



## Pharmaceuticals: When language gives an industry the edge

By Andrew Jack

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The hours are long and the time difference tough but, shuttling between their offices in Cambridge and Ahmedabad, Sunil and Prashant Shah co-ordinate a fledgling company that is riding India's fast-growing pharmaceuticals wave.

Since April 2005, cheap travel, telephony and cameras in their laboratories have allowed the two entrepreneurs to build Oxygen Healthcare into a business marketed from the UK to European and North American biotech clients, with their contract chemistry conducted in Gujarat.

But if they claim that the enthusiasm and flexibility of their Indian workforce helps them turn around projects quickly and effectively, they have already had to modify an initial business plan which was based on the expectations of low wages for top quality employees.

"It's really difficult to get experienced people to move," says Prashant Shah. "You have to give them a 30 to 40 per cent pay rise. That's an indication that a lot of companies are investing and increasing their capacity."

For many years, India was best known in the medical world for its thriving generic industry, and the manufacture of the active pharmaceutical ingredients from which drugs are formulated.

One company, Hetero, last month signed a sub-licensing agreement with Roche of Switzerland to produce Tamiflu, the antiviral drug experiencing soaring demand on the back of fears of a flu pandemic. The contract implicitly endorsed the Indian company's technical skills. Cipla, based in Mumbai, one of the country's largest producers by sales, has made a name for itself not only domestically, but as a leading supplier of affordable anti-retroviral drugs for HIV sufferers across the developing world. It has helped reduce the prices of the large companies that first patented Aids medicines.

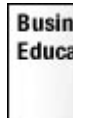
"Take a look around you at our products," says Yusuf Hamied, the chairman, gesturing towards glass cabinets stretched around a large meeting room in the corporate headquarters lined with its own-brand versions of well-known medicines.

But a short drive away into Mumbai's suburbs, in its smart new office block, Nicholas Piramal is taking a radically different strategic approach. The company's core pharmaceuticals business is contract manufacturing for western drugs companies but, increasingly, it is undertaking original research too.

It argues that Indian companies can not only mimic but develop their own innovative drugs at a fraction of western prices, by exploiting the country's genetic diversity, and lower costs for research, development and manufacturing alike. It has several in the pipeline, and in a sign of new-found confidence, recently acquired a UK business.



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Ranbaxy may be suing GlaxoSmithKline (GSK) over patents in the west, but it has also signed a contract with the same multinational to carry out research and development at home. The Indian company is also working with the Medicines for Malaria Venture to produce a new synthetic drug.

“More and more companies are trying to put their footprint in India,” says Simon Friend, head of the pharmaceuticals group at PwC. “Compared with China, India has the edge by four to five years because of the language and the infrastructure.”

One of the big triggers for change has been intellectual property. In the early 1970s, many multinational drugs companies left India when it introduced new patent laws that only granted protection for processes, not for the original products or compounds on which drugs were based. That created a vast copycat industry.

As a condition of joining the World Trade Organisation, however, India agreed to introduce legislation in 2005 that provides tougher patent protection on products too, and which could threaten the generic producers.

Separately, regulatory changes have helped break down other protectionist barriers, making it easier to conduct clinical trials in the country – albeit accompanied by ethical guidelines being introduced to limit past abuses.

GSK has been among the first to exploit the shifting trends. Itself the largest single pharmaceutical company in India, which it sees as a market with considerable growth, it has outsourced back office functions to India and begun collaborative research with Ranbaxy.

It is also looking more and more to conduct clinical trials in India. The company insists that this has nothing to do with simple cost cutting, arguing that the facilities are excellent and that many doctors are British trained.

“India has 8,000 to 10,000 manufacturers, 18,000 distributors and 250,000 pharmacies,” says Shailesh Gadre, head of the Indian office of IMS, the market research company. “It is a very complex system. A company that gets in early will have a very good advantage.” He says that with sales – partly because of the absence of higher margin branded drugs – at \$5bn last year, India still represents only a little more than 1 per cent of global pharmaceutical sales. These figures represent the retail market, which makes up the vast bulk of sales.

But revenue grew by 8 per cent in 2005, and Mr Gadre predicts it will increase by about 10 per cent a year for the coming five years. He points out that, by 2010, 450m Indians will have western middle class incomes. Demand for western-style chronic treatments – for the cardiovascular and central nervous systems, for instance – are already on the rise.

However, he cautions that India remains a country of vast contrasts, with widespread poverty, a very modest state-supported healthcare system, and private insurance which remains its infancy. That creates considerable tensions and uncertainties.

Others warn that it will be some time yet before western companies are confident about intellectual protection. Nearly 9,000 patents filed between 1995 and 2005 remain in the “mailbox” awaiting consideration, with none yet granted, and there are reports of inconsistent work by India’s different regional patent offices.

Mr Shah is confident but realistic about India’s pharmaceutical future. He admits that significant problems of corruption, basic infrastructure and work culture remain. “We’re at least five years away from a blockbuster drug coming from grass roots companies,” he says.

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