

biosimilar. We suspect that interchangeability status may not be highly desirable and thus not sought after by many firms.

Interchangeability of biosimilars is further discussed in Chapter 10 of this book.

16.16 EU MARKET EXPERIENCE

Biosimilars in the EU are priced on average around 30% lower than their reference products. Some examples of price decreases as a result of biosimilar competition in various EU countries are Orion's Remsima 72%, Sandoz's Binocrut 33%, and Sandoz's Omnitrope 22%.

In terms of market share in the EU, the experience is mixed. In 2011, for example, for granulocyte-colony stimulating factors (G-CSFs) biosimilars had an average market share of 42%. The average market share for the erythropoietin class was 22%, and for human growth hormone it was only 13% (Rompas et al., 2015). With respect to individual countries, market shares for EPO ranged from about 20% in Italy to 80% in the United Kingdom. For G-CSF, the market shares ranged from about 10% in Italy to around 60% in Germany, Greece, Poland, and Sweden (Rompas et al., 2015). Germany had the highest market share for both EPO and G-CSF.

Another estimate of biosimilar market penetration for individual EU countries for 2013 is in terms of patient days of treatment (IMS, 2014). In the case of Epo, the biosimilar share ranged from a low of 0% in Belgium to 66% in Slovenia. Among the larger EU countries, Germany is relatively high, with a 53% share. Norway, Bulgaria, and Sweden are all relatively high, with shares of at least 53%. In the case of G-CSF, biosimilars have a very large share in Sweden (91%), Hungary (99%), and Romania (100%). Germany, Italy, and the UK (73%) have high shares as well. For the human growth hormone (HGH), biosimilar market shares are much lower. For example, Germany had a biosimilar share in 2013 of 9%, the UK 5%, and Sweden 18%. Even Norway, which had 82% for G-CSF and 58% for EPO, had only 2% (IMS, 2014). Again the numbers show a mixed picture but one where biosimilars have begun to capture significant shares of the market.

16.17 SAVINGS FROM BIOSIMILARS

In terms of implications for the US, the experience of the EU and other countries must be reviewed with caution. In the US, generic drug prices generally have been lower and market shares generally higher than in the UK, Germany, Italy, France, and Japan. In Canada, generic drug prices have been lower by about 6% (Danzon and Furukawa, 2003). Further, in terms of biological prices, EU countries have had lower biologics prices than the US. For example, the average price for all biologics in 2005 in the US was \$59, and in France it was \$44, Germany \$14, Italy \$19, and the UK \$23 (Danzon and Furukawa, 2006). Since prices were already lower in the EU countries, a 20% or 30% discount could be viewed as more significant than in the higher priced US. In other words, one might expect greater market shares and larger price reductions in the US.

One study estimated that biosimilars will have saved between 11.8 billion and 33.4 billion euros in eight EU countries, from 2007 to 2020 (Haustein et al., 2012).