

Biosimilar medicines authorised via the EMA



Last updated 13/11/2018

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Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Pegfilgrastim (Fulphila®)	sep.-18	Neutropenia	Mylan	Awaiting authorisation
Pegfilgrastim (Pelmeg®)	sep.-18	Neutropenia	Cinfa Biotech S.L.	Awaiting authorisation
Pegfilgrastim (Ziextenzo®)	sep.-18	Neutropenia	Sandoz	Awaiting authorisation
Pegfilgrastim (Pelgraz®)	jul.-18	Neutropenia	Accord Healthcare	sep.-18
Pegfilgrastim (Udenyca®)	jul.-18	Neutropenia	ERA Consulting	sep.-18
Adalimumab (Hulio®)	jul.-18	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	sep.-18
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 (Hyrimoz®)	mei-18	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	jul.-18
Adalimumab (Hefiya®)	mei-18	Juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul.-18
Trastuzumab (Trazimera®)	mei-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Pfizer	jul.-18
Trastuzumab (Kanjinti®)	mrt.-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Amgen	mei-18
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 glargine (Semglee®)	jan.-18	Diabetes Mellitus	Mylan	mrt.-18
Trastuzumab (Herzuma®)	dec.-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Celltrion	feb.-18

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Bevacizumab (Mvasi®)	nov.-17	Fallopian tube neoplasms, Non-Small-Cell Lung Carcinoma, ovarian neoplasms, Renal Cell Carcinoma, Peritoneal Neoplasms, Breast Neoplasms	Amgen	jan.-18
Trastuzumab (Ontruzant®)	sep.-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Samsung Bioepis	nov.-17
Adalimumab (Cyltezo®)	sep.-17	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	Boehringer Ingelheim	nov.-17
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 disease, ulcerative colitis and uveitis	Samsung Bioepis	aug.-17
Insulin Lispro (Insulin lispro Sanofi®)	may-17	Diabetes mellitus	Sanofi	jul.-17
Rituximab (Blitzima®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul.-17
Rituximab (Rituzena®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul.-17
Rituximab (Ritemvia®)	may-17	Non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul.-17
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
Rituximab (Riximyo®)	apr.-17	Non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun.-17
Rituximab (Rixathon®)	apr.-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun.-17
Adalimumab (Amgevita®)	jan.-17	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	mrt.-17
Adalimumab (Solymbic®)	jan.-17	Rheumatoid arthritis, enthesitis-related arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, hidradenitis suppurativa, Crohn's disease, ulcerative colitis and uveitis	Amgen	mrt.-17

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Rituximab (Truxima®)	dec.-16	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	feb.-17
Insulin glargine (Lusduna®)	nov.-16	Diabetes Mellitus	MSD	jan.-17
Teriparatide (Movymia®)	nov.-16	Osteoporosis	STADA Arzneimittel	jan.-17
Teriparatide (Terrosa®)	nov.-16	Osteoporosis	Gedeon Richter	jan.-17
Enoxaparin (Inhixa®)	jul.-16	Prophylaxis of venous thromboembolic disease, deep vein trombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Techdow	sep.-16
Enoxaparin (Thorinane®)	jul.-16	Prophylaxis of venous thromboembolic disease, deep vein trombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Pharmathen	sep.-16
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
Etanercept (Benepali®)	nov.-15	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis	Samsung Bioepis	jan.-16
Filgrastim (Accofil®)	jul.-14	Neutropenia	Accord Healthcare	sep.-14
Insulin glargine (Abasaglar®)	jun.-14	Diabetes Mellitus	Eli Lilly	sep.-14
Follitropin alfa (Bemfola®)	jan.-14	Anovulation	Finox	mrt.-14
Filgrastim (Grastofil®)	jul.-13	Neutropenia	Apotex	okt.-13
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 (Inflectra®)	jun.-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Hospira	sep.-13
Follitropin alfa (Ovaleap®)	aug.-13	Anovulation	Teva	sep.-13
Filgrastim (Nivestim®)	mrt.-10	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hospira/Pfizer	jun.-10
Filgrastim (Filgrastim Hexal®)	nov.-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hexal	feb.-09
Filgrastim (Zarzio®)	nov.-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Sandoz	feb.-09
Filgrastim (Ratiograstim®)	jul.-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Ratiopharm	sep.-08

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Filgrastim (Tevagrastim®)	jul.-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Teva	sep.-08
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
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
Somatropin (Omnitrope®)	jun.-03	Growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, small for gestational age	Sandoz	apr.-06