

List
of the medicines recommended for registration by N 6-2/19 meeting decision of
the Pharmacological Council of MoH of RA dated on June 21, 2019

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.	BeneFix 250IU	nonacog alfa	powder 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 A1, Km 23, desvio Algete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden-Wuerttemberg, 88212, Germany-solvent	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18620 21.06.2019

					manufacturer					
2.	BeneFix 500IU	nonacog alfa	powder 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 A1, Km 23, desvioAlgete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden- Wuerttemberg, 88212, Germany- solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18621 21.06.2019
3.	BeneFix 1000IU	nonacog alfa	powder 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 A1, Km 23, desvioAlgete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18622 21.06.2019

					releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden- Wuerttemberg, 88212, Germany- solvent manufacturer					
4.	BeneFix 2000IU	nonacog alfa	powder 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 A1, Km 23, desvio Algete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden- Wuerttemberg, 88212, Germany- solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18623 21.06.2019

5.	Bromhexin 4 Berlin-Chemie	bromhexine (bromhexine hydrochloride)	solution oral	0,8mg/ml; glass bottle 60ml and measuring spoon	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	18624 21.06.2019
6.	Bromhexin 8 Berlin-Chemie	bromhexine (bromhexine hydrochloride)	coated tablets	8mg; (25/1x25/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin, Germany- bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	18625 21.06.2019
7.	Tramadol Denk 100mg/2ml	tramadol (tramadol hydrochloride)	solution for injection	50mg/ml; (5) ampoules 2ml	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	18626 21.06.2019
8.	Priorix	live attenuated measles virus(Schwarz strain), live attenuated mumps virus(RIT 4385 strain), live attenuated rubella virus(Wistar RA	powder and solvent for solution for injection	not less than 103.0CCID50/dose+not less than 103.7CCID50/dose+not less than 103.0CCID50/dose; (100(200 dose)) glass vial, (100) solvent in	GlaxoSmithKline Biologicals SA, Belgium, Parc de la Noire Epine, Avenue Fleming 20, Wavre, 1300-secondary packager, batch releaser, Fidia	Germany	GlaxoSmithKline Biologicals s.a., Rue de l Institut, 89 B-1330 Rixensart	Belgium	R	18627 21.06.2019

		27/3 strain)		ampoule 1ml	Farmaceutici S.P.A., Via Ponte Della Fabbrica 3/A-35031 Abano Terme (PD), Italy-bulk manufacturer, primary packager, Delpharm Tours Rue Paul Langevin BP 9024, 37172 Chambray-les- Tours, France- solvent manufacturer					
9.	Ambroxol- Zdorovye	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml plastic container and measuring spoon	Limited Liability Company "Pharmaceutical Company "Zdorovye", 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company "Pharmaceutical Company "Zdorovye", 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	OTC	18628 21.06.2019
10.	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film-coated	40mg+12,5mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Takeda Pharmaceuticals USA, Inc, One Takeda Parkway, Deerfield,Illinois 60015	USA	R	18629 21.06.2019

11.	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film-coated	40mg +25mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Takeda Pharmaceuticals USA, Inc, One Takeda Parkway, Deerfield, Illinois 60015	USA	R	18630 21.06.2019
12.	Refacto AF 250IU	moroctocog alfa	powder 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 A1, Km 23, desvio Algete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden-Wuerttemberg, 88212, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18631 21.06.2019
13.	Refacto AF 500IU	moroctocog alfa	powder for solution for injection	500IU; glass vial, solvent in pre-filled syringe 4ml, vial	Wyeth Farma S.A., Autovia del Norte A1, Km 23, desvio Algete, Km.	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18632 21.06.2019

				adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden-Wuerttemberg, 88212, Germany-solvent manufacturer					
14.	Refacto AF 1000IU	moroctocog alfa	powder 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 A1, Km 23, desvioAlgete, Km. 1, 287000 San Sebastian de los Reyes, Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, 87 und 99-101, Ravensburg, Baden-	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18633 21.06.2019

					Wuerttemberg, 88212, Germany- solvent manufacturer					
--	--	--	--	--	---	--	--	--	--	--

List
of the medicines recommended for registration (NEW RULE) by N 6-2/19 meeting decision of
the Pharmacological Council of MoH of RA dated on June 21, 2019

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.	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 5ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	R	18634 21.06.2019
2.	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 10ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	R	18635 21.06.2019
3.	Hypomed	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (40/1x40/) 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	18636 21.06.2019
4.	Glycine	glycine	tablets sublingual	100mg; (50/1x50/) 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	OTC	18637 21.06.2019

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	Ceraxon	citicoline (citicoline sodium)	solution oral	100mg/ml; (30) sachets 10ml	Ferrer Internacional, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Joan Gran Via Carlos III, 94 08028, Barcelona	Spain	R	18638 21.06.2019

List
of the variation recommended for registration by N 6-2/19 meeting decision of
the Pharmacological Council of MoH of RA dated on June 21, 2019

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.	Berodual	fenoterol (fenoterol hydrobromide), ipratropium bromide (ipratropium bromide monohydrate)	solution inhalation	500mcg/ml+261mcg/ml; 20ml glass container	Istituto de Angeli S.R.L. Loc. Prulli, 103/C 50066 Reggello, Firenze	Italy	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	R	16436/1 21.06.2019
2.	Berodual N	ipratropium bromide (ipratropium bromide monohydrate), fenoterol (fenoterol hydrobromide)	aerosol for inhalation, dosed	20mcg/dose+50mcg/dose; 10ml (200doses) aluminium container with measuring pump	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	R	16418/1 21.06.2019
3.	Remicade	infliximab	powder lyophilized for concen-	100mg; (1) 20ml glass vial	Cilag AG, Hochstrasse 201, CH-8200	Switzerland	Johnson & Johnson LLC, 121614, Moscow,	Russia	Г	17799/1 21.06.2019

			trate for solution for infusion		Schaffhausen		Krylatskaya str., 17/2			
4.	Hypothiazid	hydrochlorothiazide	tablets	25mg; (20/1x20/) in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5,	Hungary	Sanofi-Aventis Private Co. Ltd.,1045 Budapest, To u. 1- 5	Hungary	☞	14893/1 21.06.2019
5.	Hypothiazid	hydrochlorothiazide	tablets	100mg; (20/1x20/), in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	Sanofi-Aventis Private Co. Ltd.,1045 Budapest, To u. 1- 5	Hungary	☞	14894/1 21.06.2019
6.	Sea Buckthorn Oil	hippopheae oil	suppositori es rectal	500mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	У☞	18117/1 21.06.2019
7.	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	1000mg; (1) glass vial with powder and (1) glass vial with solvent 15,6ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B- 2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	16070/1 21.06.2019

8.	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	250mg; (1) Act-O-Vial (250mg powder and 4ml solvent)	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B- 2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	16071/1 21.06.2019
9.	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	500mg; (1) glass vial with powder and (1) glass vial with solvent 7,8ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B- 2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	16069/1 21.06.2019
10.	Macmiror complex	nifuratel, nystatine	cream vaginal	10g/100g+400 0000IU/100g; 30g aluminium tube and dosing syringe applicator	Doppel Farmaceutici S.R.L., Via Martiri delle Foibe, 1- 29016 Cortemaggiore (PC)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11- 20121 Milan (MI)	Italy	R	15244/1 21.06.2019
11.	Macmiror	nifuratel	tablets coated	200mg; (20/2x10/), in blister	Doppel Farmaceutici S.R.L., Via Volturno, 48- Quinto de` Stampi-20089 Rozzano Milan (MI)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11- 20121 Milan (MI)	Italy	R	15246/1 21.06.2019

12.	Macmiror complex	nifuratel, nystatin	suppositori es vaginal	500mg+200 000IU; (8/1x8/) in blister	Doppel Farmaceutici S.R.L., Via Voturno, 48- Quinto de` Stampi-20089 Rozzano Milan (MI)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11- 20121 Milan (MI)	Italy	R	15245/1 21.06.2019
13.	Captopril Denk 25	captopril	tablets	25mg; (20/2x10/) and (100/10x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17813/1 21.06.2019
14.	Verospiron 50mg	spironolactone	capsules	50mg; (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	14013/1 21.06.2019
15.	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	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18535/1 21.06.2019

					Bay Lane, 637461 Singapore, Singapore-bulk manufacturer					
--	--	--	--	--	--	--	--	--	--	--

List
of the medicines recommended for **re-registration** (NEW RULE) by N 6-2/19 meeting decision of
the Pharmacological Council of MoH of RA dated on June 21, 2019

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.	Bonviva	ibandronic acid (ibandronic acid monosodium salt, monohydrate)	tablets film-coated	150mg; (1), (3), in blister	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel-batch releaser, Penn Pharmaceuticals Services limited units 23-24, Tafarnaubach industrial estate, Tafarnaubach, Tredegar, NP22 3AA, UK- bulk manufacturer, F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst, Switzerland-packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	17978/1 21.06.2019
2.	Bonviva	ibandronic acid	solution for i/v injection	1mg/ml; (1) pre-filled glass syringe 3ml and (1) needle	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-	Germany	F. Hoffmann La Roche Ltd., Grenzacherstrasse	Switzerland	R	15997/1 21.06.2019

					68305 Mannheim - batch releaser, secondary packager, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahn strasse 2-4, 88085 Langenargen, Germany- bulk manufacturer, primary packager		124 Basel, CH-4070			
3.	Bonviva	ibandronic acid (ibandronic acid monosodium monohydrate)	tablets film-coated	150mg (1), (3), in blister	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel -batch releaser, bulk manufacturer, F. Hoffmann-La Roche Ltd., Wurmisweg, CH- 4303, Kaiseraugst, Switzerland- packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	15175/1 21.06.2019
4.	Nifedi-Denk10 Retard	nifedipine	tablets extended- release	10mg; (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17818/1 21.06.2019