Will 2009 Usher in the Era of Biогenerics?

By Dalia Buffery, MA, ABD

While the market share of small-molecule generics continues to expand—now at 67% of all prescription drugs dispensed in the United States, according to the Generic Pharmaceutical Association (GPhA)—the issue of biogenerics (or biosimilars, or biologics follow-on) remains unresolved. Unlike the European Union, which has established a regulatory system for the approval of biogenerics, the US Food and Drug Administration (FDA) has so far resisted moving in that direction, awaiting legislation from Congress, according to Biosimilars Business Review. With a greater percentage of FDA approvals now involving biologics, their impact on patient care is considerable, especially in cancer, infectious diseases, and autoimmune disorders. More than 400 biologic drugs and vaccines have so far been added to the market, treating more than 325 million patients. By 2010, biologics are expected to account for 50% of all drug approvals.

Cost concerns and safety issues are finally forcing Congress to address the question of biogenerics, which would enable many patients to benefit from the unique properties of these products, without the attendant exorbitant cost. According to one source, between 1998 and 2006 “the average cost of biologics has gone up 505 percent,” at an annual cost of $100,000 to $500,000 to patients. In today’s economy, this means many patients will have to forego the benefits of these therapies, unless the cost and access issues are resolved.

Of the safety concerns unique to biologics, immunogenicity—“the patient’s adverse antibody reaction to a drug in which the body perceives a drug to be a foreign microorganism or virus”—which claimed the lives of several patients in 2001, may lead to a more rigorous regulatory system for biogenerics than the current system for traditional generics.

Although the question of marketing exclusivity remains the Achilles’ heel of the industry, as more and more biologics go off patent in the coming years, the route to biogenerics seems inevitable. Of the 4 proposals now in Congress for the creation of a pathway for FDA approval of biogenerics, 3 would give biologic manufacturers longer marketing exclusivity than for small-molecule drugs—“up to an additional 3 to 12 years” longer. But not so fast.

At the 2009 annual meeting of GPhA, House Energy and Commerce Committee Chairman Henry Waxman said (via video) that “a workable scientific regulation and legal pathway for biogenerics and biosimilar pharmaceuticals will ensure more affordable medications for Americans, and we believe it will spur innovation in the biotech markets,” adding, however, that the Hatch-Waxman Act model of exclusivity should also work well for biogenerics (expressing dismay at suggestions of longer exclusivity periods). Waxman emphasized that creating a biogenerics pathway “will be an important contribution to health reform….I intend to use my position as chairman to improve the health and well-being of this nation, and I know that a critical piece of achieving this goal is to bring generic competition to the biotech drug market.”

Representing the biotech industry, however, BIO President and Chief Executive Officer Jim Greenwood agreed that the time for biogenerics has come, but said his company’s position is “that there should be 14 years of market exclusivity,” GPhA President Kathleen Jaeger expressed GPhA’s position that “biogenerics are achievable, imperative, and inevitable,” noting that the “FDA has clearly stated that the science exists to ensure safety and efficacy.”

With health reform and cost-cutting now top priorities for the new administration, 2009 may indeed be the year that ushers in biogenerics to the United States.

References