

## Biosimilar medicines authorised via the EMA

Table last updated on 17/09/2022

based on last CHMP meeting highlights: 12-15 September 2022

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Adalimumab (Amgevita®)	jan-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis	Amgen	mrt-17
Adalimumab (Amsparity®)	dec-19	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	Pfizer Europe MA EEIG	feb-20
Adalimumab (Halimatoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul-18
Adalimumab (Hefiya®)	mei-18	Juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and	Sandoz	jul-18
Adalimumab (Hukyndra)	sep-21	Treatment of inflammatory auto-immune disorders	STADA Arzneimittel AG	nov-21
Adalimumab (Hulio®)	jul-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis	Mylan	sep-18
Adalimumab (Hyrimoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis	Sandoz	jul-18
Adalimumab (Idacio®)	jan-19	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis	Fresenius Kabi	apr-19
Adalimumab (Libmyris)	sep-21	Treatment of inflammatory auto-immune disorders	STADA Arzneimittel AG	nov-21
Adalimumab (Yuflyma®)	dec-20	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis	Celltrion Healthcare Hungary Kft.	feb-21
Adalimumab (Imraldi®)	jun-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's	Samsung Bioepis	aug-17
Bevacizumab (Abevmy)	feb-21	Colorectal Neoplasms, Breast Neoplasms Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell Uterine Cervical Neoplasms	Mylan IRE Healthcare Limited	apr-21
Bevacizumab (Alymsys®)	jan-21	Colorectal Neoplasms; Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Mabxience Research SL	mrt-21
Bevacizumab (Aybintio®)	jun-20	Colorectal Neoplasms, Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	aug-20

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Bevacizumab (Equidacent®)	jul-20	Colorectal Neoplasms, Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Centus Biotherapeutics Europe Limited	sep-20
Bevacizumab (Mvasi®)	nov-17	Fallopian tube neoplasms, Non-Small-Cell Lung Carcinoma, ovarian neoplasms, Renal Cell Carcinoma, Peritoneal Neoplasms, Breast	Amgen	jan-18
Bevacizumab (Onbevti®)	nov-20	Colorectal Neoplasms; Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	jan-21
Bevacizumab (Oyavas®)	jan-21	Colorectal Neoplasms; Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	STADA Arzneimittel AG	mrt-21
Bevacizumab (Vegzelma)	jun-22	Treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary	Celltrion Healthcare Hungary Kft	Pending EC decision
Bevacizumab (Zirabev®)	dec-18	Colorectal Neoplasms, Breast Neoplasms Carcinoma, Non-Small-Cell Lung Carcinoma, Renal Cell Uterine Cervical Neoplasms	Pfizer	feb-19
Enoxaparin (Inhixa®)	jul-16	Prophylaxis of venous thromboembolic disease, deep vein trombosis, pulmonary embolism, acute coronary syndrome and extra corporeal	Techdow	sep-16
Epoetin alfa (Abseamed®)	okt-08	Anaemia, chronic renal failure, cancer	Medice	aug-07
Epoetin alfa (Binocrit®)	jun-07	Anaemia, chronic renal failure, cancer	Sandoz	aug-07
Epoetin alfa (Epoetin Alfa Hexal®)	jun-07	Anaemia, chronic renal failure, cancer	Hexal	aug-07
Epoetin zeta (Retacrit®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Hospira	dec-07
Epoetin zeta (Silapo®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Stada	dec-07
Etanercept (Benepali®)	nov-15	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis	Samsung Bioepis	jan-16

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Etanercept (Erelzi®)	apr-17	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis.	Sandoz	jun-17
Etanercept (Nepexto®)	mar/20	The treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis non-	Mylan IRE Healthcare Limited	mei-20
Filgrastim (Accofil®)	jul-14	Neutropenia	Accord Healthcare	sep-14
Filgrastim (Filgrastim Hexal®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hexal	feb-09
Filgrastim (Grastofil®)	jul-13	Neutropenia	Apotex	okt-13
Filgrastim (Nivestim®)	mrt-10	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hospira/Pfizer	jun-10
Filgrastim (Ratiograstim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Ratiopharm	sep-08
Filgrastim (Tevagrastim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Teva	sep-08
Filgrastim (Zarzio®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Sandoz	feb-09
Follitropin alfa (Bemfola®)	jan-14	Anovulation	Finox	mrt-14
Follitropin alfa (Ovaleap®)	aug-13	Anovulation	Teva	sep-13
Infliximab (Flixabi®)	mrt-16	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Samsung Bioepis	mei-16
Infliximab (Inflectra®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and	Hospira	sep-13

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Infliximab (Remsima®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Celltrion	sep-13
Infliximab (Zessly®)	mrt-18	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Sandoz	mei-18
Insulin aspart (Insulin aspart)	apr-20	Treatment of diabetes mellitus	sanofi-aventis groupe	jun-20
Insulin aspart (Kixelle®)	dec-20	Treatment of diabetes mellitus	Mylan IRE Healthcare Limited	feb-21
Insulin aspart (Truvelog Mix 30)	feb-22	Treatment of diabetes mellitus	sanofi-aventis groupe	Pending EC decision
Insulin glargine (Abasaalar®)	jun-14	Diabetes Mellitus	Eli Lilly	sep-14
Insulin glargine (Semglee®)	jan-18	Diabetes Mellitus	Mylan	mrt-18
Insulin human (rDNA) (Innremzia)	feb-22	Treatment of diabetes mellitus	Baxter Holding B.V.	Pending EC decision
Insulin Lispro (Insulin lispro Sanofi®)	may-17	Diabetes mellitus	Sanofi	jul-17
Pegfilgrastim (Cegfila®)	okt-19	Neutropenia	Mundipharma Biologics S.L.	dec-19
Pegfilgrastim (Fulphila®)	sep-18	Neutropenia	Mylan	nov-18
Pegfilgrastim (Grasustek®)	apr-19	Neutropenia	Juta Pharma GmbH	apr-19
Pegfilgrastim (Nyvepria®)	sep-20	Neutropenia	Pfizer Europe MA EEIG	nov-20
Pegfilgrastim (Pelgraz®)	jul-18	Neutropenia	Accord Healthcare	sep-18

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Pegfilgrastim (Pelmeg®)	sep-18	Neutropenia	Cinfa Biotech S.L.	nov-18
Pegfilgrastim (Stimufend)	jan-22	Reduction of the duration of neutropenia and the incidence of febrile neutropenia after cytotoxic	Fresenius Kabi Deutschland	mrt-22
Pegfilgrastim (Udenyca®)	jul-18	Neutropenia	ERA Consulting	sep-18
Pegfilgrastim (Ziextenzo®)	sep-18	Neutropenia	Sandoz	nov-18
Ranibizumab (Byooviz)	June/21	Wet Macular Degeneration; Macular Edema Diabetic Retinopathy; Myopia, Degenerative	Samsung Bioepis NL B.V.	aug-21
Ranibizumab (Ranivisio)	jun-22	Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema or choroidal neovascularisation	Midas Pharma GmbH	Pending EC decision
Ranibizumab (Ximluci)	sep-22	Treatment of neovascular age-related macular degeneration	STADA Arzneimittel AG	Pending EC decision
Rituximab (Blitzima®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and	Celltrion	jul-17
Rituximab (Ritemvia®)	may-17	Non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul-17
Rituximab (Rixathon®)	apr-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis	Sandoz	jun-17
Rituximab (Riximvo®)	apr-17	Non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic	Sandoz	jun-17
Rituximab (Ruxience®)	jan-20	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	apr-20
Rituximab (Truxima®)	dec-16	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	feb-17
Somatropin (Omnitrope®)	jun-03	Growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, small	Sandoz	apr-06
Teriparatide (Livogiva®)	jun-20	Treatment of osteoporosis	Theramex Ireland Limited	aug-20
Teriparatide (Movvmia®)	nov-16	Osteoporosis	STADA Arzneimittel	jan-17
Teriparatide (Sondelbay)	jan-22	Treatment of osteoporosis	Accord Healthcare S I I I	Pending EC decision
Teriparatide (Terrosa®)	nov-16	Osteoporosis	Gedeon Richter	jan-17
<b>Total</b>				

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

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Trastuzumab (Herzuma®)	dec-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Celltrion	feb-18
Trastuzumab (Kaniinti®)	mrt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Amgen	mei-18
Trastuzumab (Ogivri®)	okt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Mylan	dec-18
Trastuzumab (Ontruzant®)	sep-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Samsung Bioepis	nov-17
Trastuzumab (Trazimera®)	mei-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Pfizer	jul-18