

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 5-2/20 on May 26, 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	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5/ ampoules 1ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznyakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345-quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, rural settlement Bereznyakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm " CJSC, Bld. 11, village Belikovo, rural settlement Bereznyakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	R	19244 26.05.2020

2	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5/ ampoules 2ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev- Posad municipal district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, rural settlement Bereznjakovskoe, Sergiev- Posad municipal district, Moscow Region, 141345, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm " CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	R	19245 26.05.2020
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of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 5-2/20 on May 26, 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	Faslodex	fulvestrant	solution for injection	50mg/ml, (2) pre-filled syringes, (2) needles	AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK102NA- secondary packager, quality control, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99-101, Ravensburg, Baden-Wuerttemberg, 88212, Germany- bulk manufacturer, primary packager	UK	AstraZeneca AB Gartunavagen, Sodertalje, SE-15185	Sweden	R	19246 26.05.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 5-2/20 on May 26, 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	5% Glucose solution for injection	glucose anhydrous	solution for infusion	50mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack and 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19247 26.05.2020
2	10% Glucose solution for injection	glucose anhydrous	solution for infusion	100mg/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	19248 26.05.2020

3	Metformin Denk 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10/) in blister, (100/10x10/) 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	19249 26.05.2020
4	Codelac Broncho	ambroxol (ambroxol hydrochloride), sodium glycyrrhizinate (glycyrrhizinic acid trisodium), thermopsis extract, sodium hydrocarbonate	tablets	20mg+30mg+10mg+200 mg; (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	19250 26.05.2020
5	Immunate	human blood coagulation factor VIII/Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	250IU/190IU; (1) glass vial, (1) vial with solvent 5ml, (1) transfer/filter set, (1) disposable syringe 5ml, (1) disposable needle, (1) winged infusion set	Baxter AG, Industriestrasse 67, A-1221 Vienna- secondary packager, quality control, batch releaser, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria- powder manufacturer, primary packager, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- solvent manufacturer, primary packager	Austria	Baxter AG, Industriestrasse 67, A-1221 Vienna	Austria	R	19251 26.05.2020

6	Immunate	human blood coagulation factor VIII/Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	500IU/375IU; (1) glass vial, (1) vial with solvent 5ml, (1) transfer/filter set, (1) disposable syringe 5ml, (1) disposable needle, (1) winged infusion set	Baxter AG, Industriestrasse 67, A-1221 Vienna- secondary packager, quality control, batch releaser, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria- powder manufacturer, primary packager, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- solvent manufacturer, primary packager	Austria	Baxter AG, Industriestrasse 67, A-1221 Vienna	Austria	R	19252 26.05.2020
7	Immunate	human blood coagulation factor VIII/Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	1000IU/750IU; (1) glass vial, (1) vial with solvent 10ml, (1) transfer/filter set, (1) disposable syringe 10ml, (1) disposable needle, (1) winged infusion set	Baxter AG, Industriestrasse 67, A-1221 Vienna- secondary packager, quality control, batch releaser, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria- powder manufacturer, primary packager, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- solvent manufacturer, primary packager	Austria	Baxter AG, Industriestrasse 67, A-1221 Vienna	Austria	R	19253 26.05.2020
8	Aripegis	aripiprazole	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19254 26.05.2020

9	Aripegis	aripiprazole	tablets	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19255 26.05.2020
10	Aerius 5mg	desloratadine	tablets film-coated	5mg; (10/1x10/) in blister	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	R	19256 26.05.2020
11	Neoderm	gramicidin, neomycin (neomycin sulfate), nystatin, triamcinolone acetonide	cream	0,25mg/g+2,5mg/g+100 000IU/g+1mg/g; aluminium tube 10g	Birzeit Pharmaceutical Company (BPC), Ramallah, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Palestine, Ramallah, Almasion, Alnahda str. Jerusalem, P.O. box 51621	Palestine	R	19257 26.05.2020
12	Paracetamol GIGAfarm	paracetamol	tablets	500mg; (200/20x10/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Giga Farm LLC, Gogunts st. 3/5, Gyumri	Republic of Armenia	OTC	19258 26.05.2020
13	Pimafucort	natamycin, neomycin (neomycin sulfate), hydrocortisone (hydrocortisone micronized)	ointment for external use	10mg/g+3500U/g+10mg/g; aluminium tube 15g	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	R	19259 26.05.2020

14	Puregon	follitropin beta (recombinant)	solution for s/c injection	300IU/0,36ml; (1) cartridge 0,42ml, (6/2x3/) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weystrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	19260 26.05.2020
15	Puregon	follitropin beta (recombinant)	solution for s/c injection	600IU/0,72ml; (1) cartridge 0,78ml, (6/2x3/) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weystrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	19261 26.05.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 5-2/20 on May 26, 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	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	R	18320/2/1 26.05.2020
2	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	R	18321/2/1 26.05.2020
3	Nonpres	eplerenone	tablets film-coated	25mg; (20/2x10/) and (30/3x10/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	15108/1/2 26.05.2020

4	Nonpres	eplerenone	tablets film-coated	50mg; (20/2x10/) and (30/3x10/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	15107/1/2 26.05.2020
5	Suprastin	chloropyramine (chloropyramine hydrochloride)	tablets	25mg; (20/2x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15025/1/1 26.05.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 5-2/20 on May 26, 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	Zoloft	sertraline (sertraline hydrochloride)	tablets coated	50mg; (28/2x14/) in blister	Haupt Pharma Latina S.r.l., S.S 156, KM 47, 600 Borgo San Michele, 04100 Latina	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	R	16721/1 26.05.2020
2	Zoloft	sertraline (sertraline hydrochloride)	tablets film-coated	50mg; (28/2x14/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	R	18687/2 26.05.2020
3	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18505/2 26.05.2020
4	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18506/2 26.05.2020

5	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18507/2 26.05.2020
6	Amoxicillin	amoxicillin	granules for oral suspension	250mg/5ml; 40g granules in 100ml glass bottle and measuring spoon 5ml	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb-batch releaser, Hemofarm A.D., Vrsac, 26224, Dubovac, str. Cara Lazara bb, Serbia-bulk manufacturere, packager	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	R	16171/2 26.05.2020
7	Anusol	xeroform, belladonna extract, zinc (zinc sulfate)	suppositories rectal	100mg+20mg+50mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	16951/1 26.05.2020
8	Hepathrombin	heparin sodium, allantoin, dexpanthenol	gel for external use	300IU/g+2,5mg/g+2,5mg/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, Serbia-bulk manufacturer, packager	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	OTC	16316/1 26.05.2020
9	Ketoprofen	ketoprofen	gel for external use	25mg/g; 30g aluminum tube	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	R	16280/1 26.05.2020

10	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	cream	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, CH-6000 Lucerne 6	Switzerland	R	18445/2 26.05.2020
11	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	0,5mg/g+10mg/g+1mg/g; 15g aluminium tube	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	17677/1 26.05.2020
12	5-NOK	nitroxoline	tablets coated	50mg; (50) in plastic container	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana-quality control(microbiological), batch releaser, Lek Pharmaceuticals d.d., Kolodvorska cesta 27, Menges, 1234, Slovenia-bulk manufacturer, packager, quality control (physicochemical)	Slovenia	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18976/1 26.05.2020
13	Ferrum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	19069/1 26.05.2020
14	Dexalgin	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (10/1x10/), (30/3x10/) and (50/5x10/) in blister	Laboratorios Menarini S.A., str. Alfonso XII, 587 08918 Badalona (Barcelona)	Spain	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	OTC	16358/1 26.05.2020

15	Dexalgin	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (10/1x10/), (30/3x10/) and (50/5x10/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L` Aquila	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	OTC	17060/1 26.05.2020
16	Dexalgin sachet	dexketoprofen (dexketoprofen trometamol)	granules for oral solution	25mg; (10), (20), (30) sachets	Laboratorios Menarini S.A., str. Alfonso XII, 587 08918 Badalona (Barcelona)	Spain	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	OTC	16763/1 26.05.2020
17	Dilatrend	carvedilol	tablets	6,25mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald-batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20090 Segrate (MI), Italy- bulk manufacturer, packager	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	R	18234/1 26.05.2020
18	Dilatrend	carvedilol	tablets	12,5mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald-batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20090 Segrate (MI), Italy- bulk manufacturer, packager	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	R	18235/1 26.05.2020

19	Dilatrend	carvedilol	tablets	25mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald-batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20090 Segrate (MI), Italy-bulk manufacturer, packager	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	R	18236/1 26.05.2020
20	Ketonal Forte	ketoprofen	tablets film-coated	100mg; (20) in glass container	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18639/1 26.05.2020
21	ACC 200	acetylcysteine	tablets effervescent	200mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma Ges.m.b.H, Allgau 36, 9400 Wolfsberg, Austria-bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18716/1 26.05.2020
22	Dicloton 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection/infusion	25mg/ml; (5) ampoules 3ml	Medochemie Ltd., 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	R	14621/1 26.05.2020

23	Tiregis D	telmisartan, hydrochlorothiazide	tablets	40mg+12,5mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	14629/2 26.05.2020
24	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+12,5mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	14630/2 26.05.2020
25	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+25mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	14631/2 26.05.2020
26	Diclac gel 5%	diclofenac (diclofenac sodium)	gel for external use	50mg/g; 50g aluminium tube	Salutas Pharma GmbH, Betriebsstaette Osterweddigen, Lange Goehren 3,Suelzetal, OT Osterweddigen,Sachsen- Anhalt, 39171	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	16183/1 26.05.2020

27	Suprastin	chloropyramine (chloropyramine hydrochloride)	solution for injection	20mg/ml; (5/1x5/ ampoules 1ml, in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	15026/1 26.05.2020
28	Memantine Canon	memantine (memantine hydrochloride)	tablets film- coated	10mg; (30/3x10/) and (30/1x30/) in blister	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	R	15993/2 26.05.2020