Generic versions of biologic medications are coming

September 8 2009, By Val Brickates Kennedy

The days of market exclusivity could soon come to an end for the biotech industry if Congress moves forward with plans to allow generic biologics on the U.S. market.

Because of their eye-popping price tags, pressure to rein in the cost of biologics has been mounting on Capitol Hill for some time. A process for approving generic versions of traditional chemical medications has been in place for more than a decade, but Congress has yet to establish a similar legal pathway for biologics.

But all that could change in the next few months. Currently, almost all of the leading healthcare reform bills circulating on the Hill call for allowing the Food and Drug Administration to establish an approval process for generic biologics, also known as biogenerics or biosimilars.

Unlike traditional drugs, which are made up of chemicals, biologics use living cells to treat diseases and disorders. The drug category includes some of the most popular therapies on the market: Cancer treatments such as Roche's Avastin and Herceptin; rheumatoid arthritis drugs such as Amgen Inc.'s and Wyeth's Enbrel, Johnson & Johnson's and Schering-Plough Corp.'s Remicade, and Abbott Laboratories' Humira; and multiple sclerosis therapies such as Biogen Idec's Avonex.

Although the impact of the cost of biologics on American health care has arguably been exaggerated by some lobbying groups, it is not insignificant.

Currently, only about 10 percent of the nation's health-care dollars annually are spent on prescription drugs. But, as opposed to other areas of health care, it is an area where spiraling costs can be kept somewhat in check through the expanded use of cheaper, generic formulations. See "Who wins, who loses"

According to Medco Health Solutions, the nation's largest manager of drug benefits for employer healthcare plans, out of approximately $300 billion that Americans spent last year on branded and generic prescription medications, up to 15 percent were on biologics.

Expensive to develop and manufacture, the price tag on biologics can be staggering, ranging from around $14,000 a year for some of the leading multiple-sclerosis therapies to $250,000 a year for treatments such as Genzyme Corp.'s Cerezyme, a treatment for the rare genetic disorder Gaucher disease.

Meanwhile, the use of biologics is expected to mushroom. Industry observers say that by 2012, about half the drugs approved by the Food and Drug Administration will be biologics.

What's in it for consumers?

Industry experts say that allowing biogenerics will help create more competition in the marketplace, which, in turn, should help keep prices in check.

"They'll dampen down price inflation for branded biologics," said Timothy Wentworth, group president for Medco's employer accounts, in a recent interview.

Wentworth adds that biogenerics will also be of great help to patients who have maxed out their insurance policies and are now forced to pay

out-of-pocket. He points out that many lifetime users of high-priced biologics end up financially ruined and on Medicaid.

"The majority of people who need these drugs are probably already getting them, but the people who are paying the bill are going broke," said Wentworth. "And the end-payer in many of these cases, the payer of last resort, is the government."

How cheap is cheap?

But don't expect biogenerics to be as gut-cheap as traditional generics, which can sell for up to 80 percent less than their branded rivals, say experts. In Europe, for example, the biogenerics that have been introduced so far are selling at about a 20 percent discount.

James Greenwood, president of the Biotechnology Industry Organization, said he thinks biogenerics could eventually cost 35 percent less and have a market penetration of about 25 percent.

"As the science improves, the costs of manufacturing them would decrease," said Greenwood.

Even if health-care reform legislation passes this fall, biogenerics wouldn't be available right away, as the FDA still needs to draft guidelines for an approval process. Most of the bills on the Hill also allow the FDA to determine what studies are needed for approval on a case-by-case basis, given how complex the drugs are, which could lead to further delays.

Likewise, an applicant would also still have to wait until a product's patents expire before they could legally market a generic. And they would have to wait out the FDA-mandated market exclusivity period, which currently runs at least five years from date of approval. Current

legislation plans to extend that period to 12 years, in an effort, lawmakers say, to encourage further drug development.

"They'll be slow in coming, so there won't be an initial shock," said Les Funtleyder, a healthcare industry analyst for Miller Tabak.

"Some companies like Amgen or Biogen may lose market share," Funtleyder added, "but it won't be like falling off a cliff."

___