

Biosimilars – status in July 2020 in 16 countries

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The World Health Organization (WHO) has provided specific guidance for biosimilar products to assist regulators, manufacturers and other professionals involved in the development and evaluation of these products. The development and approval of biosimilars are important for health care, as they allow the marketing of safe, efficacious and affordable biological products. Since the first biosimilars were approved in the EU in 2006, a series of biosimilars have been approved in many countries/geographical regions. This manuscript provides the figures on the status of approved biosimilars in 16 countries based on the information from regulatory experts and from publicly available data. It is clear that increasing numbers of biosimilars are now available in many countries and provide more options for treatments. It is expected that adoption of biosimilars will allow affordable health care and greater patient access to important medicinal products. It will also contribute to the overall WHO goal recognized by the World Health Assembly in 2014 by adopting a resolution on access to biotherapeutic products including biosimilars and on ensuring their quality, safety and efficacy.

Keywords: Approval, biosimilar, survey, WHO

Introduction

Development of biosimilars is important for health care as it allows the marketing of safe, efficacious and affordable biological products. The European Medicines Agency (EMA) was the first regulatory agency to establish a process for the approval of biosimilars and approved the first biosimilars in 2006.

Since then, there has been much progress in establishing the regulatory pathway for biosimilars and a wide range of biosimilars have been approved for marketing in many countries/geographical regions [1]. An extensive number of biosimilars are now being used globally and are contributing considerably to widening patient access to appropriate biological medicines at reduced costs.

The World Health Organization (WHO) has taken a lead in the biosimilar field at the global level and has developed specific guidance for biosimilar development and approval as well as a number of other pertinent guidelines [2-4]. WHO has also organized a number of implementation workshops to assist regional regulatory agencies and manufacturers in the biosimilars area. As part of these workshops, surveys have been conducted to understand the current situation with biosimilars in the participants' countries [1, 5, 6]. These surveys provide a unique opportunity to establish the situation with currently marketed biosimilars/similar biotherapeutic products in 16 countries. This publication presents this information.

Methods

The survey was conducted as previously described [1], but the information was updated and confirmed in July 2020. The information contained in this survey report is from participants of 15 countries who agreed for their information to be disclosed. The feedback from the UK refers to the situation in the

European Union (EU) rather than specifically for the UK. Information from the US was not derived from the survey, but from the website of the US Food and Drug Administration (FDA). It should be noted that biological products in Table 1 have been approved as biosimilars in the countries as surveyed, but biosimilars approved in certain countries might not have been approved following a strict comparative regulatory process as recommended by WHO guidelines. The term 'approval' used in the manuscript is referring to the approval by the national regulatory authority. WHO did not conduct assessment of these products nor of the procedure for regulatory evaluation conducted by the national regulatory authorities as a basis for the 'approval'.

Results

Table 1 shows a breakdown of information received which includes country participating (in survey), International Nonproprietary Name (INN), brand name and manufacturer/company name of product, the location of the producer of the product, the clinical indications approved, the reference product used and its manufacturer and the date the biosimilar/similar biotherapeutic products was approved. Table 2 shows the numbers of biosimilars/similar biotherapeutic products approved by regulatory authorities in the 16 countries (updated July 2020) specified by product type.

Discussion/Conclusions

Following the EU's lead after their first biosimilar approvals in 2006, other countries have approved biosimilars/similar biotherapeutic products not only with increasing numbers but also with expanding the available product classes. 'Big pharma', e.g. in the EU and the US, continues to dominate the biosimilar market, but local manufacturers have played a significant role in producing biosimilars/similar biotherapeutic products in some countries, e.g. in China, India, Iran, Japan, Republic of Korea.

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

The information below provided based on the categorization of similar biotherapeutic products/biosimilars by each national regulatory authority. Thus, similar biotherapeutic products/biosimilars approved in certain countries might not have been approved following as strict a regulatory process as is required by WHO guidelines. Indications also as reported by survey participants; not necessarily representing WHO approval of these.

Country	INN	Brand name (product-specific addition, e.g. suffix, if any)	Manufacturer/ company name	Origin of country	Indications	Reference product (manufacturer)	Date approved
Brazil (30)	Adalimumab (3)	Amgevita	Amgen	USA	<u>In adult patients:</u> Axial SpA, CD, HS, PsA, PsO, RA <u>In paediatric patients</u> (patients over 13 years of age): Polyarticular JIA <u>In paediatric patients</u> (from 6 years onwards): CD	Humira (AbbVie)	Apr 2019
		Hyrimoz	Sandoz	Austria/India	<u>In adult patients:</u> Axial SpA, UC, CD, HS, PsA, PsO, RA, Uveitis <u>In paediatric patients:</u> CD, ERA, Poly-articular JIA, Uveitis	Humira (AbbVie)	Nov 2019
		Xilbrilada	Wyeth	USA	<u>In adult patients:</u> Axial SpA, UC, CD, HS, PsA, PsO, RA, Uveitis <u>In paediatric patients:</u> CD, ERA, Poly-articular JIA, Uveitis	Humira (AbbVie)	May 2020
	Bevacizumab (2)	Mvasi	Amgen	USA	mCRC, nsNSCLC, mRCC, CC, mBC, m and/or advanced CRC, EOC, FTC, pPC	Avastin (Roche)	Feb 2019
		Zirabev	Wyeth	USA	mCRC, nsNSCLC, mRCC, CC, MBC, m and/or CRC, EOC, FTC, pPC	Avastin (Roche)	Mar 2020
	Etanercept (3)	Brenzys	Catalent Belgium SA/ Patheon Italia SpA/Samsung Bioepis	Belgium/ Italy/South Korea	RA, AS, PsA, nr-axS, PsO	Enbrel (Roche)	Dec 2017
			Bio-Manguinhos Etanercepte	Fundação Oswaldo Cruz	Belgium/ Italy	RA, AS, PsA, nr-axS, PsO	Enbrel (Roche)
		Erelzi	Sandoz	Switzerland/ Germany	Paediatric PsO	Enbrel (Roche)	Dec 2019
	Filgrastim (2)	Fiprima	Eurofarma Laboratórios	Brazil	Neutropenia	Granulokine (Roche)	Oct 2015
		Zarzio	Gp Grenzach Productions GmbH/Sandoz	Germany	Neutropenia	Granulokine (Roche)	Oct 2016

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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
Brazil (30)	Infliximab (3)	Remsima	Celltrion Inc	South Korea	RA, AS, PsA, PsO, CD, Fistulizing CD, UC	Remicade (Janssen-Cilag)	Apr 2015
		Renflexis	Biogen Denmark Manufacturing ApS/ Patheon Italia SpA/Samsung Bioepis	Denmark/ Italy South Korea	RA, AS, PsA, PsO, CD, UC	Remicade (Janssen-Cilag)	Jul 2018
		Xilfyra	Pfizer Manufacturing NV	Belgium/USA	RA, AS, PsA, PsO, CD, Fistulizing CD, UC	Remicade (Janssen-Cilag)	May 2019
	Insulin glargine (3)	Basaglar	Lilly France Fegersheim/Eli Lilly	France	Diabetes	Lantus (Sanofi)	May 2015
		Glargilin	Gan & Lee Pharmaceuticals	China	Diabetes	Lantus (Sanofi)	Jul 2018
		Glatus	Aspen	India	Diabetes	Lantus (Sanofi)	Nov 2019
	Insulin isophane	Visulin N	Biocon Limited	India	Diabetes	Novolin N (Novo Nordisk)	Oct 2017
	Human insulin	Insuliv R	Biocon Limited	India	Diabetes	Novolin R (Novo Nordisk)	Mar 2018
	Insulin lispro	Admelog	Sanofi	Germany	Diabetes	Humalog (Eli Lilly)	Sep 2018
	Low molecular weight heparin	Heparinox	Nanjing King-friend Bio-chemical Pharmaceutical Co Ltd/Cristalia	China/Brazil	Deep venous thrombosis, Unstable angina and non-ST-segment elevation myocardial infarction, Acute myocardial infarction with ST segment elevation, Prophylaxis of venous thromboembolism, Prophylaxis of venous thromboembolism, Prevention of thrombus formation	Clexane (Sanofi)	Apr 2019
	Rituximab (4)	Riximyo	Lek pharmaceuticals d d/ Sandoz	Slovenia	RA, NHL, Leukaemia, GPA, MPA	MabThera (Roche)	Apr 2019
		Vivaxxia	Libbs Farmacêutica Ltda	Brazil (Tech transfer)	NHL, Leukaemia	MabThera	Jun 2019
		Truxima	Celltrion Healthcare	Republic of Korea	RA, NHL, Leukaemia, GPA, MPA	MabThera (Roche)	Oct 2019
Ruxience		Wyeth	Belgium	RA, NHL, Leukaemia, GPA, MPA	MabThera (Roche)	May 2020	

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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
Brazil (30)	Somatropin	Criscy	Cristália Produtos Químicos Farmacêuticos Ltda	Brazil	GH deficiency in adults and children	Genotropin	May 2019
	Trastuzumab (5)	Zedora	Biocon Ltd	India	Early BC, mBC, mGC	Herceptin (Roche)	Dec 2017
		Ontruzant	Patheon Italia SpA	Italy	Early BC, mBC, mGC	Herceptin (Roche)	May 2019
		Kanjinti	Actavis Italy SpA	Italy	Early BC, mBC, mGC	Herceptin (Roche)	May 2019
		Herzuma	Celltrion Inc	South Korea	Early BC, mBC, mGC	Herceptin (Roche)	May 2019
Trazimera	Wyeth	Belgium	Early BC, mBC, mGC	Herceptin (Roche)	Dec 2019		
Canada (26)	Adalimumab (3)	Hadlima	Samsung Bioepis	South Korea	AS, Adult CD, Adult HS, PsA, PsO, Polyarticular JIA, RA, UC, Adult uveitis	Humira (AbbVie)	May 2018
		Amgevita	Amgen	USA	RA	Humira (AbbVie)	On IP hold
		Hyrimoz (217314)	Sandoz	Switzerland	RA	Humira (AbbVie)	On IP hold
	Bevacizumab (2)	Mvasi	Amgen	USA	CRC, NSCLC	Avastin (Genentech)	Oct 2018
		Zirabev	Pfizer	USA	CRC, NSCLC	Avastin (Genentech)	Jun 2019
	Eterncept (2)	Brenzys	Samsung Bioepis/Merck	South Korea/ USA	AS, RA	Enbrel (Amgen)	Aug 2016
		Erelzi	Sandoz	Switzerland	AS, JIA, RA	Enbrel (Amgen)	Aug 2017
	Filgrastim (2)	Grastofil	Apotex (Apobiologix)	Canada	Neutropenia	Neupogen (Amgen)	Dec 2015
		Nivestym	Pfizer	USA	Neutropenia	Neupogen (Amgen)	Apr 2020
	Infliximab (4)	Inflectra	Celltrion	South Korea	AS, PsA, PsO, RA	Remicade (Janssen Biologics)	Jan 2014
Remsima		Celltrion	South Korea	AS, PsA, PsO, RA	Remicade (Janssen Biologics)	Jan 2014	
Renflexis		Samsung Bioepis	South Korea	CD, AS, PsA, PsO, RA, UC	Remicade (Schering Canada)	Mar 2018	
Avsola (226189)		Amgen	USA		Remicade (Janssen Biologics)	Mar 2020	

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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
Canada (26)	Insulin lispro	Admelog	Sanofi	Switzerland	Diabetes	Humalog (Lilly)	Nov 2017
	Insulin glargine	Basaglar (177405)	Eli Lilly	USA	Diabetes	Lantus (Sanofi)	Sep 2015
	Pegfilgrastim (3)	Lapelga	Apotex	Canada	Neutropenia	Neulasta (Amgen)	Apr 2018
		Fulphila	BGP Pharma ULC	Canada	Neutropenia	Neulasta (Amgen)	Dec 2018
		Ziextenzo (220445)	Sandoz	Switzerland	Neutropenia	Neulasta (Amgen)	Apr 2020
	Rituximab (3)	Truxima	Celltrion	South Korea	NHL, Leukaemia, RA	Rituxan (F. Hoffmann-La Roche)	Apr 2019
		Riximyo 214058	Sandoz	Switzerland	NHL, Leukaemia, RA	Rituxan (F. Hoffmann-La Roche)	Apr 2020
		Ruxience 224164/224672	Pfizer	USA	NHL, Leukaemia, RA, GPA	Rituxan (F. Hoffmann-La Roche)	May 2020
	Somatropin	Omnitrope	Sandoz	Switzerland	GH deficiency in adults and children	Genotropin (Pfizer)	Apr 2009
	Trastuzumab (4)	Trazimera	Pfizer	USA	BC, GC	Herceptin (Roche)	Aug 2018
Ogivri		BGP Pharma ULC	India and USA	BC, GC	Herceptin (Roche)	May 2019	
Kanjinti		Amgen	USA	BC, GC	Herceptin (Roche)	Feb 2020	
Herzuma (209878, 210238, 210677)		Celltrion	South Korea	BC, GC	Herceptin (Roche)	On IP Hold	
China (6)	Adalimumab (2)	Ge Leli	Bio-Thera Solutions	China	AS, PsO, RA	Humira (AbbVie)	Nov 2019
		Anjianning	Hisun Biological Pharmaceutical Co Ltd	China	AS, PsO, RA	Humira (AbbVie)	Dec 2019
	Bevacizumab (2)	An Keda	Qilu Pharmaceutical	China	NSCLC, mCRC	Avastin (Roche)	Dec 2019
		Da Youtong	Innovent Biologics	China	NSCLC, mCRC	Avastin (Roche)	Jun 2020
	Rituximab	Hanlikon (HLX01)	Henlius	China	NHL including three subtypes: 1) treatment of relapsed or resistant follicular central lymphoma; 2) previously untreated CD20-positive stage III-IV follicular NHL; 3) CD20bj diffuse large B-cell NHL	MabThera/ Rituxan (Roche)	Feb 2019

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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
China (6)	Trastuzumab	TBD (HLX02)	Henlius	China	TBD (HLX02)	Herceptin (Roche)	Finish review in Jul 2020; target for approval in Aug 2020
EU (68 approved, 3 positive opinion, but 8 withdrawn, 1 cessation later)	Adalimumab (11 approved, 3 withdrawn)	Amgevita	Amgen	USA	AS, CD, Juvenile RA, PsO, PsA, RA, UC	Humira (AbbVie)	Mar 2017
		<i>Solymbic</i>	<i>Amgen</i>	<i>USA</i>	<i>AS, CD, HS, PsO, PsA, RA, UC</i>	<i>Humira (AbbVie)</i>	<i>Mar 2017 Withdrawn Jun 2018</i>
		Imraldi	Samsung Bioepis	South Korea	AS, JIA, CD, HS, PsA, PsO, RA, UC, Uveitis	Humira (AbbVie)	Aug 2017
		<i>Cyltezo</i>	<i>Boehringer Ingelheim</i>	<i>Germany</i>	<i>CD, HS, JUA, PsO, PsA, RA, UC, Uveitis</i>	<i>Humira (AbbVie)</i>	<i>Nov 2017 Withdrawn Jan 2019</i>
		Halimatoz	Sandoz	Switzerland	AS, HS, JIA, PsA, PoS, RA, Uveitis	Humira (AbbVie)	Jul 2018
		Hefiya	Sandoz	Switzerland	AS, HS, Juvenile RA, PsO, Uveitis	Humira (AbbVie)	Jul 2018
		Hyrimoz	Sandoz	Switzerland	AS, CD, HS, Juvenile RA, Papulosquamous skin disease, PsA, RA, UC, Uveitis	Humira (AbbVie)	Jul 2018
		Hulio	Mylan/Fujifilm Kyowa Kirin Biologics	USA/Japan	AS, CD, HS, PsO, PsA, RA, UC, Uveitis	Humira (AbbVie)	Sep 2018
		Idacio	Fresenius Kabi	Germany	AS, CD, HS, PsO, PsA, RA, Juvenile RA, UC, Uveitis	Humira (AbbVie)	Jan 2019
		<i>Kromeya</i>	<i>Fresenius Kabi</i>	<i>Germany</i>	<i>AS, CD, PsO, PsA, RA, Juvenile RA, UC, Uveitis</i>	<i>Humira (AbbVie)</i>	<i>Jan 2019 Withdrawn Dec 2019</i>
Amsparity	Pfizer Europe	Belgium	AS, CD, HS, PsO, PsA, RA, Juvenile RA, UC, Uveitis	Humira (AbbVie)	Feb 2020		
	Bevacizumab (4)	Mvasi	Amgen	USA	BC, FTC, NSCLC, OC, PC, RCC	Avastin (Genentech)	Jan 2018
		Zirabevv	Pfizer	USA	CRC, BC, NSCLC, RCC, CC	Avastin (Roche)	Feb 2019
		Aybintio	Samsung Bioepis	Netherlands	CRC, BC, NSCLC, RCC, OC, CC	Avastin (Roche)	Aug 2020

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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
EU (68 approved, 3 positive opinion, but 8 withdrawn, 1 cessation later)		Equidacent	Centus Biotherapeutics Europe Ltd		CRC, BC, NSCLC, RCC, EOC, FTC, pPC, CC		Positive opinion Jul 2020
	Enoxaparin sodium (2 approved, 1 ceased)	Inhixa	Techdow Europe		Venous thromboembolism	Clexane (Sanofi)	Sep 2016
		<i>Thorinane</i>	<i>Pharmathen</i>		<i>Venous thromboembolism</i>	<i>Clexane (Sanofi)</i>	<i>Sep 2016 Cessation of validity of MA in Sep 2019 as product not marketed in the EU since MA</i>
	Epoetin alfa (3)	Abseamed	Medice Arzneimittel Pütter	Germany	Anaemia, Cancer, CKF	Eprex/Erypo (Janssen-Cilag)	Aug 2007
		Binocrit	Sandoz	Switzerland	Anaemia, CKF	Eprex/Erypo (Janssen-Cilag)	Aug 2007
		Epoetin alfa Hexal	Hexal	Germany	Anaemia, CKF	Eprex/Erypo (Janssen-Cilag)	Aug 2007
	Epoetin zeta (2)	Retacrit	Hospira (Pfizer)	USA	Anaemia, Cancer, CKF, Autologous blood transfusion	Eprex/Erypo (Janssen-Cilag)	Dec 2007
		Silapo	Stada R & D	Germany	Anaemia, Cancer, CKF, Autologous blood transfusion	Eprex/Erypo (Janssen-Cilag)	Dec 2007
	Etanercept (3)	Benepali	Samsung Bioepis	South Korea	AS, Axial SpA, JIA, PsA, PsO, RA	Enbrel (Amgen)	Jan 2016
		Erelzi	Sandoz	Switzerland	AS, JIA, PsO, PsA, RA	Enbrel (Amgen)	Jun 2017
Nepexto		Mylan IRE Healthcare	Ireland	AS, JIA, SpA, PsO, RsA, RA	Enbrel (Amgen)	May 2020	
Filgrastim (9 approved, 2 withdrawn)	<i>Biograstim</i>	<i>AbZ-Pharma</i>	<i>Germany</i>	<i>Cancer, neutropenia, haematopoietic stem cell transplantation</i>	<i>Neupogen (Amgen)</i>	<i>Sep 2008 With-drawn Dec 2016</i>	
	Ratiograstim	Ratiopharm	Germany	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	Sep 2008	
	Tevagrastim	Teva Generics	Israel	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	Sep 2008	
	<i>Filgrastim ratiopharm</i>	<i>Ratiopharm</i>	<i>Germany</i>	<i>Cancer, Neutropenia, Haematopoietic stem cell transplantation</i>	<i>Neupogen (Amgen)</i>	<i>Sep 2008 With-drawn Apr 2011</i>	

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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
EU (68 approved, 3 positive opinion, but 8 withdrawn, 1 cessation later)		Filgrastim Hexal	Hexal	Germany	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	Feb 2009
		Zarzio	Sandoz	Switzerland	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	Feb 2009
		Nivestim	Hospira (Pfizer)	USA	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Neupogen (Amgen)	Jun 2010
		Grastofil	Apotex	Canada	Neutropenia	Neupogen (Amgen)	Oct 2013
		Accofil	Accord Healthcare	Spain	Neutropenia	Neupogen (Amgen)	Sep 2014
	Pegfilgrastim (7)	Udenyca	ERA Consulting (Coherus Biosciences)	USA	Neutropenia	Neulasta (Amgen)	Sep 2018
		Pelgraz	Accord Healthcare	Spain	Neutropenia	Neulasta (Amgen)	Sep 2018
		Ziextenzo	Sandoz	Switzerland	Neutropenia	Neulasta (Amgen)	Nov 2018
		Fulphila	Mylan	USA	Neutropenia	Neulasta (Amgen)	Dec 2018
		Pelmeg	Cinfa Biotech/ Mundipharma	Spain/USA	Neutropenia	Neulasta (Amgen)	Nov 2018
		Grasustek	Juta Pharma GmbH	Germany	Neutropenia	Neulasta (Amgen)	Jun 2019
		Cegfila	Mundipharma	Ireland	Neutropenia	Neulasta (Amgen)	Dec 2019
	Follitropin alfa (2)	Ovaleap	Teva Pharma	Israel	Anovulation (IVF)	Gonal-F (Merck Serono Europe)	Sep 2013
		Bemfola	Gedeon Richter Plc	Hungary	Anovulation (IVF)	Gonal-F (Merck Serono Europe)	Mar 2014
	Infliximab (4)	Inflectra	Hospira (Pfizer)	USA	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Sep 2013
Remsima		Celltrion	South Korea	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	Sep 2013	
Flixabi		Samsung Bioepis	South Korea	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	May 2016	
Zessly		Sandoz	Switzerland	AS, CD, PsA, PsO, RA, UC	Remicade (Janssen Biologics)	May 2018	

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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
EU (68 approved, 3 positive opinion, but 8 withdrawn, 1 cessation later)	Insulin glargine (3) (3 approved, 1 withdrawn)	Abasaglar (previously Abasria)	Eli Lilly/ Boehringer Ingelheim	Netherlands	Diabetes	Sanofi (Lantus)	Sep 2014
		Lusduna	Merck (MSD)	USA	Diabetes	Lantus (Sanofi)	Jan 2017 Withdrawn Oct 2018
		Semglee	Mylan	USA	Diabetes	Lantus (Sanofi)	Mar 2018
	Insulin lispro (1)	Insulin lispro Sanofi	Sanofi Aventis	Switzerland	Diabetes	Humalog (Lilly)	Jul 2017
	Insulin aspart (1)	Insulin aspart Sanofi	Sanofi Aventis	Switzerland	Diabetes	NovoRapid (Novo Nordisk)	Jun 2020
	Rituximab (7 approved, 1 withdrawn)	Truxima	Celltrion	South Korea	CLL, GPA, MPA, NHL, RA	MabThera (Roche)	Feb 2017
		Rixathon	Sandoz	Switzerland	CLL (B-cell), MPA, NHL, RA, GPA	MabThera (Roche)	Jun 2017
		Riximyo	Sandoz	Switzerland	As above	MabThera (Roche)	Jun 2017
		Blitzima	Celltrion	South Korea	NHL, CLL (B-cell)	MabThera (Roche)	Jul 2017
		Ritemvia	Celltrion	South Korea	GPA, MPA, NHL	MabThera (Roche)	Jul 2017
		Rituzena (previously Tuxella)	Celltrion	South Korea	GPA, MPA, NHL, CLL (B-cell)	MabThera (Roche)	Jul 2017 Withdrawn Jul 2019
	Ruxience	Pfizer Europe	Belgium	NHL, CLL (B-cell), MPA, GPA, RA, Pempfigus vulgaris	MabThera (Roche)	Apr 2020	
	Somatropin (2 approved, 1 withdrawn)	Omnitrope	Sandoz	Switzerland	Pituitary dwarfism, Prader-Willi syndrome, Turner syndrome	Genotropin (Pfizer)	Apr 2006
Valtropin		BioPartners		Pituitary dwarfism, Turner syndrome	Humatrope (Eli Lilly)	Apr 2006 Withdrawn May 2012	
Teriparatide (4)	Movymia	Stada Arzneimittel	Germany	Osteoporosis	Forteo/Forsteo (Lilly)	Jan 2017	
	Terrosa	Gedeon Richter	Hungary	Osteoporosis	Forteo/Forsteo (Lilly)	Jan 2017	
	Livogiva	Theramax Ireland	Ireland	Osteoporosis	Forteo/Forsteo (Lilly)	Positive opinion Jun 2020	
	Qutavina	Eurogenerics		Osteoporosis	Forteo/Forsteo (Lilly)	Positive opinion Jun 2020	

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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
EU (68 approved, 3 positive opinion, but 8 withdrawn, 1 cessation later)	Trastuzumab (6)	Ontruzant	Samsung Bioepis	South Korea	Early BC, mBC, mGC	Herceptin (Roche)	Nov 2017
		Herzuma	Celltrion	South Korea	Early BC, mBC, mGC	Herceptin (Roche)	Feb 2018
		Kanjinti	Amgen/ Allergan	USA	Early BC, mBC, mGC	Herceptin (Roche)	May 2018
		Trazimera	Pfizer	USA	Early BC, mBC, mGC	Herceptin (Roche)	Jul 2018
		Ogivri	Biocon/Mylan	India/USA	Early BC, mBC, mGC	Herceptin (Roche)	Dec 2018
		Zercepac	Accord Healthcare SLU	Spain	Early BC, mBC, mGC	Herceptin (Roche)	Jul 2020
Ghana (13)	Epoetin alfa (2)	Binocrit	Sandoz GmbH	Austria	Symptomatic anaemia associated with CRF	Eporex/Erypo (epoetin alfa) (Janssen-Cilag GmbH)	Mar 2019
		Repoitin 4000 IU, 2000 IU	Serum Institute of India	India	Anaemia	Eporex/Erypo (epoetin alfa) (Janssen-Cilag GmbH)	Jan 2019
	Follicle stimulating hormone (2)	Foligraf 75 IU, 150 IU	Bharat Serums/ Vaccines Limited	India		Gonal-F (Merck Serono SA)	May 2018
		Menopur 75 IU	Ferring Pharmaceuticals	Germany	Female infertility	Gonal-F (Merck Serono SA)	Jan 2019
	Insulin (8)	Wosulin N	Wockhardt Towers	India	Diabetes mellitus	Insulatard and/or Actrapid (Novo Nordisk A/S Denmark as applicable)	Apr 2017
		Wosulin R	Wockhardt Towers	India			Apr 2017
		Wosulin 30/70	Wockhardt Towers	India			Apr 2017
		Insugen-R	Biocon Ltd	India			Mar 2020
		Insugen 30/70	Biocon Ltd	India			Mar 2020
		Insugen-N	Biocon Ltd	India			Mar 2020
		Insunova N in 10 mL vial and 3 mL cartridge	Biocon Ltd	India			Mar 2017
		Insunova R in 10 mL vial and 3 mL cartridge	Biocon Ltd	India			Feb 2017
	Trastuzumab	Hertraz 150 mg, 440 mg	Biocon Ltd	India		Herceptin (F. Hoffmann-La Roche Ltd) Registered in Ghana	May 2018

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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
India (96)	Abciximab	AbcixiRel	Reliance Life Sciences	India	Angina, Cardiac ischaemia		Apr 2013
	Adalimumab (4)	Exemptia	Zydus Cadila	India	RA		Sep 2014
		Adfrar	Torrent Pharmaceuticals	India	AS, PsO, PsA, RA, UC		Jan 2016
		Mabura	Hetero Drugs	India			Jan 2018
		AdaliRel	Reliance Life Sciences Pvt Ltd	India	RA, JIA, PsA, AS, Axial SpA, CD, UC	Humira (AbbVie)	Jun 2015
	Becaplermin	rh-PDGF-BB + -TCP	Virchow Biotech	India	Peridontal defect, Gingival recession		Apr 2010
	Bevacizumab (5)	Bevacirel	Reliance Life Sciences (Lupin)	India	CC		Jun 2016
		Cizumab	Hetero	India	CC		Jun 2016
		Krabeva	Biocon	India	mCRC, LC, KC, CC, OC, BrC		Nov 2017
		Bevatas	Intas Pharmaceuticals Ltd	India	Advanced, metastatic or recurrent NSCLC		Jun 2016
		Bryxta	Cadila Healthcare Ltd	India	mCRC, nsNSCLC, MBC, Gliblastma, mRCC, Persistent, Recurrent or Metastatic CC, EOC, FTC, pPC		May 2017
	Chorionic gonadotrophin hormone r-hCG	Choriorel	Reliance Life Sciences	India	Female infertility		Jun 2011
	Darbepoetin alfa (4)	Cresp	Dr Reddy's Laboratories	India	Anaemia, Cancer, CKF		Mar 2010
		DarbeRel	Reliance Life Sciences Pvt Ltd	India	Anaemia due to CKF, chemotherapy in patients with cancer, or with non-myeloid malignancies		Jun 2016
Actorise Darbatitor		Cipla/Hetero Torrent Pharmaceuticals		Anaemia, Cancer, CKF Anaemia, Cancer, CKF		Jan 2014 2014	
Denosumab	Olimab 60 mg/mL PFS	Intas Pharmaceuticals Ltd	India	Osteoporosis at high risk for fracture		Jan 2018	
Epoetin alfa (11)	Ceriton	Ranbaxy	India	Anaemia, Cancer, CKF			
	Epofer	Emcure	India	Anaemia, Cancer, CKF			
	Wepox	Wockhardt	India	Anaemia, Cancer, CKF		Mar 2001	

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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)		Shanpoietin	ShanthaBio-technics/Merieux Alliance	India	Anaemia, CKF		Jan 2005	
		EpoFit/Erykine	Intas Pharmaceuticals	India	Anaemia, Cancer, CKF		Aug 2005	
		Relipoietin	Reliance Life Sciences	India	Anaemia, Autologous blood transfusion, CKF, HIV		2008	
		Zyrop	Cadila Healthcare	India	CKF		Apr 2010	
		Repoitin	Serum Institute of India	India	Anaemia, CKF		Nov 2011	
		Eporec	Bioviz Technologies		Anaemia, Cancer, CKF		Aug 2011	
		Erypro	Biocon	India	Anaemia, Cancer, CKF			
		Epotin	Claris Lifesciences	India	Anaemia, Cancer, CKF			
		Etanercept (2)	Etacept	Cipla	India	AS, RA, PsA, PsO, JRA		Apr 2013
			Intacept	Intas Pharmaceuticals	India	AS, JIA, PsO, PsA, RA		Mar 2015
		Filgrastim (9)	Fegrast	Claris Lifesciences	India	Cancer, Neutropenia, Haematopoietic stem cell transplantation		
			Grafeel	Dr Reddy's Laboratories	India	Cancer, Neutropenia, Haematopoietic stem cell transplantation		
			Nufile	Biocon	India	Cancer, Neutropenia		
			Neukine	Intas Pharmaceuticals	India	Cancer, Neutropenia, Haematopoietic stem cell transplantation		Jul 2004
			Religrast	Reliance Life Sciences	India	Neutropenia		2008
			Emgrast	Gennova Biopharmaceuticals (Emcure)	India	Cancer, Neutropenia		Mar 2010
			Filgrastim	Cadila Pharmaceutical	India	Neutropenia		Oct 2013
			Filgrastim	Lupin	India	Neutropenia		Mar 2013
			Filgrastim	USV	India	Neutropenia		Jun 2013
		Pegfilgrastim (7)	Neupeg	Intas Pharmaceuticals	India	Cancer, Neutropenia		Aug 2007
			Pegex	Gennova Biopharmaceuticals (Emcure)	India	Cancer, Neutropenia		Jan 2010

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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	
India (96)		Peg-grafeel	Dr Reddy's Laboratories	India	Cancer, Neutropenia		May 2010	
			Lupin limited	India	Chemotherapy-induced febrile neutropenia (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)		Sep 2013	
			Wockhardt Limited	India	Chemotherapy-induced neutropenia in non-myeloid malignancies		Feb 2015	
			Reliance Life Sciences Pvt Ltd	India	Chemotherapy-induced neutropenia		May 2016	
			Cadila Healthcare Ltd	India	NA		May 2015	
		Follitropin alfa (4)	FostiRel	Reliance Life Sciences Pvt Ltd	India	Female infertility		Apr 2010
			Folisurge	Intas Pharmaceuticals	India	Female infertility, Spermatogenesis in men		May 2013
				Intas Biopharmaceuticals	India	<u>In adult women:</u> An ovulation, Stimulation of multi-follicular development, e.g. IVF, FSH in association with LH <u>In adult men:</u> Stimulation of spermatogenesis		May 2013
			Theramex	Cadila Healthcare Ltd	India			Jan 2018
		Follitropin beta	FostiRel	Reliance Life		Female infertility		Apr 2010
		Hepatitis B vaccine	Biovac-B	Wockhardt		Hepatitis B		2000
		Infliximab (2)	Infimab	Ranbaxy/ Epirus	India/USA	AS, CD, PsO, PsA, RA, UC		Sep 2014
			Liarta			AS, CD, PsO, PsA, RA, UC	Remicade	Jan 2020
		Insulin (3)	Insugen	Biocon	India	Diabetes mellitus		
			Wosulin	Wockhardt		Diabetes		Aug 2003
			Insulin	Gland Pharma		Diabetes mellitus		Aug 2011
	Recombinant human insulin		Scigen Biopharma Pvt ltd	India	NA		Feb 2015	

(Continued)

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)	Insulin glargine (2)	Basalog	Biocon	India	Diabetes		2009	
		Glartus	Wockhardt		Diabetes		Mar 2009	
	Interferon alfa-2b (4)	Shanferon	ShanthaBio-technics/Mer-ieux Alliance			BCR-ABL positive, Carcinoid tumour, Chronic hepatitis B, Chronic hepatitis C, Chronic myelogenous leukaemia, Follicular lymphoma, Hairy cell leukaemia, Melanoma, Multiple myeloma		Apr 2002
		Reliferon	Reliance Life Sciences	India			2008	
		Intalfa	Intas Pharmaceuticals	India			Apr 2017	
		Zavinex	Cadila Healthcare	India			Jun 2011	
	Pegylated recombinant human interferon alfa-2b (2)		Cadila Healthcare Ltd	India		Chronic hepatitis B and Chronic hepatitis C patients		Jun 2011
			Intas Biopharmaceuticals	India			Chronic hepatitis C and Chronic hepatitis B	
	Interferon beta-1a	Relibeta	Reliance Life Sciences	India		Multiple sclerosis		May 2011
	Recombinant interferon beta-1a		Reliance Life Sciences Pvt Ltd	India		For the treatment of relapsing multiple sclerosis		May 2011
	Itolizumab (T1hmAb) injection		Biocon Ltd	India		For the treatment of patients with active to moderate to severe chronic plaque psoriasis who are candidates for systemic therapy		Dec 2012
	Molgramostim	Molgramostim	Zenotech Laboratories	India		Neutropenia		May 2013
	Omalizumab	Not yet in market	Reliance Life Sciences Pvt Ltd, Dhirubhai Ambani Life Sciences Centre	India		Asthma, Chronic Idiopathic Urticaria	Xolair	Feb 2020
Ranibizumab (2)		Intas Pharmaceuticals Ltd	India		Neovascular AMD, DME, Macular edema following RVO, Vaisula imparment due to CNV secondary to pathological myopia		Feb 2015	

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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
India (96)		Not yet in market	CJSC BIOCAD, Russia Liter A, bld. 34, Svyazi str, Strelna, Petrodvortsovyy District, St Petersburg, Russian Federation, 198515		Neovascular (Wet) AMD	Lucentis	Mar 2020
	Rasburicase injection	Rasburicase	Virchow Biotech Pvt Ltd	India	Malignancy associated hyperuricemia		Aug 2012
	Recombinant hCG		Bharat Serum & vaccines Pvt Ltd	India	IVF		May 2017
	Recombinant human granulocyte macrophage colony stimulating factor (Molgramostim)		Zenotech Laboratories	India	Reduction of the severity of neutropenia in patients receiving myelosuppressive therapy (cancer chemotherapy)		May 2013
	Recombinant human growth hormone		USV Limited	India	Treatment of pre-pubertal children (4 to 12 years) with growth hormone deficiency		Jun 2013
	Retepase	Mirel	Reliance Life Sciences	India	Myocardial infarction		2009
	Rituximab (5)	MabTas	Intas Pharmaceuticals	India	Lymphoma, NHL		Feb 2013
		Rituximab	Zenotech Laboratories	India	NHL		Feb 2013
		RituxiRel	Reliance Life Sciences	India	NHL, RA		Feb 2015
		Maball	Hetero Group	India	Lymphoma, NHL		Feb 2015
		Acellbia	Biocad	Russia	NHL, CLL (B-cell)		Jul 2017
Somatropin		Reliance Life Sciences Pvt Ltd	India	<u>In paediatrics patients:</u> 1) growth failure due to inadequate secretion of GH 2) short stature associated with Noonan syndrome or born small for gestational age with no catch-up growth by age 2-4 years		May 2018	

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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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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
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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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
Japan (26)	Darbepoetin alfa (3)	Darbepoetin alfa BS [Darbepoetin alfa BS1]	JCR Pharmaceuticals	Japan	Anaemia	NESP (Kyowa Hakkō Kirin)	Sep 2019
		Darbepoetin alfa BS [Darbepoetin alfa BS2]	Sanwa Kagaku Kenkyusho	Japan	Anaemia	NESP (Kyowa Hakkō Kirin)	Sep 2019
		Darbepoetin alfa BS [Darbepoetin alfa BS3]	Mylan	USA	Anaemia	NESP (Kyowa Hakkō Kirin)	Sep 2019
	Epoetin kappa	Epoetin alfa BS [Epoetin alfa BS1]	JCR Pharmaceuticals	Japan	Anaemia, Renal anaemia	Espo (Epoetin alfa) (Kyowa Hakkō 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 Hakkō Kirin)	Nov 2012
		Filgrastim BS [filgrastim BS2]	Teva Pharma Japan	Israel	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Gran (Filgrastim) (Kyowa Hakkō Kirin)	Feb 2013
		Filgrastim BS [filgrastim BS3]	Sandoz	Switzerland	Cancer, Neutropenia, Haematopoietic stem cell transplantation	Gran (Filgrastim) (Kyowa Hakkō 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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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
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

(Continued)

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
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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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
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

(Continued)

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
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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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
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 Belmedpreparati Belmedpreparati 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 Pharmaceuticals Gan and Li Pharmaceuticals Geropharm	China		Humalog (Eli Lilly)	2017
				China		Lantus Solo-Star (Sanofi)	2017
				Russia		Humalog (Eli Lilly)	2019

(Continued)

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
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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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
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

(Continued)

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)		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) Nyvepria (pegfilgrastim-apgf)	Sandoz			Neulasta (Amgen)	Nov 2019 Jun 2020
	Infliximab (4)	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	

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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.

When compared with the situation in August 2019 [1], the major biosimilar products being approved as of July 2020 are monoclonal antibodies. For example, six and seven monoclonal antibody similar biotherapeutic products/biosimilars have been approved in Brazil and in Canada, respectively, during the updating period.

The quality of similar biotherapeutic products/biosimilars approved in some countries is still an issue for concern. Some products in certain countries were approved prior to adoption of regulations or guidelines for biosimilar evaluation, see Table 1. As mentioned above, EMA was the first agency to adopt the biosimilar concept in 2006, so products called 'biosimilars' approved before 2006 are unlikely to be biosimilars [1]. Regulators need to reassess such products to ensure whether they meet the current requirements and to identify the inappropriate labelling of non-innovator and copy-version products (approved when regulatory procedures were not well defined) as biosimilars [7-9].

It is clear that increasing numbers of biosimilars are now available in many countries and provide more options for treatments. In certain countries, the availability of various product classes has been expanded by approval of biosimilars for which product classes were not available on the market previously. This is important for relatively expensive products, e.g. monoclonal antibodies. It is expected that adoption of biosimilars will allow affordable health care and greater patient access to important medicinal products [1].

Disclaimer

The authors alone are responsible for the views expressed in this manuscript and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated. The survey participants are listed in alphabetical order in the author section after the three primary authors.

Table 2: Numbers of similar biotherapeutic products/biosimilars approved by regulatory authorities in 16 countries (July 2020)

The information below provided based on the categorization of similar biotherapeutic products/biosimilars by each national regulatory authority. Thus, similar biotherapeutic products/biosimilars approved in certain countries might not have been approved following as strict a regulatory process as is required by WHO guidelines. Indications also as reported by survey participants; not necessarily representing WHO approval of these.

INN	Brazil	Canada	China	EU	Ghana	India	Iran	Japan	Jordan	Malaysia	Republic of Korea	Russia	Singapore	Thailand	Ukraine	USA
Others*				1		15	1	1								
hCG						2										
Teriparatide				2 (2)		3		1			1					
Somatropin	1	1		2		1		1	1	1	1		1		1	
LMWH	1			2												
Peg-interferon						2	1									
Interferon						6	6					6				
Human insulin	1				8	4	1		1	1		10				
Insulin isophane	1															
Insulin glargine	3	1		3		2		2		1	2	2	2			
Insulin lispro	1	1		1				1				2				
FSH					2	2	1								1	
Peg-filgrastim		3				7	2			1				1		4
Filgrastim	2	2		9		9	2	3	2	2		4	2	4	2	2
Etanercept	3	2		3		2	1	2			3			1		2
EPO				5	2	11	2	1	1	3	1	3			1	1
Darbepoetin						4		3			1					
Rituximab	4	3	1	7		5	2	2	3	1	1	2	2	3	1	2
Infliximab	3	4		4		2		3	1	1	2	2	1			4
Trastuzumab	5	4	1	6	1	5	1	3	2	3	2	2	2	4	2	5
Ranibizumab						2										
Bevacizumab	2	2	2	3 (1)		5	1	2		1		1		1		2
Adalimumab	3	3	2	11		4	1	1	1	1	1	1	1	1		6
Total	30	26	6	68 (3)	13	96	22	26	12	16	15	35	11	15	8	28

In EU: 1 numbers in brackets indicate biosimilars with positive opinions; 2) nine biosimilars approved then withdrawn (3 adalimumab, 2 filgrastim, 1 insulin glargine, 1 rituximab, 1 somatropin); or ceased (LMWH). *Others: EU (insulin aspart); India (abciximab, becaplermin, denosumab, granulocyte macrophage colony-stimulating factor, hepatitis B vaccine, itolizumab, molgramostim, omalizumab, rabaricase, reteplase, streptokinase); Iran (eptacog alfa); Japan (agalsidase beta). EPO: erythropoietin; FSH: follicle stimulating hormone; hCG: human chorionic gonadotropin; INN: International Nonproprietary Name; LMWH: low molecular weight heparin; WHO: World Health Organization.

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The information in this manuscript provided based on the categorization of biosimilars by each national regulatory authority. Thus, biosimilars approved in certain countries might not have been approved following as strict a regulatory process as is required by WHO guidelines. Indications in Table 1 also

as reported by survey participants; not necessarily representing WHO approval of these.

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Acronyms and abbreviations

AMD	age-related macular degeneration
AS	ankylosing spondylitis
BC	breast cancer
BrC	brain cancer
CC	cervical cancer
CD	Crohn's disease
CKF	chronic kidney failure
CLL	chronic lymphocytic leukaemia
CNV	choroidal neovascularization
CRC	colorectal cancer
CRF	chronic renal failure
DME	diabetic macular edema
EMA	European Medicines Agency
EOC	epithelial ovarian cancer
EPO	erythropoietin
ERA	entesitis-related arthritis
FSH	follicle stimulating hormone
FTC	fallopian tube cancer
GC	gastric cancer
GH	growth hormone
GPA	granulomatosis with polyangiitis
hCG	human chorionic gonadotropin
HS	hidradenitis suppurativa
INN	International Nonproprietary Name
IVF	<i>in vitro</i> fertilization
JIA	juvenile idiopathic arthritis
JRA	juvenile rheumatoid arthritis
KC	kidney cancer
LC	lung cancer
LH	luteinizing hormone
LMWH	low molecular weight heparin
m	metastatic
MA	marketing authorization
MPA	Microscopic Polyangiitis
NHL	Non-Hodgkin lymphoma
nr-axS	Non-radiographic axial spondylitis
nsNSCLC	Non-squamous non-small cell lung cancer
OC	Ovarian cancer
p	primary
PBPC	peripheral blood progenitor cells
PC	peritoneal cancer
PsA	psoriatic arthritis
PsO	plaque psoriasis
PWS	Prader-Willi syndrome
RA	rheumatoid arthritis/
RCC	renal cell carcinoma
RVO	retinal vein occlusion
SpA	spondyloarthritis
UC	ulcerative colitis

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