

## Biosimilar medicines authorised via the EMA

Table last updated on 31/08/2023

based on last CHMP meeting highlights: 17-20 July 2023



[www.biosimilars-nederland.nl](http://www.biosimilars-nederland.nl)

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Aflibercept (Yesafili®)	1-jul-2023	Treatment of age-related macular degeneration (AMD) and visual impairment	Viartis Limited	Pending EC decision
Natalizumab (Tyruko®)	1-jul-2023	Therapy for active relapsing remitting multiple sclerosis (RRMS)	Sandoz GmbH	Pending EC decision
Tocilizumab (Tyenne®)	1-jul-2023	Rheumatoid Arthritis; Cytokine Release Syndrome; Juvenile Rheumatoid Arthritis COVID-19 virus infection; Giant Cell Arteritis	Fresenius Kabi Deutschland GmbH	Pending EC decision
Eculizumab (Epysqli®)	1-mrt-2023	Treatment of paroxysmal nocturnal haemoglobinuria in adults and children	Samsung Bioepis NL B.V.	26-mei-2023
Eculizumab (Bekemv®)	1-feb-2023	Treatment of paroxysmal nocturnal haemoglobinuria in adults and children	Amgen Technology (Ireland) Unlimited Company	19-apr-2023
Teriparatide (Kauliv®)	1-nov-2022	Treatment of osteoporosis	Strides Pharma Cyprus	12-jan-2023
Ranibizumab (Ximluci®)	1-sep-2022	Treatment of neovascular age-related macular degeneration	STADA Arzneimittel AG	9-nov-2022
Ranibizumab (Ranivisio®)	1-jun-2022	Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema or choroidal neovascularisation, and proliferative diabetic retinopathy	Midas Pharma GmbH	25-aug-2022
Bevacizumab (Vegzelma®)	1-jun-2022	Treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix	Celltrion Healthcare Hungary Kft	17-aug-2022
Insulin aspart (Truvelog Mix 30®)	1-feb-2022	Treatment of diabetes mellitus	sanofi-aventis groupe	25-apr-2022
Insulin human (rDNA) (Inpremia®)	1-feb-2022	Treatment of diabetes mellitus	Baxter Holding B.V.	25-apr-2022
Pegfilgrastim (Stimufend®)	1-jan-2022	Reduction of the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic chemotherapy	Fresenius Kabi Deutschland GmbH	28-mrt-2022
Teriparatide (Sondelbay®)	1-jan-2022	Treatment of osteoporosis	Accord Healthcare S.L.U.	24-mrt-2022
Adalimumab (Libmyris®)	1-sep-2021	Treatment of inflammatory auto-immune disorders	STADA Arzneimittel AG	12-nov-2021
Adalimumab (Hukyndra®)	1-sep-2021	Treatment of inflammatory auto-immune disorders	STADA Arzneimittel AG	16-nov-2021

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Ranibizumab (Byooviz®)	June/21	Wet Macular Degeneration, Macular Edema, Diabetic Retinopathy, Degenerative Myopia	Samsung Bioepis NL B.V.	18-aug-2021
Bevacizumab (Abevmy®)	1-feb-2021	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Mylan IRE Healthcare Limited	21-apr-2021
Bevacizumab (Oyavas®)	1-jan-2021	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	STADA Arzneimittel AG	26-mrt-2021
Bevacizumab (Alymsys®)	1-jan-2021	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Mabxience Research SL	26-mrt-2021
Insulin aspart (Kixelle®)	1-dec-2020	Treatment of diabetes mellitus	Mylan IRE Healthcare Limited	5-feb-2021
Adalimumab (Yuflyma®)	1-dec-2020	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Celltrion Healthcare Hungary Kft.	11-feb-2021
Bevacizumab (Onbevzi®)	1-nov-2020	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	11-jan-2021
Pegfilgrastim (Nyvepria®)	1-sep-2020	Neutropenia	Pfizer Europe MA EEIG	18-nov-2020
Bevacizumab (Equidacent®)	1-jul-2020	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Centus Biotherapeutics Europe Limited	24-sep-2020
Teriparatide (Livogiva®)	1-jun-2020	Treatment of osteoporosis	Theramex Ireland Limited	27-aug-2020
Bevacizumab (Aybintio®)	1-jun-2020	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	19-aug-2020
Insulin aspart (Insulin aspart Sanofi®)	1-apr-2020	Treatment of diabetes mellitus	sanofi-aventis groupe	1-jun-2020
Trastuzumab (Zercepac)	1-mei-2020	Treatment of breast and gastric cancer	Accord Healthcare S.L.U.	1-jul-2020

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Etanercept (Nepexto®)	mar/20	The treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis, non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.	Mylan IRE Healthcare Limited	20-mei-2020
Rituximab (Ruxience®)	1-jan-2020	The treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, and Pemphigus vulgaris.	Pfizer Europe MA EEIG	1-apr-2020
Adalimumab (Amsparity®)	1-dec-2019	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Pfizer Europe MA EEIG	13-feb-2020
Pegfilgrastim (Cegfila®)	1-okt-2019	Neutropenia	Mundipharma Biologics S.L.	1-dec-2019
Pegfilgrastim (Grasustek®)	26-apr-2019	Neutropenia	Juta Pharma GmbH	26-apr-2019
Adalimumab (Idacio®)	31-jan-2019	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Fresenius Kabi	2-apr-2019
Bevacizumab (Zirabev®)	13-dec-2018	Colorectal Neoplasms; Breast Neoplasms; Non-Small-Cell Lung Carcinoma; Renal Cell Carcinoma; Uterine Cervical Neoplasms	Pfizer	19-feb-2019
Trastuzumab (Ogivri®)	19-okt-2018	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Mylan	12-dec-2018
Pegfilgrastim (Fulphila®)	20-sep-2018	Neutropenia	Mylan	20-nov-2018
Pegfilgrastim (Pelmeg®)	20-sep-2018	Neutropenia	Cinfa Biotech S.L.	20-nov-2018
Pegfilgrastim (Ziextenzo®)	20-sep-2018	Neutropenia	Sandoz	20-nov-2018
Pegfilgrastim (Pelgraz®)	26-jul-2018	Neutropenia	Accord Healthcare	20-sep-2018
Pegfilgrastim (Udenyca®)	26-jul-2018	Neutropenia	ERA Consulting	20-sep-2018

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Adalimumab (Hulio®)	26-jul-2018	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Mylan	16-sep-2018
Adalimumab (Halimatoz®)	31-mei-2018	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	26-jul-2018
Adalimumab (Hefiya®)	31-mei-2018	Juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	26-jul-2018
Adalimumab (Hyrimoz®)	31-mei-2018	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Sandoz	26-jul-2018
Trastuzumab (Trazimera®)	31-mei-2018	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Pfizer	26-jul-2018
Infliximab (Zessly®)	22-mrt-2018	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Sandoz	18-mei-2018
Trastuzumab (Kanjinti®)	22-mrt-2018	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Amgen	18-mei-2018
Insulin glargine (Semglee®)	1-jan-2018	Diabetes Mellitus	Mylan	23-mrt-2018
Trastuzumab (Herzuma®)	15-dec-2017	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Celltrion	9-feb-2018
Bevacizumab (Mvasi®)	1-nov-2017	Fallopian tube neoplasms, Non-Small-Cell Lung Carcinoma, ovarian neoplasms, Renal Cell Carcinoma, Peritoneal Neoplasms, Breast Neoplasms	Amgen	1-jan-2018
Trastuzumab (Ontruzant®)	1-sep-2017	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Samsung Bioepis	1-nov-2017
Adalimumab (Imraldi®)	1-jun-2017	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Samsung Bioepis	1-aug-2017

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Insulin Lispro (Insulin lispro Sanofi®)	may-17	Diabetes mellitus	Sanofi	1-jul-2017
Rituximab (Blitzima®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	1-jul-2017
Rituximab (Ritemvia®)	may-17	Non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	1-jul-2017
Etanercept (Erelzi®)	1-apr-2017	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis.	Sandoz	1-jun-2017
Rituximab (Rixathon®)	1-apr-2017	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	1-jun-2017
Rituximab (Riximyo®)	1-apr-2017	Non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	1-jun-2017
Adalimumab (Amgevita®)	1-jan-2017	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Amgen	1-mrt-2017
Rituximab (Truxima®)	1-dec-2016	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	1-feb-2017
Teriparatide (Movymia®)	1-nov-2016	Osteoporosis	STADA Arzneimittel	1-jan-2017
Teriparatide (Terrosa®)	1-nov-2016	Osteoporosis	Gedeon Richter	1-jan-2017
Enoxaparin (Inhixa®)	1-jul-2016	Prophylaxis of venous thromboembolic disease, deep vein thrombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Techdow	1-sep-2016
Infliximab (Flixabi®)	1-mrt-2016	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Samsung Bioepis	1-mei-2016
Etanercept (Benepali®)	1-nov-2015	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis	Samsung Bioepis	1-jan-2016
Filgrastim (Accofil®)	25-jul-2014	Neutropenia	Accord Healthcare	1-sep-2014

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Insulin glargine (Abasaglar®)	27-jun-2014	Diabetes Mellitus	Eli Lilly	1-sep-2014
Follitropin alfa (Bemfola®)	24-jan-2014	Anovulation	Finox	1-mrt-2014
Filgrastim (Grastofil®)	26-jul-2013	Neutropenia	Apotex	1-okt-2013
Follitropin alfa (Ovaleap®)	1-aug-2013	Anovulation	Teva	1-sep-2013
Infliximab (Inflectra®)	1-jun-2013	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Hospira	1-sep-2013
Infliximab (Remsima®)	1-jun-2013	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Celltrion	1-sep-2013
Filgrastim (Nivestim®)	19-mrt-2010	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hospira/Pfizer	1-jun-2010
Filgrastim (Filgrastim Hexal®)	19-nov-2008	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hexal	1-feb-2009
Filgrastim (Zarzio®)	1-nov-2008	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Sandoz	1-feb-2009
Filgrastim (Ratiograstim®)	25-jul-2008	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Ratiopharm	1-sep-2008
Filgrastim (Tevagrastim®)	25-jul-2008	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Teva	1-sep-2008
Epoetin zeta (Retacrit®)	23-okt-2007	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Hospira	1-dec-2007
Epoetin zeta (Silapo®)	23-okt-2007	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Stada	1-dec-2007
Epoetin alfa (Abseamed®)	23-okt-2007	Anaemia, chronic renal failure, cancer	Medice	1-aug-2007
Epoetin alfa (Binocrit®)	1-jun-2007	Anaemia, chronic renal failure, cancer	Sandoz	1-aug-2007
Epoetin alfa (Epoetin Alfa Hexal®)	1-jun-2007	Anaemia, chronic renal failure, cancer	Hexal	1-aug-2007
Somatropin (Omnitrope®)	26-jun-2003	Growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, small for gestational age	Sandoz	1-apr-2006