

Table EU Approved / positive opinion biosimilars by molecule January 2021

(not available in all EU-countries) (status CHMP-meeting January 29, 2021, 67 products, from which 5 pending EC approval)

Molecule	Reference	Biosimilar(s)
Adalimumab	Humira	Amgevita, Amsparity, Halimatoz, Hefiya, Hulio, Hyrimoz, Idacio, Imraldi; positive opinion: Yuflyma (new formulation)
bevacizumab	Avastin	MVasi, Zirabev, Aybintio, Equidacent; positive opinion: Onbevzi, Alymsys, Oyavas
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; positive opinion: Kixelle
Insulin glargine	Lantus	Abasaglar, Semglee
Insulin Lispro	Humalog	Insulin Lispro Sanofi
Pegfilgrastim	Neulasta	Cegfila, Fulphila, Grasustek, Pelgraz, Pelmeg, Udenyca, Ziextenzo, Nyvepria
Rituximab	Mabthera IV	Blitzima, Ritemvia, Rixathon, Riximyo, Ruxience, Truxima
Somatropine	Genotropin	Omnitrope
Teriparatide	Forsteo	Movymia, Terrosa, Livogiga, Qutavina.
Trastuzumab	Herceptin IV	Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera, Zercepac

Source: EMA website

https://www.ema.europa.eu/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_medicine/field_ema_med_status/authorised36/ema_medicine_types/field_ema_med_biosimilar/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar

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For a comparison with US/FDA (October 2020) see:

<https://www.biosimilarsip.com/2020/10/12/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-5/>

FDA approved biosimilars (status January 21, 2021)

<https://biosimilarsrr.com/us-biosimilar-filings/>

12 Biosimilar-products in the licensing pipeline at EMA (Status: 7/1/2021).

Adalimumab (1x); Bevacizumab (5x), insulin aspart (1x), Insulin Human (rDNA) 1x; pegfilgrastim (1x), ranibizumab (1x), teriparatide (2x), trastuzumab (1x).