

Table EU Approved / positive opinion biosimilars by molecule August 1, 2023

(not available in all EU-countries) (status CHMP-meeting July 17-20t, 2023, 23 reference molecules, 84 biosimilar products, from which 3 pending EC approval)

Molecule	Reference	Biosimilar(s)
Adalimumab	Humira	Amgevita, Amsparity, Halimatoz, Hefiya, Hukyndra, Hulio, Hyrimoz, Idacio, Libmyris, Imraldi; Yuflyma (new formulation)
Aflibercept	Eylea	Yesafili (pending EC decision)
Bevacizumab	Avastin	Abevmy, Alymsys, Aybinto, Equidacent; MVasi, Onbevzi, Oyavas, Zirabev, Vegzelma
Eculizumab	Soliris	Bekemv, Epysqii
Enoxaparine	Clexane	Inhixa
Epoetine alfa	Eprex	Absaemed, Binocrit, Epoetin alfa Hexal, Retacrit, Silapo
Etanercept	Enbrel	Benepali, Erelzi, Nepexto
Filgrastim	Neupogen	Accofil, Filgrastim Hexal, Grastofil, Nivestim, Ratiograstim, Tevagrastim, Zarzio
Follitropin alfa	Gonal-f	Bemfola, Ovaleap
Infliximab	Remicade	Flixabi, Inflectra, Remsima, Zessly
Insulin Aspart	Novo Rapid	Insulin Aspart Sanofi; Kixelle, Truvelog Mix30
Insulin glargine	Lantus	Abasaglar, Semglee
Insulin Human	Actrapid	Inpremia
Insulin Lispro	Humalog	Insulin Lispro Sanofi
Natalizumab	Tysabri	Tyruko (Pending EC-commission decision)
Pegfilgrastim	Neulasta	Cegfila, Fulphila, Grasustek, Nyvepria, Pelgraz, Pelmeg, Stimufend, Udenyca, Ziextenzo
Ranibizumab	Lucentis	Byooviz, Ranivisio, Ximluci
Rituximab	Mabthera IV	Blitzima, Ritemvia, Rixathon, Riximyo, Ruxience, Truxima
Somatropine	Genotropin	Omnitrope
Teriparatide	Forsteo	Movymia, Terrosa, Livogiga, Sondelbay, Kauliv
Tocilizumab	RoActemra	Tyenne
Trastuzumab	Herceptin IV	Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera, Zercepac

Source: EMA website (<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/biosimilar-medicines-marketing-authorisation>) Accessed: August 31. 2023_LB

15 Biosimilar-products in the licensing pipeline at EMA (Status: July 28, 2023).

Bevacizumab (1x), Denosumab (2x), Insulin human (1x), Omalizumab (1x); Ranibizumab (1x), Rituximab (1x); Teriparatide (1x); Tocilizumab (1x); Trastuzumab (1x), Ustekinumab (5x)

FDA approved biosimilars (updates by Stanton Mehr)see: <https://biosimilarsrr.com/us-biosimilar-filings/>