have been using similar biologics longer, those products do not enjoy the structural similarity, the clinical equivalence, or the regulatory rigor that biosimilars in highly regulated markets do. Currently, there are 41 approved biosimilars in Europe, more than the combined biosimilars approved in the rest of the developed markets. India leads the biosimilar approval list in the developing countries. Table 2.2 shows the biosimilars licensed by the FDA as of mid-2018.

2.3.1 FDA-Approved biosimilar products

Biosimilar products are sold under their own brand names in Europe, but WHO and the United States have suggested differentiating the generic name with a suffix to differentiate it from the name of the generic form used by the originator. The debate still goes on in the United States, where the FDA has licensed its first product with a suffix but suggests that this is not finalized.

2.3.2 Future of biosimilars

Biosimilar biological products, a category of their own, have a great potential, as every biological product is subject to being developed as a biosimilar product. Table 2.3 shows a current listing of possible biosimilar products over the next two decades. Given that a majority of future regulatory filings in the United States are likely to be biological products, the

Table 2.2 Biosimilars Approved by FDA by 2017

Drug Name	Approval Date	FDA Information Link
Zarxio (Filgrastim-sndz)	March 2015	https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm
Inflectra (Infliximab-dyyb)	April 2016	https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm
Erelzi (Etanercept-szzs)	August 2016	https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518639.htm
Amjevita (Adalimumab-atta)	September 2016	https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm
Renflexis (Infliximab-abda)	May 2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761054
Cyltezo (Adalimumab-adbm)	August 2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=761058
Mvasi (Bevacizumab-awwb)	September 2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=761028
Ogivri (trastuzumab-dkst)	December 2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761074
Ixifi (infliximab-qbtx)	December 2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761072