

# Generics Capture 65% of U.S. Market as Costs Rise

By Catherine Larkin

Feb. 12 (Bloomberg) -- Two-thirds of prescriptions filled in the U.S., the most ever, are cheap copies of brand names made by generic-drug companies.

Generics accounted for 65 percent of the U.S. market last year, up from 63 percent in 2006, according to data released today at the Generic Pharmaceutical Association's annual industry meeting in Boca Raton, Florida. Costlier brand-name drugs made up about 80 percent of dollars spent on prescriptions in each year.

The figures, compiled by the research firm IMS Health Inc., show generic drugmakers are capitalizing on expiring patents and efforts by insurers to rein in health-care costs. The companies seek further gains this year as drugs with \$20 billion in annual sales lose patent protection and the presidential candidates promise to make generic drugs more widely available.

"We're poised to do very well," said Kathleen Jaeger, president of the Arlington, Virginia-based Generic Pharmaceutical Association, in an interview yesterday. "All the candidates believe that generics are part of the answer."

Drugs facing generic competition for the first time this year include Merck & Co.'s osteoporosis treatment Fosamax and Johnson & Johnson's antipsychotic therapy Risperdal. Generic-drug companies are permitted under a 1984 U.S. law to apply for approval to copy conventional medicines, made through chemical synthesis, once patents expire or are ruled invalid.

Executives from the world's biggest sellers of generic drugs -- including Israel's Teva Pharmaceutical Industries Ltd., the Sandoz unit of Swiss drugmaker Novartis AG, and U.S.-based Mylan Inc. -- gather each year to discuss strategies for success in the competitive, low-margin business.

This year's topics include proposals by presidential candidates and lawmakers to overhaul the U.S. health-care system and to create a pathway for copies of medicines made through biotechnology. Costs for medical services have risen faster than wages and White House hopefuls from both parties have vowed to slow health-care inflation.

Paul Bisaro, chief executive officer of Watson Pharmaceuticals Inc., said changes in health-care policy may not benefit his company and other generic drugmakers unless they play an active role to ensure the new rules aren't manipulated by brand-name companies with more lobbying power in Washington.

"We have to be careful with health-care reform," Bisaro of Corona, California-based Watson said yesterday in an interview. "Well-meaning, well-intentioned efforts could be very damaging to our industry."

Democratic presidential candidate Hillary Clinton co-sponsored legislation last year that would for the first time allow the U.S. Food and Drug Administration to approve copies of biotechnology drugs that have been on the market at least 12 years.

Generic companies have called for revisions to the proposal, saying 12 years is too long to delay competition for drugs that can cost as much as \$200,000 a year. Americans now spend \$40 billion annually on medicines made from living cells, including Amgen Inc.'s anemia treatment Epogen.

Generic drugmakers also want the FDA to be able to consider on a case-by-case basis when clinical trials are needed to approve a copy of a biotechnology drug and when the copy can be substituted for the brand product at a pharmacy.

“We must achieve a balance of affordability, access and innovation,” said Senator Charles Schumer, a New York Democrat and longtime advocate of generics, in a taped speech today at the industry conference. “We need a clean approval pathway that is driven by science and allows FDA discretion based on that science.”

Clinton, a New York senator, has said that if elected president she would increase funding for the FDA's Office of Generic Drugs to speed reviews of new medicines and eliminate “loopholes” in U.S. law that allow brand-name companies to block generic products from entering the market.

Generic companies say they don't want to start paying regulators to handle their drug applications, as proposed by President George W. Bush this month in his budget, unless quicker reviews are guaranteed.

Clinton's Democratic rival Barack Obama, a senator from Illinois, has said he also would prevent brand-name companies from blocking copies and would encourage wider use of generics in U.S. health programs, including Medicare for the elderly and Medicaid for the poor, to lower costs.

Obama and Senator John McCain of Arizona, the leading Republican candidate for president, want to allow Americans to buy drugs from Canada and other countries if the medicines are shown to be safe and less expensive. McCain also has said he wants to improve the approval process for generic drugs and biotechnology medicines.