

Table 1: Similar biotherapeutic products/biosimilars approved in 16 countries (continued)

Country	INN	Brand name (product-specific addition, e.g. suffix, if any)	Manufacturer/ company name	Origin of country	Indications	Reference product (manufacturer)	Date approved	
India (96)	Streptokinase (2)	Myokinase	Biocon	India	Acute myocardial infarction, Deep venous thrombosis, Acute pulmonary embolism		Jun 2004	
		Shankinase	ShanthaBio-technics/Mer-ieux Alliance		Arterial occlusions, Deep vein thrombosis, Pulmonary embolism			
	Tenecteplase		Reliance Life Sciences Pvt Ltd	India	Thrombolytic treatment		Mar 2018	
	Teriparatide (3)	Terifrac	Intas Pharma-ceuticals	India	Postmenopausal women with osteo-porosis who are at high risk for fracture		Nov 2010	
		Teriparatide	Cadila Healthcare	India		Aug 2012		
		Teriparatide	USV	India		Aug 2012		
	Trastuzumab (5)	TrastuRel		Reliance Life Sciences Pvt Ltd	India	HER2 adjuvant BC, HER2 mBC, HER2 mGC or gastroeso-phageal junction adenocarcinoma		Jun 2015
			Vivitra	Cadila Health-care Pvt Ltd	India	HER2 mBC		Oct 2015
				Dr Reddy's Laboratories	India	HER2 early BC, HER2 mBC, HER2 mGC or gastroesophageal junction adenocarcinoma		Mar 2018
			150 mg/vial and 440 mg/vial	Biocon limited	India	HER2 mBC		Oct 2013
Trastuzumab, Mfd			Intas Biophar-maceuticals Ltd	India			Feb 2015	
Iran (22)	Adalimumab	CinnoRa	CinnaGen Co	Iran	RA	Humira	2016	
	Bevacizumab	Stivant	Aryogen pharmed	Iran	Colon cancer	Avastin	2017	
	EPO (2)	Epolyrec	Notarkib Bio-pharmaceuti-cals	Iran	Anaemia	Eporex	2013	
		PDpoetin	Pooyesh Darou	Iran	Anaemia	Eporex	2005	
	Eptacog alfa	Aryoseven	Aryogen pharmed	Iran	Factor VII deficient patient	Novoseven	2014	
	Etanercept	Altebrel	Aryogen pharmed	Iran	RA	Enbrel	2014	

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Iran (22)	Filgrastim (2)	PDgrastim	Pooyesh Darou	Iran	Neutropenia after Chemotherapy	Zarzio, Neupogen	2013
		Tinagrast	Tinagen	Iran	Neutropenia after Chemotherapy	Zarzio, Neupogen	2017
	Pegylated-filgrastim (2)	PegaGen	CinnaGen Co	Iran	Neutropenia after chemotherapy	Neulasta	2014
		PDlasta	Pooyesh Darou	Iran	Neutropenia after chemotherapy	Neulasta	2015
	Follitropin alfa	Cinnal-f	CinnaGen Co	Iran	Infertility	Gonal F	2014
	Interferon alpha-2b	PD-feron	Pooyesh Darou	Iran	Immunomodulator	Intron A	2005
	PEG-interferon alpha-2b	PD-feron	Pooyesh Darou	Iran	Immunomodulator	PEG-Intron	2010
	Interferon beta-1a (3)	CinnoVex	CinnaGen Co	Iran	Multiple sclerosis	Avonex, Rebif, Rebidose	2011
		Actovex	Actover	Iran	Multiple sclerosis	Avonex, Rebif, Rebidose	2011
		Reecigen	CinnaGen Co	Iran	Multiple sclerosis	Avonex, Rebif, Rebidose	2013
	Interferon beta-1b	Ziferon	Zist Darou Danesh	Iran	Multiple sclerosis	Betaferon	2008
	Interferon gamma	Gamma-Immunex	Exir	Iran	Immunomodulator	Imukin	2009
Rituximab (2)	Reditux	CinnaGen Co	Iran	NHL	MabThera	2014	
	Zitux	Aryogen pharmed	Iran	NHL	MabThera	2014	
Trastuzumab	Aryotrust	Aryogen pharmed	Iran	BC	Herceptin	2014	
Insulin N Insulin R	Vitasulin N Vitasulin R	Vitan pharmed	Iran	Diabetes	Insulatard actrapid	2017	
Japan (26)	Adalimumab	Adalimumab BS [Adalimumab BS1]	Kyowa Kirin Fujifilm Biologics	Japan	RA, PsO, CD	Humira Adalimumab (AbbVie)	Jun 2020
	Agalsidase Beta	Agalsidase Beta BS [Agalsidase Beta BS1]	JCR Pharma	Japan	Fabry disease	Fabrazyme injection Agalsidase Beta (Genzyme)	Sep 2018
	Bevacizumab (2)	Bevacizumab BS [Bevacizumab BS1]	Pfizer	USA	Progress/recurrence CRC	Avastin Bevacizumab (Chugai)	Jun 2019
Bevacizumab BS [Bevacizumab BS2]		Daiichi Sankyo	Japan	Progress/recurrence CRC	Avastin Bevacizumab (Chugai)	Sep 2019	

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Japan (26)	Darbepoetin alfa (3)	Darbepoetin alfa BS [Darbepoetin alfa BS1]	JCR Pharmaceuticals	Japan	Anaemia	NESP (Kyowa Hakko Kirin)	Sep 2019
		Darbepoetin alfa BS [Darbepoetin alfa BS2]	Sanwa Kagaku Kenkyusho	Japan	Anaemia	NESP (Kyowa Hakko Kirin)	Sep 2019
		Darbepoetin alfa BS [Darbepoetin alfa BS3]	Mylan	USA	Anaemia	NESP (Kyowa Hakko Kirin)	Sep 2019
	Epoetin kappa	Epoetin alfa BS [Epoetin alfa BS1]	JCR Pharmaceuticals	Japan	Anaemia, Renal anaemia	Espo (Epoetin alfa) (Kyowa Hakko Kirin)	Nov 2009
	Etanercept (2)	Etanercept BS [etanercept BS1]	Mochida Pharmaceutical	Japan	RA, JIA	Enbrel (Etanercept) (Pfizer)	Jan 2018
		Enbrel [Etanercept BS2]	Yoshindo/ Kyowa Pharmaceuticals	Japan	RA, JIA	Enbrel (Etanercept) (Pfizer)	Mar 2019
	Filgrastim (3)	Filgrastim BS [filgrastim BS1]	Fuji Pharma	Japan	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Gran (Filgrastim) (Kyowa Hakko Kirin)	Nov 2012
		Filgrastim BS [filgrastim BS2]	Teva Pharma Japan	Israel	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Gran (Filgrastim) (Kyowa Hakko Kirin)	Feb 2013
		Filgrastim BS [filgrastim BS3]	Sandoz	Switzerland	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Gran (Filgrastim) (Kyowa Hakko Kirin)	Mar 2014
	Infliximab (3)	Infliximab BS (Remsima) [infliximab BS1]	Celltrion/ Nippon Kayaku	South Korea/ Japan	CD, RA, UC	Remicade (Johnson & Johnson)	Jul 2014
		Infliximab BS [infliximab BS2]	Nichi-Iko Pharmaceutical/ Yakuhan Pharmaceutical	Japan	CD, RA, PsO, UC	Remicade (Johnson & Johnson)	Sep 2017
		Infliximab BS [infliximab biosimilar BS3]	Pfizer Japan	USA	CD, RA, PsO, UC	Remicade (Johnson & Johnson)	July 2018
Insulin glargine (2)	Insulin glargine BS [insulin glargine biosimilar 1]	Eli Lilly		Diabetes for which insulin therapy is indicated	Lantus (Sanofi)	Dec 2014	
	Insulin glargine BS [insulin glargine biosimilar 2]	Fujifilm Toyama Kagaku	India/Japan	Diabetes for which insulin therapy is indicated	Lantus (Sanofi)	Mar 2016	

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Japan (26)	Insulin Lispro	Insulin Lispro BS [Insulin Lispro BS1]	Sanofi	France	Diabetes for which insulin therapy is indicated	Insulin Lispro Injection Insulin Lispro (Eli Lilly)	Mar 2020
	Rituximab (2)	Rituximab BS [Rituximab BS1]	Sandoz	Switzerland	B-cell NHL, B-cell lymphoproliferative disorder, MPA, GPA	MabThera (Roche)	Sep 2017
		Rituximab BS [Rituximab BS2]	Pfizer	USA	B-cell NHL, B-cell lymphoproliferative disorder, MPA, GPA	MabThera (Roche)	Sep 2019
	Somatropin	Somatropin BS	Sandoz	Switzerland	GH deficiency	Genotropin (Somatropin) (Pfizer)	Jun 2009
	Teriparatide	Teriparatide BS [Teriparatide BS1]	Mochida Pharmaceutical	Japan	Osteoporosis	Teriparatide injection Teriparatide (Eli Lilly)	Sep 2019
	Trastuzumab (3)	Trastuzumab BS [Trastuzumab BS1]	Nippon Kayaku/ Celltrion	South Korea	HER2 GC	Herceptin (Roche)	Mar 2018
Trastuzumab BS [Trastuzumab BS2]		Daiichi Sankyo		HER2 GC	Herceptin (Roche)	Sep 2018	
Trastuzumab BS [Trastuzumab BS3]		Pfizer	USA	HER2 BC, HER2 mGC, gastroesophageal junction adenocarcinoma	Herceptin (Roche)	Sep 2018	
Jordan (12)	Adalimumab	Amgevita	Amgen	Holland	RA, Polyarticular JIA, Axial SpA, PsA, CD, UC	Humira	2019
	Epoetin alfa	Binocrit	Sandoz	Germany	Anaemia, CKF	Eprex (Janssen-Cilag)	2012
	Filgrastim (2)	Nivestim	Hospira	UK	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	2013
		Zarzio	Sandoz	Austria	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	2014
	Infliximab	Remsima 100 mg Powder for solution for infusion vial	Celltrion Inc/ الحكة	Korea Jordan	RA, Adult CD, Paediatric CD, UC, Paediatric UC, AS, PsA	Remicade (Janssen)	2014
	Soluble Insulin	Insugen-R	Biocon	India as contract with JPM/Jordan	Diabetes	Humulin R	2013
	Rituximab (3)	Ritox (Tromax (الحاي التاج اري الاسم))	Sinergium-mAbxience	Argentine AS contract with Jordanian company	NHL	MabThera (Roche)	2018

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Jordan (12)		Truxima	Celltrion Inc/ لح كورنا	Korea/Jordan	NHL, CLL, PA, GPA, MPA	MabThera (Roche)	2019
		Rixathon	Sandoz GmbH	Austria	Follicular lymphoma, CLL, severe RA, GPA, Pemphigus vulgaris	MabThera	2019
	Somatropin	Omnitrope	Sandoz	Austria	GH deficiency in adults and children	Genotropin (Pfizer)	2014
	Trastuzumab (2)	Hertraz Herzuma	Biocon Celltrion Inc/ الاح كورنا	India Korea/Jordan	BC, GC Anticancer monoclonal antibody	Herceptin Herceptin	2019 2019
Malaysia (16)	Adalimumab	Amgevita	Amgen	USA	RA, PsA, Axial SpA, Non-radiographic Axial SpA (Axial SpA without radiographic evidence of AS), PsO, CD, UC, HS, Polyarticular JIA, Paediatric CD, Uveitis	Hummira (AbbVie)	Jul 2019
	Bevacizumab	Mvasi	Amgen	USA	mCRC, mBC, Advanced, metastatic or recurrent NSCLC, Advanced and/or mRCC, Glioblastoma, EOC, FTC, pPC, CC	Avastin (Roche)	Jul 2019
	Epoetin alfa (2)	Erysaa	Duopharma Sdn Bhd/ PanGen	Malaysia/ South Korea	Anaemia with CRF, Autologous blood collection	Eprex (Johnson & Johnson)	Jan 2019
		Binocrit	Novartis	Sandoz Austria	Anaemia with CRF, Reduction of transfusion in chemotherapy, Increase the yield of autologous blood from patients in a predonation, Reduce exposure to allogeneic blood transfusions	Eprex (Johnson & Johnson)	Apr 2011
	Epoetin Zeta	EPO Stada	InnoBio	STADA Arzneimittel AG (Germany)	Anaemia with CRF, severe anaemic of renal origin	Eprex (Johnson & Johnson)	Oct 2015
Filgrastim (2)	Nivestim	Hospira	Croatia	Chemotherapy-induced febrile neutropenia, PBPC, Persistent neutropenia (ANC less than or equal to 1.0 x 10 ⁹ /l) in advanced HIV patients	Neupogen (Amgen-current Roche-previous)	Aug 2013	
	Zarzio	Novartis	IDT Germany		Neupogen (Roche)	Mar 2012	

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Malaysia (16)	Pegfilgrastim	Pelgraz	Intas Pharmaceuticals Ltd, Biopharma Division (India)/ Accord Healthcare Sdn Bhd	India	Neutropenia, Chemotherapy-induced febrile neutropenia (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)	Neulastim	Jul 2020
	Infliximab	Remsima	Celltrion	South Korea	AS, CD, PsO, RA, UC	Remicade (Johnson & Johnson)	Jan 2015
	Recombinant human insulin	Insugen	Biocon	India	Diabetes	Actrapid/Insulatard/Mixtard (Novartis)	Jan 2014
	Insulin glargine	Basalog	Biocon	India	Diabetes	Lantus (Sanofi)	Jun 2016
	Rituximab	Truxima	Celltrion	South Korea	NHL, CLL, RA with GPA and MPA *Initially these indications are approved but the company intent to remove due to local patent issue	MabThera (Roche)	Aug 2018
	Somatropin	Scitropin A	United Italian	Sandoz Austria	<u>In children:</u> Growth disturbance due to GH deficiency, associated with Turner syndrome, associated with chronic renal insufficiency, or in short children/ adolescents born small; PWS <u>In adults:</u> GH deficiency	Genotropin (Pfizer)	Aug 2010
	Trastuzumab (3)	Zuhera	Biocon	India	HER2+ BC (m, early), Advanced GC	Herceptin (Roche)	Dec 2018
Hertraz		Duopharma	India	Early BC, mBC, mGC	Herceptin (Roche)	Oct 2018	
Herzuma		Celltrion	South Korea	Early BC, mBC, mGC	Herceptin (Roche)	May 2019	
Republic of Korea (15)	Adalimumab	Hadlima	Samsung Bio	South Korea	PsO, PsA, JIA, RA, UC, Adult CD, AS	Humira (AbbVie)	Sep 2017
	Darbepoetin alfa	Nesbell	Chongkundang	South Korea	Treatment of anaemia	Nesp Darbepoetin alfa	Nov 2018
	Epoetin alfa	Panpotin	Pangen Biotech	South Korea	Anemia associated with chronic renal failure	Eprex (Johnson & Johnson)	Nov 2019

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Republic of Korea (15)	Eternacept (3)	Davictrel	Hanwha Chemical	South Korea	AS, PsO, PsA, RA	Enbrel (Amgen)	Nov 2014
		Etoloce	Samsung Bioepis	South Korea	AS, PsO, PsA, RA	Enbrel (Amgen)	Sep 2015
		Eucept	LG Chem	South Korea	AS, PsO, PsA, RA	Enbrel (Amgen)	Mar 2018
	Infliximab (2)	Remalocce	Samsung Bioepis	South Korea	AS, CD, PsO, RA, UC	Remicade (Johnson & Johnson)	Jul 2012
		Remsima	Celltrion	South Korea	AS, CD, PsO, PsA, Ra, UC	Remicade (Johnson & Johnson)	Jul 2012
	Insulin glargine (2)	Basaglar	Eli Lilly/ Boehringer Ingelheim	South Korea	Diabetes	Lantus (Sanofi)	Nov 2015
		Glarzia	GC Pharma		Diabetes	Lantus (Sanofi)	Mar 2018
	Rituximab	Truxima	Celltrion	South Korea	CLL, NHL, RA	MabThera/ Rituxan (Roche)	Nov 2016
	Somatropin	Scitropin A (= Omnitrope)	Scizen (Korean agency) import from Sandoz	Switzerland	Pituitary dwarfism, Growth disturbance due to chronic renal insufficiency, Turner syndrome, PWS, Idiopathic short stature	Genotropin (Pfizer)	Jan 2014
	Teriparatide	Terosa	Daewon Pharmaceutical	Hungary	Osteoporosis	Fosteo (Lily)	Oct 2019
Trastuzumab (2)	Herzuma	Celltrion	South Korea	HER2+ BC (m, early)	Herceptin (Roche)	Jan 2014	
	Samfenet	Samsung Bio/ Daewoong Pharmaceutical	South Korea	Early BC, mBC, mGC	Herceptin (Roche)	Nov 2017	
Russia (35)	Adalimumab	Dalibra	Biocad	Russia		Humira (AbbVie)	2019
	Bevacizumab	AvegraBiocad	Biocad	Russia		Avastin (Roche)	2015
	Epoetin alfa (2)	Darbestim	Biocad	Russia		Aranesp (Amgen)	2019
		Binocrit	Sandoz	Germany		Eprex (Janssen)	2012
	Epoetin beta	Vero-epoetin	Veropharm	Russia		Rekormon (Roche)	2010
	Filgrastim (4)	Zarzio	Sandoz	Germany		Neupogen (Amgen)	2011
Tevagrastim		Teva	Israel		Neupogen (Amgen)	2010	

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Russia (35)		Leucostim	Biocad	Russia		Neupogen (Amgen)	2011
		Grasalva	Teva	Israel		Neupogen (Amgen)	2010
	Interferon alfa-2b (2)	Peginterferon alfa-2b PegAltevir	Wirchow Bio- tech Private Ltd Pharmstandard	India		PegIntron (Merk)	2016
				Russia		PegIntron (Merk)	2014
	Interferon beta-1a (2)	Teberif Genfaxon	Biocad MP Pharma SA	Russia		Rebif (Merk)	2017
				Argentina		Rebif (Merk)	2010
	Interferon beta-1b (2)	Infibeta Interferon beta-1b	Generium Biocad	Russia		Betaferon (Bayer AG)	2011
				Russia		Betaferon (Bayer AG)	2009
	Insulin (10)	Gensulin H Humudar B 100 Rek Humudar R 100 Rek Humudar K25 100 Rek Insuman- RapidGT MonoinsulinChS Protamin-insulin ChS Insuman Basal GT Gensulin P Gensulin M30	Bioton SA Indar Indar Indar Sanofi Aventis Belmedpre- parati Belmedpre- parati Sanofi Aventis Bioton SA Bioton SA	Poland		Humulin NPH (Eli Lilly)	2010
				Ukraine		Humulin NPH (Eli Lilly)	2010
				Ukraine		Humulin Regular (Eli Lilly)	2010
				Ukraine		Humulin M3 (Eli Lilly)	2010
				Russia/ Germany		Humulin Regular (Eli Lilly)	2016
				Belarus		Aktrapid HM (NovoNordisk)	2015
				Belarus		Protafan (Novo-Nordisk)	2015
				Germany		Humulin NPH (Eli Lilly)	2011
				Poland		Humulin Regular (Eli Lilly)	2010
				Poland		Humulin M3 (Eli Lilly)	2010
	Insulin (analogue) (4)	Insulin lizpro Insulin glargin RinLiz	Gan and Li Pharmaceuti- cals Gan and Li Pharmaceuti- cals Geropharm	China		Humalog (Eli Lilly)	2017
China					Lantus Solo-Star (Sanofi)	2017	
Russia					Humalog (Eli Lilly)	2019	

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Russia (35)		RinGlar	Geropharm	Russia		Lantus (Sanofi)	2019
	Infliximab (2)	Infliximab	Biocad	Russia		Remicade (MSD)	2018
		Flammegis	Celltrion Healthcare Co Ltd	South Korea		Remicade (MSD)	2015
	Rituximab (2)	AcellBia	Biocad	Russia		MabThera (Roche)	Apr 2014
		Reditux	Dr Reddy's Laboratories	India		MabThera (Roche)	2016
Trastuzumab (2)	HERtiCAD	Biocad	Russia		Herceptin (Roche)	Jan 2016	
	Trazimera	Pfizer	Belgium		Herceptin (Roche)	2019	
Singapore (11)	Adalimumab	Amgevita	Amgen	USA	RA, PsA, AS, CD, UC, PsO, HS, Uveitis, JIA, Paediatric CD, Paediatric PsO, adolescent HS	Humira (Abbott)	2019
	Filgrastim (2)	Nivestim	Hospira	Croatia	Neutropenia, PBPCs	Neupogen (Amgen)	2012
		Zarzio	Novartis	Germany	Neutropenia, PBPCs	Neupogen (Amgen)	2016
	Insulin glargine (2)	Basaglar	Eli Lilly	France, Italy	Diabetes	Lantus (Sanofi)	2016
		Basalog One	Biocon	Malaysia	Diabetes	Lantus (Sanofi)	2020
	Infliximab	Remsima	Celltrion	South Korea	RA, CD, paediatric CD, UC, paediatric UC, AS, PsA, PsO	Remicade (Johnson & Johnson)	2016
	Rituximab (2)	Truxima	Celltrion	South Korea	B-cell NHL, Follicular lymphoma, CLL	MabThera (Roche)	2019
Rixathon		Lek Pharmaceuticals d d (Ljubljana)	Slovenia	NHL, CLL, GPA, MPA	Remicade (Johnson & Johnson)	2020	
Somatropin	Scitropin	Sandoz	Austria	GH deficiency, Growth disturbance associated with Turner syndrome	Genotropin (Pfizer)	2009	
Trastuzumab (2)	Ogivri 440	Biocon	India	Adjuvant BC	Herceptin	2019	
	Herzuma 150 mg Herzuma 440 mg	Celltrion	Korea	Adjuvant BC	Herceptin	2019	
Thailand (15)	Adalimumab	Exemptia	Cadila Healthcare Ltd	India		Humira	2018
	Eterncept	Erelzi	Sandoz GmbH Schaftenau	Austria	RA, JIA	Enbrel	2019
	Filgrastim (4)	Zarzio (30 mcg)	Sandoz GmbH	Austria		Neupogen	2017

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Thailand (15)		Zarzio (48 mcg)	Sandoz GmbH	Austria		Neupogen	2017	
		Nivestim solution for injection/infusion (120 mcg/0.2 mL, 300 mcg/0.5 mL)	Hospira Zagreb Ltd	Croatia	Febrile neutropenia, PBPC, Severe congenital, cyclic, or idiopathic neutropenia, Persistent neutropenia		2018	
		Nivestim solution for injection/infusion (480 mcg/0.5 mL)	Hospira Zagreb Ltd	Croatia			2018	
		Pegfilgrastim	Fuphila	Biocon Ltd	India	Febrile neutropenia	Neulastim	2019
		Rituximab (3)	Redditux	Dr Reddy's Laboratories	India	NHL, CLL, RA	MabThera	2018
			Rixathon	Lek Pharmaceuticals	Republic of Slovenia	NHL, CLL, RA, GPA, MPA	MabThera	2019
			Truxima	Celltrion, Inc	South Korea	NHL, CLL, RA	MabThera	2018
		Trastuzumab (4)	Herzuma 150 mg	Celltrion, Inc	South Korea	BC, mGC	Herceptin	2018
			Herzuma 440 mg	Celltrion, Inc	South Korea	BC, mGC	Herceptin	2018
			Ogivri 150 mg	Biocon Ltd	India	Adjuvant BC, mBC, mGC		2018
	Ogivri 440 mg		Biocon Ltd	India	Adjuvant BC, mBC, mGC		2018	
Ukraine (8)	Epoetin alfa	Binocrit	Sandoz	Switzerland	as in EU	Eprex/Erypo (Janssen-Cilag)	Aug 2012	
	Filgrastim (2)	Tevagrastim	Teva Generics	Israel	as in EU	Neupogen (Amgen)	Jun 2016	
		Zarzio	Sandoz	Switzerland	as in EU	Neupogen (Amgen)	Sep 2012	
	Somatropin	Omnitrope	Sandoz	Switzerland	as in EU	Genotropin (Pfizer)	Feb 2013	
	Rituximab	Truxima	Celltrion	South Korea	CLL	Rituximab	Mar 2019	
	Trastuzumab (2)	Ogivri	Biocon/Mylan	India/USA	Early BC	Trastuzumab	Apr 2019	
	Gerzuma	Celltrion	South Korea	Early BC	Herceptin (Roche)	Positive opinion Expected in Sep 2020		
	Follitropin alfa	Bemfola	Gedeon Richter	Hungary	Anovulation (IVF)	Gonal-F (Merck Serono Europe)	Jul 2019	
USA (28)	Adalimumab (6)	Amjevita (adalimumab-atto)	Amgen	USA	AS, CD, Juvenile arthritis, PsA, PsO, RA, UC	Humira (AbbVie)	Sep 2016	
		Cyltezo (adalimumab-adbm)	Boehringer Ingelheim	Germany	AS, CD, Juvenile arthritis, PsA, PsO, RA, UC	Humira (AbbVie)	Aug 2017	

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USA (28)		Hyrimoz (adalimumab-adaz)	Sandoz	Switzerland	AS, CD, Juvenile arthritis, PsA, PsO, RA, UC	Humira (AbbVie)	Oct 2018
		Hadlima (adalimumab-bwwd)	Samsung Bioepis	South Korea	AS, CD, Juvenile arthritis, PsA, PsO, RA, UC	Humira (AbbVie)	Jul 2019
		Abrilada (adalimumab-afzb)	Pfizer	USA	AS, CD, Juvenile arthritis, PsA, PsO, RA, UC	Humira (AbbVie)	Nov 2019
		Hulio (adalimumab-fkjp)	Mylan	Japan		Humira	Jul 2020
	Bevacizumab (2)	Mvasi (bevacizumab-awwb)	Amgen/ Allergan	USA	NSCLC, CRC, RCC, OC, BC	Avastin (Roche)	Sep 2017
		Zirabev (bevacizumab-bvzr)	Pfizer	USA	Various cancers, including CRC, LC, BC, glioblastoma, KC, OC	Avastin (Roche)	Jun 2019
	Epoetin alfa	Retacrit (epoetin alfaepbx)	Pfizer (Hospira)	USA	Anaemia (chronic kidney disease, Zidovudine, chemotherapy) Reduction of allogeneic red blood cell transfusions	Epogen/ Procrit (Amgen)	May 2018
	Etanercept (2)	Erelzi (etanercept-szsz)	Sandoz	Switzerland	Axial SpA, Polyarticular JIA, PsA, PsO, RA	Enbrel (Amgen)	Aug 2016
		Eticovo (etanercept-ykro)	Samsung Bioepis	South Korea		Enbrel (Amgen)	Apr 2019
	Filgrastim (2)	Zarxio (filgrastim-sndz)	Sandoz	Switzerland	Autologous PBPC, Bone marrow transplantation, Cancer, Myeloid leukaemia, Neutropenia	Neupogen (Amgen)	Mar 2015
		Nivestym (filgrastim-aafi)	Pfizer (Hospira)	USA		Neupogen (Amgen)	Jul 2018
	Pegfilgrastim (4)	Fulphila (pegfilgrastim-jmdb)	Biocon/Mylan	India/USA	Febrile neutropenia	Neulasta (Amgen)	Jun 2018
		Udenyca (pegfilgrastim-cbqv)	Coherus Biosciences			Neulasta (Amgen)	Nov 2018
		Ziextenzo (pegfilgrastim-bmez)	Sandoz				Nov 2019
Infliximab (4)	Nyvepria (pegfilgrastim-apgf)				Neulasta (Amgen)	Jun 2020	
	Inflectra (infliximab-dyyb)	Celltrion/ Hospira	USA	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Apr 2016	
	Renflexis (infliximab-abda)	Samsung Bioepis	South Korea	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Apr 2017	

(Continued)

ORIGINAL RESEARCH

Biosimilars for Healthcare Professionals

Table 1: Similar biotherapeutic products/biosimilars approved in 16 countries (continued)

Country	INN	Brand name (product-specific addition, e.g. suffix, if any)	Manufacturer/ company name	Origin of country	Indications	Reference product (manufacturer)	Date approved
USA (28)*		Ixifi (infliximab-qbtx)	Pfizer	USA	AS. CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Dec 2017
		Avsola (infliximab-axxq)	Amgen	USA	AS. CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Dec 2019
	Rituximab (2)	Truxima (rituximab-abbs)	Celltrion/Teva	South Korea/ Israel	NHL, RA	Rituxan (Roche)	Nov 2018
		Rujxience (rituximab-pvvr)	Pfizer	US	CLL, HNL, GPA	Rituxan (Roche)	Jul 2019
	Trastuzumab (5)	Ogivri (trastuzumab-dkst)	Biocon/Mylan	India/USA	HER2 BC, HER2 mGC, gastroesophageal junction adenocarcinoma	Herceptin (Roche)	Dec 2017
		Herzuma (trastuzumab-pkrb)	Celltrion/Teva	South Korea/ Israel		Herceptin (Roche)	Dec 2018
		Ontruzant (trastuzumab-dttb)	Samsung Bio	South Korea	HER2 BC, HER2 mGC, gastroesophageal junction adenocarcinoma	Herceptin (Roche)	Jan 2019
		Trazimera (trastuzumab-qyyp)	Pfizer	USA	HER2 BC, HER2 mGC, gastroesophageal junction adenocarcinoma	Herceptin (Roche)	Mar 2019
		Kanjinti (trastuzumab-anns)	Amgen	USA		Herceptin (Roche)	Jun 2019

*All licensed as biosimilars not interchangeable products.

AMD: age-related macular degeneration; AS: ankylosing spondylitis; Axial SpA: axial spondyloarthritis; BC: breast cancer; BrC: brain cancer; CC: cervical cancer; CD: Crohn's disease; CKF: chronic kidney failures; CLL: chronic lymphocytic leukemia; CNV: choroidal neovascularization; CRC: colorectal cancer; CRF: chronic renal failure; DME: diabetic macular edema; EOC: epithelial ovarian cancer; EPO: erythropoietin; ERA: Entesitis-related arthritis; FSH: follicular-stimulating hormone; FTC: fallopian tube cancer; GC: gastric cancer; GH: growth hormone; GPA: granulomatosis with polyangiitis; hCG: human chorionic gonadotropin; HER2: human epidermal growth factor receptor 2; HIV: human immunodeficiency viruses; HS: hidradenitis suppurativa; INN: International Nonproprietary Name; IVF: *in vitro* fertilization; JIA: juvenile idiopathic arthritis; JRA: juvenile rheumatoid arthritis; KC: kidney cancer; LC: lung cancer; LH: luteinizing hormone; LMWH: low molecular weight heparin; MA: marketing authorization; m: metastatic; mBC: metastatic breast cancer; mCRC: metastatic colorectal cancer; mGC: metastatic gastric cancer; MPA: microscopic polyangiitis; mRCC: metastatic renal cell carcinoma; NA: not applicable; NHL: non-Hodgkin's lymphoma; nr-axS: non-radiographic axial spondylitis; NSCLC: non-small cell lung cancer; nsNSCLC: non-squamous non-small cell lung cancer; OC: ovarian cancer; PBPC: peripheral blood progenitor cells; PC: peritoneal cancer; PsA: psoriatic arthritis; PsO: plaque psoriasis; pPC: primary peritoneal cancer; PWS: Prader-Willi syndrome; RA: rheumatoid arthritis; RCC: renal cell carcinoma; RVO: retinal vein occlusion; SpA: spondyloarthritis; TBD: to be decided; UC: ulcerative colitis; WHO: World Health Organization.