







14 Approved Biosimilar Medicines in the U.S. Only 3 Currently Available for Patient Use

Udenyca (pegfilgrastim-cbqv)	November 2018	Patent Litigation Delaying Biosimilar Competition		
Hyrimoz (adalimumab-adaz)	October 2018	Janssen vs. Pfizer (infliximab-dyyb, Inflectra)		
Nivestym (filgrastim-aafi)	July 2018	Pfizer launched at risk Nov 2016		
Fulphila (pegfilgrastim-imdb)	June 2018	Abbie vs. Amgen (adalimumab-atto, Amjevita)		
Retacrit (epoetin alfa-epbx)	May 2018	Settlement delays U.S. launch until 2023		
lxifi (infliximab-qbtx)	December 2017	(adalimumab-adbm, Cyltezo)		
Ogivri (trastuzumab-dkst)	December 2017	U.S. launch likely delayed until 2023+ given Amgen settlement		
Mvasi (Bevacizumab-awwb)	September 2017	Amgen vs. Sandoz (etanercept-szzs, Erelzi)		
Cyltezo (Adalimumab-adbm)	August 2017	Sandoz expects launch delayed until		
Renflexis (Infliximab-abda)	May 2017	Amgen vs. Hospira(biosimilar		
Amjevita (Adalimumab -atto)	September 2016	epoetin alfa)		
Erelzi (Etanercept-szzs)	August 2016	 Amgen vs. Sandoz (biosimilar pegfilgrastim) 		
Inflectra (Infliximab-dyyb)	April 2016	 Amgen vs. Apotex (biosimilar pegfilgrastim and filgrastim) 		
Zarxio (Filgrastim-sndz)	March 2015	 Amgen vs. Mylan (biosimilar pegfilgrastim) 		

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53 EU AUL	nonseu	Biosimilars for 15 reference product		
Active substance	Reference product	Biosimilar medicines		
Adalimumab (8)	Humira®	Amgevita®, Solymbic®, Cytelzo®, Imraldi®, Halimatoz®, Hyrimoz®, Hefiya®, Hulio®		
Bevacizumab (1)	Avastin®	Mvasi*		
Enoxaparin sodium (2)	Lovenox®	Inhixa®, Thorinane®		
Epoetin (5)	Erypo®/Eprex®	Abseamed®, Binocrit®, Epoetin Alfa Hexal®, Retacrit®, Silapo®		
Etanercept (2)	Enbrel®	Benepali®, Erelzi®		
Filgrastim (7)	Neupogen®	Accofil®, Filgrastim Hexal®, Grastofil®, Nivestim®, Ratiograstim®, Tevagrastim, Zarzio®		
Follitropin alfa (2)	Gonal-f®	Bemfola®, Ovaleap®		
Infliximab (4)	Remicade [®]	Flixabi*, Inflectra*, Remsima*, Zessly*		
Insulin glargine (3)	Lantus*	Abasaglar*, Lusduna*, Semglee*		
Insulin Lispro (1)	Humalog®	Insulin Lispro Sanofi®		
Pegfilgrastim (5)	Neulasta®	Fulphila*, Pelgraz*, Pelmeg*, Udenyca*, Ziextenzo*		
Rituximab (6)	MabThera®	Blitzima®, Ritemvia®, Rituzena®, Rixathon®, Riximyo®, Truxima®		
Somatropin (1)	Genotropin®	Omnitrope [®]		
Teriparatide (2)	Forsteo*	Movymia [®] , Terrosa [®]		
Trastuzumab (4)	Herceptin®	Ontruzant [®] , Herzuma [®] , Kanjinti [®] , Trazimera [®]		

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	Price per TD 2016 / Year before Biosimilar entrance		Price per TD 2016 / Year before Biosimilar entrance		Volume TD 2016/ Year before Biosimilar	
EPO	Total market	G-CSF	Total market	Anti-TNF	entrance	The entrance of
Portugal	-66%	Romania	-62%	Bulgaria	190%	his similars
Slovakia	-53%	Slovakia	-61%	Slovakia	93%	biosimilars
Norway	-51%	Slovenia	-57%	Sweden	74%	increases price
HGH		Anti-TNF		Portugal	63%	competition
Finland	-52%	Sweden	-39%	Czech	59%	
Poland	-42%	Norway	-32%	EPO		Competition drives
Norway	-37%	Denmark	-24%	Poland	237%	down price
Fertility		Insulins		Greece	196%	
Denmark	-24%	Finland	-18%	Italy	39%	Lower prices
Spain	-14%	France	-5%	Czech	36%	increase patient
Sweden	-10%	Ireland	-3%	Bulgaria	36%	access

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Key Discussion Points The US Biosimilars Market is at a "critical juncture" as uptake has failed to materialize compared to Europe due to patent litigation amongst pharmaceutical companies, restricted access by PBMs/insurers, lack of physician and patient education regarding availability and efficacy This is despite the fact that there are substantial financial savings to be gained through the use of biosimilars Biosimilar adoption provides a solution to the drug pricing and spending debate like generics did for brand name drugs Additional policies should be considered to help uptake and viability of the biosimilars market in the U.S.