

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 6-1/20 on June 12, 2020

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	Sildenafil	sildenafil (sildenafil citrate)	tablets film-coated	100mg; (4/1x4/) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	R	19262 12.06.2020
2	Caffetin Duo	ibuprofen, paracetamol	tablets film-coated	200mg+500mg; (10/1x10/) in blister, (20/2x20/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	19263 12.06.2020
3	Protadil	alprostadil	solution for infusion	500mcg/ml; (5) ampoules 1ml	Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	R	19266 12.06.2020
4	Oftaquix	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; 5ml plastic bottle-dropper	Santen Oy, Niittyhaankatu 20, 33720 Tampere-batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	R	19267 12.06.2020

5	Imbruvica	ibrutinib	capsules	140mg; (90) plastic bottle, (120) plastic bottle	Cilag AG, Hochstrasse 201, 8200 Schaffhausen	Switzerland	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17/2	Russia	R	19268 12.06.2020
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LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 6-1/20 on June 12, 2020

President _____ E. Amroya

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	Charcoal activated	charcoal activated	tablets	250mg; (10) in blister, (10/1x10/) in blister, (30/3x10) in blister, (50/5x10/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19163/1 12.06.2020

LIST

of the medicines recommended for the registration (new indication) by the Center according to the meeting decision N 6-1/20 on June 12, 2020

President _____ E. Amroya

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	Pabal	carbetocin	solution for injection	100mcg/ml; (5/1x5/) glass vial 1ml in plastic tray	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 Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS	UK	R	18360/1 12.06.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 6-1/20 on June 12, 2020

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	Deslora-Denk 5mg	desloratadine	tablets film-coated	5mg; (10/1x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	19269 12.06.2020
2	Verospiron	spironolactone	tablets	25mg; (20/1x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19270 12.06.2020
3	Eurofer	iron (III)-hydroxide polymaltose complex	syrup	10mg/ml; glass bottle 60ml, glass bottle 120ml	Osoth Inter Laboratories Co., Ltd., 600/9 Moo 11, Sukhaphiban 8 Road, Nong Kham, Si Racha, Chonburi 20230	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19271 12.06.2020

4	Tiregis D	telmisartan, hydrochlorothiazide	tablets	40mg+12,5mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	19272 12.06.2020
5	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+12,5mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	19273 12.06.2020
6	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+25mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	19274 12.06.2020
7	Amaryl M	glimepiride, metformin (metformin hydrochloride)	tablets film- coated	2mg+500mg; (30/3x10/) in blister	Handok Inc., 78 Daepungsandan-ro, Daeso- myeon, Eumseong-gun, Chungcheongbuk-do	Korea South	Sanofi-aventis group, 54, rue La Boetie, 75008 Paris	France	R	19275 12.06.2020

8	Normodipine	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19276 12.06.2020
9	Normodipine	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19277 12.06.2020
10	Rheopolyglucin-PharmaTech	dextran 40	solution for infusion	100mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19278 12.06.2020
11	Ringer	sodium chloride, potassium chloride, calcium chloride (calcium chloride dihydrate)	solution for infusion	8,6mg/ml+0,3mg/ml+0,33mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack, 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19279 12.06.2020
12	Sodium chloride solution 0.9%	sodium chloride	solution for infusion	9mg/ml; 50ml plastic pack, 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack, 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19280 12.06.2020

13	Polyglucin-PharmaTech	dextran 70	solution for infusion	60mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19281 12.06.2020
14	Floxadex	ciprofloxacin (ciprofloxacin hydrochloride), dexamethasone	suspension eye/ear	3mg/ml+1mg/ml; 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	R	19282 12.06.2020
15	Ceftriaxone 1g powder for solution for injection	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (10) glass vials	CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF- batch releaser, Labesfal-Laboratorios Almiro, S.A, Zona Industrial do Lagedo, Santiago de Besteiros, 3465-157, Portugal- bulk manufacturer, packager, quality control	UK	Wockhardt UK Ltd., Ash Road North, Wrexham, LL13 9UF	UK	R	19283 12.06.2020
16	Octanate 250IU	human blood coagulation factor VIII	powder and solvent for solution for injection	50IU/ml; (1) glass vial, (1) solvent in glass vial 5ml, (1) transfer set ((1) double-ended needle, (1) filter needle), (1) disposable syringe, (1) 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	R	19284 12.06.2020

17	Octanate 500IU	human blood coagulation factor VIII	powder and solvent for solution for injection	50IU/ml; (1) glass vial, (1) solvent in glass vial 10ml, (1) transfer set ((1) double-ended needle, (1) filter needle), (1) disposable syringe, (1) 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	R	19285 12.06.2020
18	Octanate 1000IU	human blood coagulation factor VIII	powder and solvent for solution for injection	100IU/ml; 1) glass vial, (1) solvent in glass vial 10ml, (1) transfer set ((1) double-ended needle, (1) filter needle), (1) disposable syringe, (1) 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	R	19286 12.06.2020
19	Sermion	nicergoline	powder lyophilized for solution for injection	4mg; (4) glass vials, (4) solvent in ampoules 4ml	Actavis Italy S.p.A., Viale Pasteur, 10, 20014 Nerviano, Milan	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	R	19287 12.06.2020
20	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	R	19288 12.06.2020

LIST

of the medicines recommended for the re-registration (new packaging) by the Center according to the meeting decision N 6-1/20 on June 12, 2020

President _____ E. Amroya

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	Neoderm	gramicidin, neomycin (neomycin sulfate), nystatin, triamcinolone acetonide	cream	0,25mg/g+2,5mg/g+100000IU/g+1mg/g; aluminium tube 10g; aluminium tube 20g	Birzeit Pharmaceutical Company (BPC), Ramallah,Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	R	19257/1 12.06.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 6-1/20 on June 12, 2020

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	Biseptol	sulfamethoxazole, trimethoprim	tablets	400mg+80mg; (20/1x20/) in blister, (28/2x14/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	R	18264/1/1 12.06.2020
2	Biseptol	sulfamethoxazole, trimethoprim	tablets	100mg+20mg; (20/1x20/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	R	18263/1/1 12.06.2020
3	TheraFlu	paracetamol, pheniramine (pheniramine maleate), phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	325mg+20mg+10mg+50 mg; (10) sachets 22,1g	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans Cedex 02	France	GSK Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	OTC	U7	18194/1/1 12.06.2020

4	Theraflu Extra Lemon	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate)	powder for oral solution with lemon flavour	650mg+10mg+20mg; (10) sachets 15g	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans Cedex 02	France	GSK Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18569/1/1 12.06.2020
5	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 4ml	BIOCAD CJSC, Petrovo-Dalnee, Krasnogorsky district, Moscow Region, 143422	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Petrodvortsoviy district, Saint Petersburg, 198515	Russia	R	17910/1/1 12.06.2020
6	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 16ml	BIOCAD CJSC, Petrovo-Dalnee, Krasnogorsky district, Moscow Region, 143422	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st., Strelna, Petrodvortsoviy district, Saint Petersburg, 198515	Russia	R	17911/1/1 12.06.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 6-1/20 on June 12, 2020

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	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	R	17517/1 12.06.2020
2	Allergosan	chloropyramine (chloropyramine hydrochloride)	ointment for external use	10mg/g; 18g aluminium tube	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia - batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria-bulk manufacturer, primary and secondary packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	14895/1 12.06.2020
3	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	R	18535/2 12.06.2020

4	Allergosan	chloropyramine (chloropyramine hydrochloride)	cream for external use	10mg/g; 18g aluminium tube	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia - batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria-bulk manufacturer, primary and secondary packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	14896/1 12.06.2020
5	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18673/2 12.06.2020
6	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (30/3x10/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19146/1 12.06.2020
7	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18674/2 12.06.2020

8	Sentor	losartan (losartan potassium)	tablets film-coated	50mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18374/2 12.06.2020
9	Sentor	losartan (losartan potassium)	tablets film-coated	100mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18375/2 12.06.2020
10	Fungoterbine	terbinafine (terbinafine hydrochloride)	spray for external use	10mg/g; plastic container 30g with pump dispenser	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18368/1 12.06.2020
11	Efferalgan	paracetamol	suppositories rectal	80mg; (10/2x5/)	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	18322/1 12.06.2020

12	Epclusa	sofosbuvir, velpatasvir	tablets film-coated	400mg+100mg; (28) plastic container	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill, Co. Cork-secondary packager, batch releaser, Patheon Inc., 2100 Syntex Court, Mississauga , Ontario L5N 7K9, (CAN), Canada-bulk manufacturer, primary packager	Ireland	Gilead Sciences Inc., 333 Lakeside Drive, Foster City, CA 94404	USA	R	18488/1 12.06.2020
13	Hartil	ramipril	tablets	2,5mg; (14/2x7/) and (28/4x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15070/1 12.06.2020
14	Hartil	ramipril	tablets	5mg; (14/2x7/) and (28/4x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15068/1 12.06.2020

15	Hartil	ramipril	tablets	10mg; (14/2x7/) and (28/4x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15069/1 12.06.2020
16	Herbion Iceland moss syrup	iceland moss thick extract	syrup	6mg/ml; 150ml glass bottle and measuring spoon	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	15784/2 12.06.2020
17	Ciprinol	ciprofloxacin (ciprofloxacin hydrochloride monohydrate)	tablets film-coated	250mg; (10/1x10/) 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	R	16402/1 12.06.2020
18	Ciprinol	ciprofloxacin (ciprofloxacin hydrochloride monohydrate)	tablets film-coated	500mg; (10/1x10/) 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	R	16403/1 12.06.2020

19	Cefichew	cefixime (cefixime trihydrate)	tablets chewable	400mg; (10/1x10/) blister	SRS Pharmaceuticals Pvt. Ltd., Plot No.11 & 12 Kumar Industrial Estate, Gat No. 1251-1261, Alandi-Markal Road, Markal, Pune 412 105	India	SRS Pharmaceuticals Pvt. Ltd., 602, 6th Floor, Marathon Max Bldg. No 2, Mulund Goreagon Link Road L.B.S. Marg, Mulund, Goreagon Link Road L.B.S. Marg, Mulund, Mumbai,400 080	India	R	14218/1 12.06.2020
20	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,05mg/ml; (5) ampoules 1ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	16615/3 12.06.2020
21	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB - batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel-bulk manufacturer, packager	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire , NN11 8PB	UK	R	18024/2 12.06.2020
22	Recreol	dexpanthenol	cream	50mg/g; 30g and 50g aluminium tube	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	17713/1 12.06.2020

23	Dicynone	etamsylate	tablets	250mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia-bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	17275/1 12.06.2020
24	Nicotinic acid-Darnitsa	nicotinic acid	solution for injection	10mg/ml; (10/2x5/) ampoules 1ml, in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	R	17988/1 12.06.2020
25	Heptral	ademetionine	tablets gastro-resistant	400mg; (20/2x10/) in blister	AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC - Campoverde di Aprilia (loc. Aprilia)-04011 Aprilia (LT)	Italy	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	R	15870/1 12.06.2020
26	Amaryl M	glimepiride, metformin (metformin hydrochloride)	tablets film-coated	2mg+500mg; (30/3x10/) blisters	Handok Inc., 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do, Korea South	Korea South	Sanofi-aventis group, 54, rue La Boetie, 75008 Paris	France	R	14305/2 12.06.2020
27	Stomatidin	hexetidine	solution for topical use	1mg/ml; 200ml glass vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	18051/1 12.06.2020

28	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18638/1 12.06.2020
29	Pimafucin	natamycin	suppositories vaginal	100mg; (3/1x3/), (6/2x3/)	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	R	16022/2 12.06.2020
30	Ketoconazole	ketoconazole	shampoo	20mg/ml; 100ml plastic container	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	R	14871/1 12.06.2020
31	Amlodipine	amlodipine (amlodipine besilate)	tablets	5mg; (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	R	14870/2 12.06.2020
32	Amlodipine	amlodipine (amlodipine besilate)	tablets	10mg; (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	R	18611/1 12.06.2020

33	Femoston 2/10	pink tablet- estradiol, yellow tablet- estradiol + dydrogesterone	tablets film-coated	2mg+2mg+10mg; (28/14pink tablets + 14yellow tablets/) blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	R	19006/1 12.06.2020
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