Congress Is Likely to Approve Generic Drug User Fees
Action Should Spur Faster FDA Approvals

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Congress will have its hands full with prescription drug legislation this year as it works to reauthorize the 20-year-old Prescription Drug User Fee Act (PDUFA) and to establish, for the first time, two new user-fee programs at the FDA—one for generic drugs and the other for generic biologies. One giant bill will probably cover all three programs. At hearings on February 1, House committee members said they were hoping that they could pass a “skinny” bill—one without lots of amendments by June. We’ll see.

The establishment of a new Generic Drug User Fee Act (GDUFA) may be the most important part of the legislative trifecta. The FDA and the generic drug industry agreed on a plan that would require generic marketers and producers of the commodity chemicals that go into finished products to pay fees amounting to about $300 million per year. In return, the FDA would commit to reducing the backlog of Abbreviated New Drug Applications (ANDAs) and would speed up review times for new ANDAs.

This GDUFA system differs markedly from the PDUFA system that has been in place since 1992. The FDA will have to create a whole new application-tracking and fee-assessment system, which it will have to build from the ground up.

“It will require a lot of work,” says Kurt R. Karst, an attorney with Hyman, Phelps & McNamara, P.C., which specializes in the Hatch-Waxman Act. Mr. Karst is a primary author of the FDA Law Blog (www.fdalawblog.net).

When it is built, the new generic-drug approval system, ideally, should solve some acute problems. The FDA currently has a backlog of more than 2,000 generic drugs waiting to be approved, partly because generic-brand manufacturers submit approximately 800 ANDAs each year, compared with the 100 or so NDAs submitted by brand-drug manufacturers, which, again, have been paying user fees since 1992.

FDA Commissioner Margaret Hamburg says: “No one benefits from a pending-application queue of 2,000-plus products. Uncertainty and delays are costly to consumers, costly to industry—and hurtful to the public.”

Not only are there more generic applications; they are often more complicated. For example, the active pharmaceutical ingredient is typically manufactured by a different entity than the company that markets the finished dosage form. That increases the FDA’s workload of facility inspections of the generic products. Many of the commodity chemical-input producers, not to mention the generic marketers themselves, are located overseas; this complicates inspections further. The FDA is also seeing applications for increasingly complex generic products, such as inhalational and injectable agents.

Kurt Karst says that the median approval time for an ANDA is about 33 months, and this time frame is increasing. “That is significantly longer than FDA review and action times for brand-name drugs approved under NDAs,” he explains.

The generic backlog means that the public is being denied access to a host of inexpensive versions of brand-name drugs, with implications for consumer pocketbooks and the cost of federal health programs such as Medicare and Medicaid. In the U.S., approximately 78% of prescriptions are for generic drugs, which account for about 25% of all prescription spending. The FDA says that generic drugs have saved Americans $824 billion in the last decade.

The cost savings benefit is obvious, and some even claim that generic products can be safer than their brand-name counterparts.

Edith A. Rosato, RPh, Chief Executive Officer at the Academy of Managed Care Pharmacy, explains: “Generic drugs, by definition, are versions of brand-name drugs that have been available in the marketplace for many years. The longer a drug has been available, the more health care practitioners know about possible side effects and treatment outcomes.”

Some experts, such as Marcie Bough, Senior Director of Government Affairs at the American Pharmaceutical Association, argue that when generic alternatives are approved, they expand the population of consumers who use that drug because of the lower cost. Some people switch from the brand name to the generic rather than drop the drug altogether because of financial considerations. Some patients who received prescriptions from physicians for the brand name but did not fill them because of cost might well start taking the drug after it becomes generic. Moreover, compliance is usually better, and people tend to stay with generics longer. The availability of generic products increases the number of people taking a given medication, which allows better surveillance of that drug’s safety and any adverse effects.

The FDA argues that the new user fees will not increase the cost of generic drugs by much.

Peter Beckerman, Senior Policy Advisor in the FDA’s Office of Policy, Office of the Commissioner, says, “In fact, the program is less than one-half of 1 percent of industry sales and is expected to add less than a dime per prescription.”