'Imitate' gives way to 'innovate'

India's pharmaceutical industry increasingly turning to research

By Geoff Hiscock
CNN Asia Business Editor Monday, October 17, 2005 Posted: 0639 GMT (1439 HKT)

Indian pharmaceutical companies are looking to compete globally

(CNN) -- The business proposition has changed dramatically for India's pharmaceutical industry since the beginning of this year.

Under new World Trade Organization patent protection rules that took effect on January 1, the era of being the world's "copycat" king of generic drug production is coming to an end.

No longer can Indian companies simply copy drugs patented after January 1995. That might work at home, but if they want to thrive in the tougher global environment, imitation is out and innovation is in.

In fact, it has been that way for some time for India's flagship pharmaceutical companies such as Ranbaxy Laboratories and Dr. Reddy's Laboratories.

They already spend significant amounts in the key area of research and development, recognizing that growth will come primarily from their ability to innovate and bring new drugs to market.

Making and marketing generic formulations for big regulated markets such as the United States, Europe, South Africa and Australia is still the key revenue driver for these and other Indian pharmaceutical companies, but the long-term game is being played via R&D and the search for new chemical entities (NCEs).

While finding NCEs is costly, it potentially is hugely profitable.

Dr. Reddy's, the Hyderabad-based company with a discovery research facility in Atlanta, has six NCEs in the pipeline, including two in clinical development.

Company founder Dr. K. Anji Reddy told CNN recently he believed he had a "blockbuster" drug in the pipeline.

That might help him achieve his 2010 target of $2 billion annual revenue, up from $500 million this year.

"All of our revenue now comes from generics. My ambition is that four years from now we will have our own drugs," he said.

Reddy, speaking on the sidelines of the Forbes Global CEO Conference in Sydney, said the biggest barriers to innovation were bureaucracy and politics.

"If you have politics in a scientific laboratory, nothing sprouts there at all," he said.

Money is not the problem, in Reddy's view.

"You don't need a lot of money in the discovery stage and phase one to pre-clinical. You don't need huge money to phase-two clinical test," he said.

"After that, you need real money -- but if I have a success, big [pharmaceutical companies] will come to me."

In the sphere of active pharmaceutical ingredients (APIs), Dr. Reddy's has developed more than 100 molecules, with 70 of them being marketed worldwide.

Gurgaon-based rival Ranbaxy, which is India's biggest pharmaceutical company, says it has three to five NCEs in the late discovery stage, with two molecules in phase II clinical trials.

It undertook process developmental work for 15 new APIs in 2003, and also commercialized technologies for another 10 APIs.

Like Dr. Reddy's and Ranbaxy, other Indian exporters such as Cipla sell generics to a variety of markets around the world. Between them, they sold drugs worth $3.8 billion in 2004-05 to global markets.

If things go to plan, India's pharmaceutical exports could reach $6 billion by 2010 -- still small compared to the $70 billion of manufactured goods India exported last year, but a huge advance from 30 years ago, when India made only the most basic of drugs.

Today, India has the largest number of drug manufacturing facilities approved by the U.S. Food & Drug Administration outside the United States.

Just as India has made a name globally on the strength of a vibrant information technology services sector, so too, have its drug companies made tremendous strides in the past decade.

India came to pharma with similar advantages to IT -- costs are low and high-quality intellectual capital is plentiful.

For example, costs in India for scientists, doctors and laboratory analysts are about one-fifth to one-eighth of those in the United States. India also is making a name for itself as a good place for clinical trials.

The other big bonus has been India's "copycat" regime. Domestic legislation allowed reverse-engineering of patented drugs developed at a huge cost by international pharma companies.

The rationale for this approach was a population of 1 billion people in need of cheap generic medicines to combat the ever-present risk of disease, particularly during the June-September monsoon season.

India acceded to WTO rules banning this approach for drugs patented after January 1995, under what is known as Trade Related Intellectual Property Rights (TRIPS). Now the challenge is to take the industry to the next stage, where Indian pharma companies make their own discoveries.

Reddy is convinced it will happen.

"The goal must be for India -- and China -- to develop drugs on their own soil at affordable prices for people. They must, or people will die.

"We will do that one day," he says.