

Cuba seeks new drug markets

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HAVANA — Inside modern towers that are a pride of Fidel Castro, scientists peer through huge microscopes at tiny proteins they hope to tailor to treat such major killers as AIDS, heart disease and cancer. More than 1,000 people work at Cuba's Genetic Engineering and Biotechnology Center to save lives, ease human suffering and generate more cash for their socialist country's battered economy.



Cuba's biotech products and technology reach markets in more than 40 countries, generating about \$100 million annually. Havana thinks it can do a lot better. It has plans to increase its drug profits by expanding its overseas markets through development of novel pharmaceuticals and the sale of other drugs.

A scientist at Cuba's Genetic Engineering and Biotechnology Center takes a biological sample for examination. The center, near Havana, is considered the scientific headquarters of the country.

For years as a Soviet bloc adherent, Cuba was among nations that refused to acknowledge Western intellectual property laws, manufacturing its own generic versions of popular drugs.

Now, Cuba is aiming to sell abroad the genetically engineered protein erythropoetin, or EPO, which is by far the best-selling biotechnology drug. EPO is used by kidney dialysis and chemotherapy patients and by athletes to boost oxygen-laden red cells in the body.

It accounted for \$6 billion in sales last year for three corporate giants that own commercial rights throughout the industrialized world. But in developing nations, an increasing number of biotech drugs are being produced without any attempts to obtain licenses.

The China market

With 1.3 billion people, China is the largest of these markets — and its potential for EPO sales is huge. Amgen, which invented the drug, shares patent rights with Johnson & Johnson and Kirin Brewery of Japan in the most lucrative markets: the United States, Europe and Japan.

But they have little influence over Cuba, whose well-developed biotechnology program makes EPO for sale to Argentina, Brazil, India and other countries that don't acknowledge most U.S. and European drug patents.

"We are very careful about intellectual-property laws," said Blanca Tormo, a Cuban biotechnology executive. She said Cuba sells EPO only in countries where no entity has exclusive patent rights.

U.S. patent holders consider this trade in generic drugs a challenge to their intellectual property. But from Cuba's perspective, it's merely good business, and consumers in developing countries are grateful to pay the lower prices.

In joining the World Trade Organization last year, China agreed to abide by its intellectual-property agreements. But those pacts contain mechanisms that can allow developing nations to circumvent patents — especially in pharmaceuticals — where concerns such as public health are deemed to override them.

But Cuba is not alone in trying to enter China's seductive EPO market. Amgen, Kirin, the small Canadian biotech company Dragon Pharmaceuticals and at least four Chinese companies are already selling EPO there.

While Amgen charges upward of \$36 a dose in the U.S., the generic EPO sells for as low as \$5 in China. U.S. patients each pay upward of \$10,000 annually for Amgen's product, which it calls Epogen.

Other products

Cuba has more to offer than generic EPO, including its novel biotech products: hepatitis B and meningitis B vaccines, a skin-growth factor, interferon, thrombosis and heart-attack medicines and AIDS treatments.

It is seeking more partnerships with foreign companies in research into vaccines for AIDS, cancer and cholera.

Cuban officials said negotiations for new biotech trade and production agreements were under way with Brazil and nine other countries: Malaysia, Netherlands, Spain, Mexico, Venezuela, Vietnam, Ukraine, Germany and the United States. Cuba has or is negotiating technology-transfer agreements with 14 countries, most developing nations. Meanwhile, this island nation has produced more than 78 million doses of the hepatitis B vaccine.

It has also licensed its meningitis B vaccine to Britain's Glaxo SmithKline, which hopes to eventually sell it in the United States under an exemption to the Cuban trade embargo granted by the Clinton administration.

In another North American partnership, Cuba is working with the small Canadian company YM Biosciences on trials of a head and neck cancer treatment. But not everyone is bullish on Cuban biotech.

"The U.S. believes that Cuba has at least a limited offensive biological warfare research-and-development effort," John Bolton, the U.S. undersecretary of state for arms control, said in a May speech. "Cuba has provided dual-use biotechnology to other rogue states."

Bolton's accusation was widely dismissed as unfair by scientists, by Castro and by former President Carter, whose visit to the island it directly preceded.