Box 1 Latin American countries and compulsory licenses

Brazil "complies strictly" with international rules, says Reinaldo Guimarães, Secretary of Science, Technology and Strategic Inputs of Brazil's Ministry of Health in Brasilia. The Brazilian government, he says, is committed to the agreement established by the World Trade Organization in 1995, including the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for drug patent protection.

Guimarães says that Brazil's policies lean toward price capping through negotiations with pharmaceutical companies, but for a state that offers free prescriptions to the entire population, price hikes can lead to extreme situations. Last May, President Luiz Inácio Lula da Silva declared a national emergency and issued a compulsory license to acquire a low-cost version of the antiretroviral Sustiva (efavirenz), developed by Merck of Whitehouse Station, New Jersey. The drug substitution has helped about 80,000 people with AIDS. And in April, the country said that Foster City, California-based Gilead's HIV drug Viread (tenofovir disoproxil fumarate) was in "the public interest," suggesting Brazil might not grant a patent on the product and open the country to generic forms.

In Mexico, the country's spending on antiretrovirals has almost doubled in a year, but compulsory licenses have not been invoked. That does not preclude their future application "if necessary," says Ector Ramirez Barba, president of the Health Commission's Lower House. However, the Mexican Congress has already rejected two bills requesting "biosimilar drugs" for treating critical health problems like diabetes, though a couple of regulations have been passed by Congress. The first one, passed in November, sanctioned the Mexican endorsement to the Protocol for Amending the TRIPS Agreement. In March, the legislators passed a law that, for the first time, defines and makes a distinction between chemical drugs and their generic versions, and between biotech drugs and biosimilars.

Argentina hasn't made use of compulsory licenses either. Sonia Tarragona, an official from the Argentine Ministry of Health, says they would most likely be used in a sanitary emergency, but there has been no cause "to employ any type of licenses yet." The Argentine government hasn't shaped any policy toward the import or export of compulsorily licensed products, nor has it been discussed.

Verónica Guerrero Mothelet *San Miguel Chapultepec, Mexico*

argues in such cases of communicable diseases, generic makers should be allowed to produce copies of patented drugs and vaccines on payment of a royalty. If India did not grant compulsory licenses, Hamied says, Cipla would set up factories in the least developed countries where product patents will not apply until 2016. "We have already set up a factory in Uganda and we are starting one in Morocco," he says.

Industry watchers say Cipla's model is bold, but doubt whether opening up markets for generic drugs in the least developed nations makes economic sense. "The total pharmaceutical market of Africa is less than $2 billion," says Chandra Mohan Gulalthi, editor of *Monthly Index of Medical Specialties*. Although it may be easy to set up a bicycle factory in the least developed countries, he notes, pharmaceutical manufacturing requires trained scientists. "Where will Cipla get the trained manpower for its facilities in the least developed countries?"

Killugudi Jayaranam *Bangalore*

Details
The companies will work on delivering siRNA molecules. Both Silence and AstraZeneca will be allowed to commercialize any delivery systems developed. Silence offers the functional systemic delivery of siRNA *in vivo* using its proprietary AtuPLEX technology, though both parties will contribute expertise. The deal is independent of the parties' three-year collaboration signed in July 2007.
CG Therapeutics offers CG201, a vaccine designed to produce antibodies aimed at neutralizing hCG (human chorionic gonadotropin), a hormone associated with tumor cell growth. The two will work to develop human monoclonal antibodies against hCG that can be used with CG's CG201 vaccine.
Raven entered an agreement for Monogram to evaluate selected Raven monoclonal antibodies for use with Monogram's VeraTag technology in diagnosing cancer.

IN brief

Bush pushes plant energy

US President George W. Bush early in March renewed his pledge to increase energy security through a variety of reforms, which include bolstering corn-based and cellulosic-derived ethanol for renewable energy. Bush pointed out that the Department of Energy (DOE) invested a total of nearly $1 billion since fiscal year (FY) 2001 into technologies for producing cellulosic ethanol from sources such as wood chips and switch grass. The FY 2009 budget proposal calls for an increase of nearly $27 million, or 13%, for supporting biomass and biorefinery R&D. But Carol Werner of the Washington-based Environmental and Energy Study Institute (EESI) notes that "funding priorities reflected in the President's FY 2009 budget appear to conflict with the goals of expanding renewable energy development and making the economy more energy efficient." The FY 2009 budget request for DOE programs supporting renewables is $1.26 billion—a mere 5% of the total DOE budget. This figure is "essentially flat" compared to the FY 2008 budget request and 27% below FY 2008 appropriations. To complicate matters further, a debate is raging among climate-change experts as to whether moving to greater reliance on renewable ethanol will lead to changes in agricultural land use that could exacerbate global-warming trends. More immediately, the rush to make ethanol from corn is driving up food prices.
—Jeffrey L Fox

Changes for ESAs

Recommendations March 13 by the US Food and Drug Administration (FDA)'s Oncology Drug Advisory Committee for three erythropoiesis-stimulating agents (ESAs) included suggestions of a black box warning on the products for an association with increased tumor growth and shortened survival time. And the panel voted against using ESAs in patients with metastatic breast cancer, as well as cancer of the head and neck and in patients likely to be cured by treatment. Two of the three ESAs at issue—Epogen (epoetin alfa) and Aranesp (darbepoetin alfa)—are produced by Thousand Oaks, California-based Amgen, while the third, Procrit (epoetin alfa), is sold by Johnson & Johnson of New Brunswick, New Jersey. Still, Amgen's shares traded up by nearly 5% when the news broke, mainly because of what the panel didn't recommend: dropping use in chemotherapy-induced anemia. Should the FDA adopt these recommendations, Mark Schoenebaum, a biotech analyst at Bear Stearns of New York, sees a 40% drop in cancer sales for Amgen's Aranesp, which racked up total sales of $3.6 billion last year. Last month, Amgen was hurt by a black box warning on Enbrel (etanercept), for rheumatoid arthritis and psoriasis. The FDA said the label should carry a warning about the risks of infection, including tuberculosis. Enbrel, which inhibits tumor necrosis factor, a protein involved in inflammation, earned Amgen $3.2 billion in sales last year.
—B J Spalding