

Pharmacia Nears Generics Deal On AIDS Drug for Poor Nations

By SCOTT HENSLEY

Attempting to break a stalemate over getting AIDS drugs into developing nations, Pharmacia Corp. is near a deal to allow generic drug makers to sell cheaper versions of its drug Rescriptor in poor countries only.

Pharmacia, one of the world's largest drug companies, would license Rescriptor to the nonprofit International Dispensary Association of the Netherlands. In turn the association would line up generics manufacturers to produce the medicine for use in as many as 78 poor countries.

In a novel tactic, the Pharmacia

agreement would stipulate that the medicine, known generically as delavirdine, be a different shape and color from the original pill. This distinction would make it easier for customs officials and other authorities to crack down on illegal shipments back to the U.S. and other developed countries.

The pact is an effort to make essential medicines available at reduced prices in the developing world while protecting the economic interests of brand-name drug makers in their profitable home markets. The program's developers see this as a model that could be applied to broad range of essential medicines and hope that other drug makers will follow Pharmacia's lead.

"The key is to make some things happen," said Fred Hassan, chairman and chief executive of Pharmacia, based in Peapack, N.J. "It may not be the perfect solution, but we're trying to do something instead of debate."

The architects of the agreement describe the new model—but not the role that Pharmacia will play, which is expected to be unveiled at the World Economic Forum in Davos, Switzerland—in a paper being published tomorrow in the British medical journal *Lancet*.

Until now, branded drug makers have generally resisted calls to license their patents to poor countries or to generics makers, either voluntarily or by compulsion. They fear setting a precedent that would erode profits if cheap medicines from the developing world are diverted to key industrial markets.

Merck & Co., Bristol-Myers Squibb Co. and GlaxoSmithKline PLC, among others, have offered discounted or free medicines to developing nations, but the programs haven't met the needs of tens of millions of patients dying from HIV/AIDS and some other diseases.

Nonexclusive Licenses

Under the Pharmacia approach, drug-patent holders would award nonexclusive licenses to generics makers for sale of cheap, faithful copies of key drugs only in the poor countries where they are urgently needed. Generics makers would pay a royalty to the patent holder, 5% in the Pharmacia case, and would be encouraged to compete on price. Generics makers would be prohibited from selling against the patent holder in developed markets, however, thus preserving profit incentives for the branded drug industry.

Rescriptor prevents HIV from entering the nucleus of white blood cells and is used in combination with other AIDS drugs. It currently costs more than \$300 a month in the U.S.; the generic version is expected to be considerably less.

Pharmacia has little to lose by serving as a guinea pig in the experiment. Several years ago the company made a strategic decision to emphasize drugs to treat illnesses other than HIV/AIDS and hasn't promoted Rescriptor actively or pursued research of related medicines. In 1999, in the U.S. and some other markets, Pharmacia licensed Rescriptor to Agouron Pharmaceuticals, now a division of Pfizer Inc. Sales of Rescriptor in the developing countries where Pharmacia kept its rights are so low the company hasn't been required to disclose them and they aren't immediately available, a spokeswoman said.

Details of the contract between Pharmacia and the Dutch nonprofit are still being hammered out, but the parties said they expect to reach an accord within weeks. Henk den Besten, managing direc-

Please Turn to Page A8, Column 4

Pharmacia Nears Accord Over AIDS Drug for Poor

Continued From First Page

tor of the group, said several generics makers already have expressed interest in participating, but he couldn't predict how long it would take for the first medicine to reach patients. The group has a 30-year record of having generic medicines produced and then getting them into the hands of doctors and patients in developing countries.

A potential advantage of the new plan would be faster, better production of generic drugs, which has been a stumbling block in developing nations. Under the friendly technology transfer, generics companies would receive know-how beyond the patent, such as manufacturing expertise and data that would be useful in registering the products with national regulatory authorities. The voluntary approach would also eliminate delays from legal fights.

If Pharmacia's compromise spurs imi-

tation, it could mute some protests by activists who say rich companies haven't adequately responded to the growing public-health disaster.

Pfizer, in a written statement, said it welcomes the path described in the Lancet paper for licensing patented drugs to generics makers and supports Pharmacia's plans for Rescriptor. Pfizer's support is crucial since the New York-based drug maker is expected to close its \$55 billion deal to acquire Pharmacia later this quarter.

A spokesman said London-based GlaxoSmithKline "doesn't count out generics companies" and is prepared to let them make its products subject to certain conditions. He said he couldn't comment on the specifics of the Lancet paper or the Pharmacia approach because he hadn't seen them. GlaxoSmithKline makes several HIV drugs and has offered them at cost to countries in need. The drug

maker also has given a license for some HIV drugs to Aspen Pharmacare, a South African generics maker.

Amir Attaran, a Harvard University lecturer, matchmaker for the Pharmacia deal and co-author of the Lancet paper, believes that defusing the arguments over patents could shift attention to the bigger problem: the shortage of funding for the humanitarian efforts and health-care development needed to save the ill. "An enormous debate has raged over patents and access," he said, "however, it has crowded out the debate over things such as financing." With a new approach to licensing, he hopes, the world can now discuss "the elephant in the living room: that nobody is prepared to pay for the medicines and therefore people will die by the millions" unless action is taken.

—Mark Schoofs
contributed to this article.