2x15/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto - batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	16195/2
13	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (60/6x10/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20117/2

14	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (60/4x15/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow for	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20118/2
15	Anaferon kids	affinity purified antibodies to human interferon gamma	drops oral	6mg/ml; 25ml glass vial-dropper	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139 for	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	17922/1
16	Simulect	basiliximab	powder lyophilized for solution for injection or infusion	20mg glass vial and solvent in ampoule 5ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz, Austria- solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19577/2
17	Simulect	basiliximab	powder lyophilized for solution for injection or infusion	20mg; glass vial and solvent in ampoule 5ml	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- powder bulk manufacturer, packager, quality control, batch releaser, Delpharm Dijon, 6, Boulevard de l'Europe 21800, France- solvent bulk manufacturer, primary packager, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20279/3

18	Sodium chloride	sodium chloride	solution for topical application	50mg/ml; (1) plastic vial-dropper 10ml, (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	OTC	16526/2
19	Indometacin Sopharma 25mg gastro-resistant tablets	indometacin	tablets gastro-resistant	25mg; (30/1x30/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	16493/2
20	Zyrtec	cetirizine (cetirizine dihydrochloride)	drops oral	10mg/ml; 10ml glass bottle	Aesica Pharmaceuticals S.r.l., Via Praglia, 15-10044 Pianezza (TO)	Italy	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	16816/1
21	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) glass cartridges 3ml	Lilly France S.A.S., 2, rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991, RA Houten	the Netherlands	PoM	18646/3
22	Humalog Mix 25	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., 2, rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991, RA Houten	the Netherlands	PoM	17366/2

23	Octanine F	human blood coagulation factor IX	powder and solvent for solution for injection	500IU; glass vial, 5ml solvent in glass vial, disposable syringe, transfer set (double-ended needle, filter needle), infusion set, (2) alcohol swabs	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	PoM	16708/1
24	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2,5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20382/1
25	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (10/1x10/) in blister	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	17176/2
26	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	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	17177/2

27	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	100mg (1) glass vial 15ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	17110/2
28	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	160mg; (1) glass vial 20ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	17109/2
29	Arcoxia	etoricoxib	tablets film-coated	60mg; (7/1x7/) in blister, (28/4x7/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, batch releaser, Rovi Pharma Industrial Services S.A, Via Complutense 140, 28805 Alcala de Henares, Madrid, Spain- bulk manufacturer, quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19968/1
30	Arcoxia	etoricoxib	tablets film-coated	90mg; (7/1x7/) in blister, (28/4x7/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, batch releaser, Rovi Pharma Industrial Services S.A, Via Complutense 140, 28805 Alcala de Henares, Madrid, Spain- bulk manufacturer, quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19969/1

31	Arcoxia	etoricoxib	tablets film-coated	120mg; (7/1x7/) in blister, (28/4x7/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, batch releaser, Rovi Pharma Industrial Services S.A, Via Complutense 140, 28805 Alcala de Henares, Madrid, Spain- bulk manufacturer, quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19970/1
32	Flucinar N	fluocinolone acetonide, neomycin (neomycin sulphate)	ointment for topical 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	15019/1
33	Cordarone	amiodarone (amiodarone hydrochloride)	tablets	200mg; (30/2x15/) in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5,	Hungary	Sanofi-Aventis France, 1-13, boulevard Romain Rolland, 75014 Paris	France	PoM	15080/3
34	Decapeptil	triptorelin (triptorelin acetate)	solution for s/c injection	0,1mg/ml; (7) pre-filled syringe 1ml	Ferring GmbH, Wittland 11, 24109 Kiel - bulk manufacturer, primary packager, batch releaser, Ferring-Leciva, a.s.(areal spol. ECP, a.s.) , Ke Skale 455, Vestec u Prahy, 25242, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	17949/2/1

35	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	solution for infusion	2mg/ml; 200ml plastic pack	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	16264/1
36	Vizoptin	tetryzoline (tetryzoline hydrochloride)	drops eye (solution)	0,5mg/ml; 15ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	OTC	17067/1
37	Stopdiar	nifuroxazide	suspension oral	220mg/5ml; glass bottle 90ml and dual measuring spoon (2,5ml/5ml)	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., 540306, Targu-Mures, Romania- bulk manufacturer, packager, quality control	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20230/2
38	Hemomycin	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; 60ml glass bottle with 10g powder and measuring spoon 5ml	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia-bulk manufacturer, packager	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	PoM	16289/4

39	BeneFix 250IU	nonacog alfa	powder and solvent for solution for injection	250IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	18620/3
40	BeneFix 500IU	nonacog alfa	powder and solvent for solution for injection	500IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles,	Belgium	PoM	18621/3

41	BeneFix 1000IU	nonacog alfa	powder and solvent for solution for injection	1000IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	18622/3
42	BeneFix 2000IU	nonacog alfa	powder and solvent for solution for injection	2000IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	18623/3
43	Virolex	aciclovir	powder for solution for infusion	250mg; (5) glass vial	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, secondary packager, GlaxoSmithKline Manufacturing S.p.A., Strada Provinciale Asolana, 90, 43056 San Polo di Torrile, Parma, Italy- bulk manufacturer, primary packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	16122/1

44	Zyvox	linezolid	tablets film-coated	600mg; (10/1x10/) in blister	Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693	USA	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, 10017	USA	PoM	19288/2
45	Taflotan PF	tafluprost	drops eye	15mcg/ml; pastic bottle 3ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19799/1
46	Benzylpenicillin	benzylpenicillin (benzylpenicillin sodium)	powder for solution for injection	1000000IU; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	15960/1
47	Allergosan	chloropyramine (chloropyramine hydrochloride)	ointment for external use	10mg/g; aluminium tube 18g	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	19402/1
48	TaiCold with lemon flavour	paracetamol,chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with lemon flavour	500mg+2mg+30mg; (10) sachet	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	17688/1

49	TaiCold with raspberry flavour	paracetamol, chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	500mg+2mg+30mg; (10) sachet	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	17689/1
50	Trittico	trazodone	tablets prolonged-release	150mg; (20/2x10) in blister	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Via Vecchia del Pinocchio, 22-60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Viale Amelia, 70, 00181, Rome	Italy	PoM	18798/3/1
51	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	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	16694/1
52	Zyvox	linezolid	solution for infusion	2mg/ml; (10) plastic packs 300ml	Fresenius Kabi Norge AS, Svinesundsveien 80 HALDEN, NO-1788	Norway	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	17651/4
53	Depakine enteric 300	valproate sodium (valproic acid)	tablets gastro-resistant	300mg; (100/10x10/) in blister	Sanofi-Aventis S.A., Ctra. C35 La Batlloria a Hostalric, km 63.09,17404 Riells I Viabrea (Girona)	Spain	Sanofi Winthrop Industrie, 1, rue de la Vierge-Ambares et Lagreve, 33565 Carbon Blanc-Cedex	France	PoM	15910/2

54	Zyrtec	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg; (7/1x7/) in blister	Aesica Pharmaceuticals S.r.l., Via Praglia, 15-10044 Pianezza (TO) - packager, quality control, batch releaser, UCB Farchim S.A., Z.I. de Planchy, Chemin de Croix Blanche 10, CH-1630 Bulle, Switzerland- bulk manufacturer	Italy	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9S	UK	OTC	19624/1
55	Metformin	metformin (metformin hydrochloride)	tablets	1000mg; (30/2x15/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18608/2
56	Mecol	chloramphenicol, methyluracil	ointment for external use	7,5mg/g+40mg/g; aluminium tube 40g	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	OTC	19878/1

57	Refacto AF 250IU	moroctocog alfa	powder and solvent for solution for injection	250IU; glass vial, solvent in pre-filled syringe 4ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid- powder manufacturer, solvent secondary packager, quality control, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstr. 2-4, 88085 Langenargen, Germany- solvent bulk manufacturer, primary packager, quality	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	19565/1
58	Refacto AF 500IU	moroctocog alfa	powder and solvent for solution for injection	500IU; glass vial, solvent in pre-filled syringe 4ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid- powder manufacturer, solvent secondary packager, quality control, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstr. 2-4, 88085 Langenargen, Germany- solvent bulk manufacturer, primary packager, quality	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	19566/1

59	Refacto AF 1000IU	moroctocog alfa	powder and solvent for solution for injection	1000IU; glass vial, solvent in pre-filled syringe 4ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid- powder manufacturer, solvent secondary packager, quality control, batch releaser, Vetter Pharma- Fertigung GmbH & Co. KG, Eisenbahnstr. 2-4, 88085 Langenargen, Germany- solvent bulk manufacturer, primary packager, quality	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	19567/1
60	Cinnarizine Sopharma	cinnarizine	tablets	25mg; (50/1x50/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20493/1
61	Ketonal	ketoprofen	cream for external use	50mg/g; aluminium tube 30g	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen	Germany	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19812/1
62	Recormon	epoetin beta	solution for i/v and s/c injection	2000IU/0,3ml; (6) pre- filled syringes 0,3ml and (6) needles	Roche Diagnostics GmbH, Sandhofer Strasse 116, D- 68305 Mannheim	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18566/3

63	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml, in blister	BIOCAD CJSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- bulk manufacturer, packager, batch releaser, BIOCAD CJSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- quality control	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Saint Petersburg, 198515	Russia	PoM	16421/1
64	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; 50ml glass vial	BIOCAD CJSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- bulk manufacturer, packager, batch releaser, BIOCAD CJSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- quality control	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Saint Petersburg, 198515	Russia	PoM	16420/1
65	Elocom	mometasone (mometasone furoate)	lotion	1mg/g; 30ml plastic vial-dropper	Delpharm Montreal Inc., 3535 Route Trans Canada Highway, Pointe-Claire, QC H9R 1B4	Canada	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	17857/4/1

66	Oftagel	carbomer 974P	gel eye	2,5mg/g; plastic vial-dropper 10g	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 35, 66129 Saarbrücken, Germany- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	19860/1
67	Dapsone	dapsone	tablets	100mg; (50/5x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	16759/1
68	Vegarpi	sildenafil (sildenafil citrate)	tablets coated	50mg; (10/1x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	16645/2
69	CoLosar-Denk 50/12,5	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	16076/5