

India's pharmaceutical industry: hype or high tech take-off?

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Abstract

India has built a large pharmaceutical industry through an array of measures in support of domestic firms. The absence of product patents enabled Indian companies to become world leading producers of generic versions of patented drugs. Low costs and a strong engineering tradition continue to sustain competitive strength. The implementation of the World Trade Organization patent regime in 2005 is driving a transformation of the industry. Key elements of the present shake-up include the return of 'big pharma' companies on a large scale and the emergence of several Indian firms that aim to become fully-fledged research-based multinationals. This article provides a description of the development and structure of the Indian pharmaceutical industry and explores questions and challenges arising from its integration into global markets.

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THE INDIAN PHARMACEUTICAL INDUSTRY is the largest and most advanced in the developing world, accounting for 8% of global production by volume and 1.5% by value and employing over 2 million people (Government of India 2002b). Almost every type of medicine is produced indigenously, from headache pills to sophisticated antibiotics and complex cardiac compounds. Drugs are exported to more than 65 countries

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What is known about the topic?

There have been many recent media reports about India's pharmaceutical industry and the forthcoming introduction of drug patents as required under the TRIPS agreement.

What does this paper add?

This article provides an up-to-date analysis of the Indian pharmaceutical industry and explores questions and challenges arising from its integration into global markets. It adds to a very small body of scholarly literature on this topic and is the first such analysis by Australian authors.

What are the implications for researchers and policymakers?

The Indian industry comprises an increasingly significant component of the global pharmaceutical sector. This poses challenges for Australian policymakers, most directly in respect of the domestic generics market and Australia's future as a competitive location for pharmaceutical industry activities.

including the US and other highly regulated markets. A small group of firms spearheaded by Ranbaxy and Dr Reddy's Laboratories engage in research to discover new medicines, but the production and export of generics remain the lifeblood of the industry.

After several decades of autonomous development behind high tariffs and other protectionist measures, India's pharmaceutical industry is now reintegrating into global markets and production systems. This transformation is driven by the Trade Related Intellectual Property Rights (TRIPS) agreement which India will implement in 2005. TRIPS is one of the three pillars of the World Trade Organization (WTO), the others being trade in goods and services. This agreement has implications for drug access and pharmaceutical industry development, particularly in developing countries. The new patent regime disallows the 'reverse engineering' model which underpinned

the industry's expansion in the past three decades. The industry is 'understandably ... jittery and on edge ... anyone remotely connected with the sector has only one question in mind. What after 2005?' (*Indian Pharmaceutical Reference Guide* 2003, section 1, p. 7).

The rapid growth of pharmaceutical production and exports in the past decade has generated articles in the domestic and international business media citing pharmaceuticals along with the IT and the 'business process outsourcing' sector as evidence of the rise of an Indian high tech economy. Yet the technological sophistication, entrepreneurial flair and export success of a section of the domestic industry stand in glaring contrast to the state of Indian health services. At 0.9% of gross domestic product (in 2003) India's public health expenditure is very low even by developing country standards. Only some 35% of Indians can access essential drugs (Swain et al 2002). The market is not effectively regulated; there are major problems of irrational prescribing and ready availability of fake and substandard drugs. The benefits of the high tech industry expansion in the past decade have not been widely shared. It is a moot question whether further growth and internationalisation of the pharmaceutical industry will benefit India's hundreds of millions of poor people.

The aim in this article is to provide a broad and introductory description of the development and structure of the Indian pharmaceutical industry and to explore questions and challenges arising from its integration into global markets. Some figures presented in this paper are somewhat tentative due to a lack of precise and reliable data on the composition of the industry, prices and price variability, drug quality and accessibility, and so on. Articles on this topic are indeed replete with varying figures for key economic measurements, yet general trends can be identified.

Historical context

The history of India's modern pharmaceutical industry commenced with the establishment of the Bengal Chemicals and Pharmaceutical Works

in Calcutta in 1901 (World Bank 1997). Until the 1970s the market was dominated entirely by foreign transnational corporations (TNCs) engaged mainly in the importation of finished medicines, and domestic firms supplied less than 25% of the total market (Lanjouw 1998, p. 3). India was also "well-known for having relatively high drug prices" (Lall 1974, p. 163). Cheaper, essential medicines were supplied by public sector companies established in the 1950s and 1960s with assistance from the World Health Organization (WHO), UNICEF and the Soviet Union. These state-owned companies in conjunction with public sector research organisations — notably the Council of Scientific and Industrial Research and the Indian Council of Medical Research — prepared the ground for later industrial developments through the creation of indigenous technical capacities. The fundamentals of recent economic growth in India were laid through "the pools of skilled human capital built through the technology, management, and research institutes — a sort of import substitution effort in skilled human capital development — that were integral to the Nehruvian vision", note Rodrik and Subramanian (2004). The drug companies that today remain in the public sector are of little significance (Government of India 2002b, p 688).

Colonial India recognised patents for all inventions, including pharmaceuticals, under an Act passed in 1911. By contrast, many of the OECD countries introduced such patents only when their economies had reached a much higher stage of development; thus Japan introduced drug patents in 1976, Switzerland in 1977, Holland in 1978, Spain and Norway in 1992, and so on (Subramanian 2004, p. 24). The turning point for India's drug industry came when product patents for medicines were repealed in the Patent Act 1970 (effective April 1972), which recognised only process patents (for 5–7 years). The explicit purpose was to break away from dependence on imports and provide for a self-reliant indigenous drug industry. There were also high tariff rates, restrictions on the importation of ready-made formulations, and the TNCs were required to

reduce their stake in their Indian subsidiaries to 40% (Shah & Patel 2004). This array of protectionist measures, and the weakening of the patent system, made possible the emergence of a significant domestic drug industry which by the 1990s had achieved self-sufficiency in the production of most basic medicines. All in all, India became an unattractive market for the TNCs and many abandoned the country altogether. The absence of product patents meant that every drug was a generic, and firms developed processes to manufacture at low cost a wide range of bulk and finished drugs. According to Lanjouw (1998, p. 4), Indian firms in 1991 supplied 70% of the bulk drugs (active chemicals in powder form with therapeutic value used for production of formulations) and 80% of formulations for the Indian market. Other key factors enabling the emergence of a robust domestic industry included India's strong chemistry and engineering traditions and an abundant supply of highly educated English-speaking professionals.

In 1991, India commenced a general economic policy shift towards liberalisation, privatisation, and integration into global markets, and the pharmaceutical sector was progressively 'opened up' in respect of trade and foreign investment. Since 2001, automatic approval has allowed up to 100% foreign equity in the pharmaceutical sector, and Indian law now treats TNCs as equal to Indian companies. Notwithstanding the move away from independent India's traditional protectionism and heavy state regulation, the domestic pharmaceutical industry continued to increase its market share throughout the 1990s. In 2003, eight out of the top ten companies were indigenous, supplying around 65% of the Indian market (KPMG 2003; Joshi 2003). The key remaining prop for domestic firms in this period was the absence of product patents, which enabled the 'reverse engineering' of drugs patented elsewhere, a model that will be severely circumscribed by the new intellectual property rights regime to be introduced in 2005. The State Planning Commission was concerned that with the "introduction of product patenting, the industry is on the verge of losing all its advantages" (Government of India

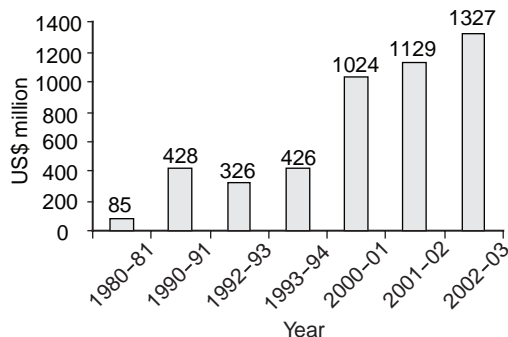
2002b, p. 687). Whether this turns out to be the case or not, the imposition of global rules of competition makes the Indian pharmaceutical industry "a prime example of an industry that is being forced to revisit its long-term strategies and business models" (Zacharias & Farias 2002).

Market and industry structure

Globalisation is not vanquishing local and national cultures in health and pharmaceuticals. In India, at least 70% of the population rely in part, or even completely, on traditional medicine (Swain et al 2002). For instance the use of gripe water, an ayurvedic syrup for toddlers, is a must for every family, including many Indians living abroad. The most widely practised forms of traditional medicine are ayurveda, homoeopathy, naturopathy, sidha, unani and yoga (Misra, Chatterjee and Rao 2003). Ayurveda and homoeopathy are complete systems of therapies; the others provide treatments for certain conditions. Western (allopathic) medicine, especially in rural areas, is often seen as a quick fix that does not ensure lasting efficacy. Traditional medicine, by contrast, is cheaper and more readily available, and is considered to be slow-working and hence more effective in the long term. Reliance on traditional medicine and poverty limit the size of the Indian pharmaceutical market in terms of per capita spending, which is just US\$3 annually; only Bangladesh, Bhutan and the States in Sub-Saharan Africa rank lower (Swain et al 2002).

Yet India's pharmaceutical industry is huge in absolute terms; its 2003 turnover was around US\$6 billion and an increase to about US\$25 billion is expected by 2010. It employs around 500 000 workers directly and 2.4 million indirectly (Organisation of Pharmaceutical Producers of India 2004). Estimates of the total number of firms differ widely. Swain et al (2002) report around 250 large enterprises and over 20 000 small to medium sized units, including five public sector enterprises. Another source suggests that the total number of manufacturers is only around 5700 (Essentialdrugs.org 2004). The top ten companies control around 30%, and

I India's exports of medicinal and pharmaceutical products



Source: CSO's Statistical Pocket Book, 1994, p. 104 (1980-81 to 1993-94); and IndianData.com (2000-01 to 2002-03).

around 300 firms about 70%, of the domestic market. No firm is reported to have more than a 6% market share (*Indian Pharmaceutical Reference Guide* 2003, p. vii). The TNCs' market share of around 35% is expected to grow rapidly from 2005. GlaxoSmithKline is the largest of these with a market share of 5.6% (Novartis India 2004). The Indian Drug Manufacturers Association (IDMA) represents domestic firms, while the Organisation of Pharmaceutical Producers of India (OPPI), a vocal proponent of the new patent regime, represents 'research-based' companies and large Indian firms.

Indian firms produce thousands of formulations with multiple copies of many drugs, and launch large numbers of new products every year. There are, for example, according to media reports, more than 92 generic versions of Vioxx (withdrawn by Merck from most markets but not India in late September 2004). Formulations make up about 80%, and bulk drugs around 20% of the value of Indian drug production. Indian firms manufacture more than 500 bulk drugs, and the country is among the top five producers in the world. This segment of the market has increased in the past decade at around 20% annually, and the production of formulations by around 15% (Joshi 2003).

Exports make up a significant proportion of total production, and around half of the revenue of top companies like Ranbaxy, Dr Reddy's and Cipla is derived from exports. Indian firms have a presence in over 65 countries and have the highest number of FDA certified plants outside the US. Exports have been growing at over 10% per year in the past decade, and generated revenue in 2001-02 of around US\$2 billion (Economist Intelligence Unit 2003). Other sources, however, report export revenue to be more moderate (Box 1). Until recently, India was exporting mainly to the erstwhile Soviet Union nations, South East Asia, Africa and Latin America. Now exports to more regulated developed markets are becoming increasingly significant as Indian companies make their mark in the global generics market, valued at more than US\$30 billion. The US is now India's largest export market (Box 2). The worldwide generic market will continue to grow rapidly as patents on blockbuster medicines expire, and Indian firms expect to capture a large share of this growth.

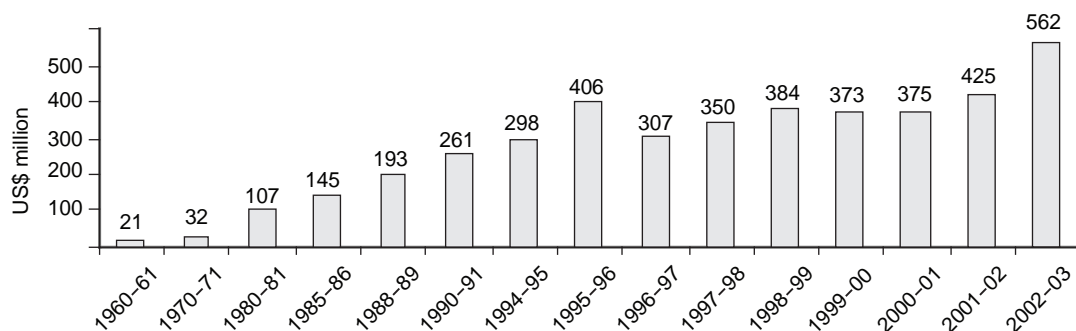
As Box 3 indicates, imports have also increased in the past decade, but at a slower rate. This is explained by over-capacity in the domestic mar-

2 Top ten destinations for India's drug and pharmaceutical exports (US\$ millions)

Rank	Country	2000-01	2001-02	2002-03
1	USA	56	136	251
2	Russia	101	93	99
3	Nigeria	74	74	71
4	UK	23	29	52
5	Germany	37	37	45
6	Brazil	19	37	41
7	Sri Lanka	34	28	40
8	China	18	22	36
9	Vietnam	34	34	35
10	Nepal	28	30	33
Total of the top ten		423	520	703

Source: IndianData.com

3 India's imports of medicinal and pharmaceutical products



Sources: Ministry of Finance Economic Survey; Tata's Statistical Outline of India (various annual issues); CSO's Statistical Pocket Book, 1994; and Reserve Bank of India's Annual Report, 2002-03.

ket and improvements in the quality of bulk drugs manufactured domestically. As a result, from being a net importer in the 1980s India has now become a net exporter of pharmaceuticals.

Pharmaceutical trade with Australia shown in Box 4 indicates an increasing Indian surplus. Exports to Australia have risen steadily, while imports from Australia peaked in 2000 and have since declined. Yet trade is small in absolute numbers and there is a strong potential for increased imports of generics from India.

As the pharmaceutical industry expanded, so did the problem of spurious and substandard drugs, which is now estimated to be anywhere from 15–20% to 35% of drugs sold. A committee set up to address this problem submitted its interim report in July 2003. The Mashelkar Committee recommended that the Drugs and Cosmetics Act be amended to maximize the penalty for the sale and manufacture of spurious drugs causing grievous bodily harm or death, from life imprisonment to death (Tribune News Service 2003).

Patents and the prospect of R&D

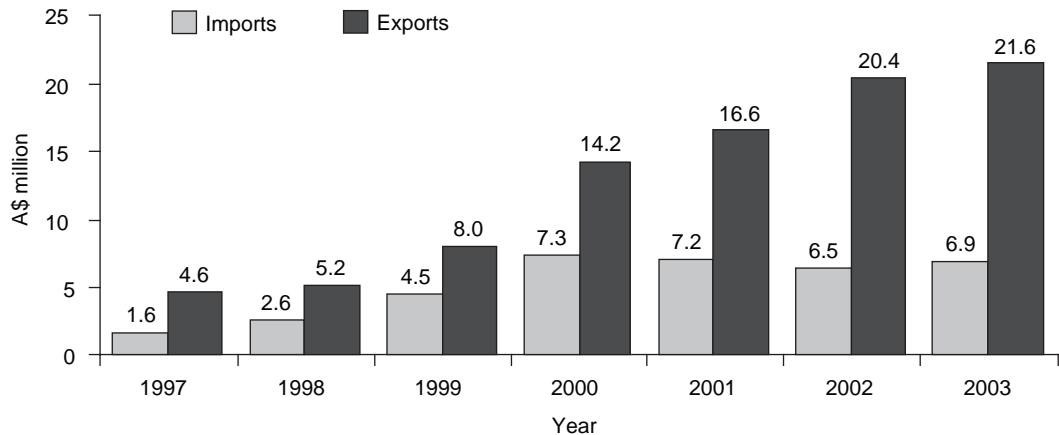
The Patents Act 1970 has been described as the result of

... parliamentary performance at its best, blending pragmatism, patriotism and eclec-

tic functionalism, and the decades that followed proved, by pharmaceutical progress registered by India, that law to be a tribute to intellectual property jurisprudence. (Krishna Iyer 2002)

In the wake of this Act, firms built 'reverse engineering' capabilities making India largely self-sufficient in medicinal drugs and an exporter of safe, effective and affordable generics. The Indian industry came to worldwide attention when the Mumbai-based firm Cipla, in 2001, offered to supply a one-year course of the triple combination drug required for treatment of AIDS to countries in Africa for US\$350, against the patent holder's price of US\$10 000 to US\$12 000 (IDMA 2004). The TNCs responded with attacks in the courts and the international institutions on Cipla and its prospective customers, notably the South African government (Haddad 2003). Public outrage ultimately forced a withdrawal of the legal action against South Africa. Subsequently, the objectors decreased their own prices for AIDS medications. Indeed Indian companies such as Cipla and Hetero were instrumental in making AIDS medications more accessible in Africa and elsewhere. The need for AIDS drugs in developing countries is still far from being met, and US resistance to generics remains one of the factors hampering supply. Cipla claims that Indian firms could readily achieve a fifty-fold increase in the

4 India's pharmaceutical trade with Australia



Source: Trade data based on Australian Bureau of Statistics' unpublished data.

production of still-under-patent Triomune (selling in the US for about US\$12 000 for a year's treatment) at a price of about US 60 cents per day (Russell 2004).

The new global intellectual property regime, set up under the auspices of the WTO, provides for twenty-year product and process patents. India signed the TRIPS agreement on April 15, 1994, against strong domestic opposition from public health advocates and most sections of the domestic pharmaceutical industry. Developing countries were given a phasing-in period until 2005, and the least developed countries until 2016 (India was not considered a least developed country). To conform to the TRIPS agreement, India's Parliament passed two amendments to the Patents Act 1970 (in 1999 and 2002). The change of government in mid-2004 has delayed and complicated the passage of the third amendment through Parliament. Discussion in India as elsewhere revolves around conflicting interpretations of the requirements of TRIPS compliance. Public health safeguards were built into the TRIPS agreement and were then made more explicit in the Doha Declaration of 2001, approved by the WTO at the instigation of India and other developing countries. The Doha Declaration affirms that "the TRIPS agreement does not and should not pre-

vent members from taking measures to protect public health" and "the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (World Health Organization 2002, p. vii). The TNCs and the US government seek to impose 'TRIPS plus' provisions — intellectual property protection that goes beyond what is required under TRIPS — notably through regional and bilateral trade agreements such as those recently entered into with Jordan, Singapore and Australia (Oxfam 2003). A further threat to the flexibilities available under TRIPS is now emerging from the agenda pursued by the US within the World Intellectual Property Organization (WIPO) with the ultimate objective of global patents that would preclude consideration of national circumstances and do away with the need for most national patent offices (Nanda 2004).

A number of complex issues come under the 'TRIPS plus' heading, including the patenting status of genes, forms of protection for traditional knowledge and biodiversity, conditions under which compulsory licensing is to be allowed (in cases of national emergencies, etc.) and the issue of data exclusivity. The term data exclusivity

refers to test and clinical trial data submitted when a company applies for market approval and the period during which other companies are precluded from using the same data when seeking market authorisation for generic versions of the same drug. The length of data exclusivity varies from five years in the US to up to ten years in some EU countries, but data exclusivity is not a TRIPS obligation. The purpose of TNC lobbying for data exclusivity in India (and elsewhere) is to extend (in certain circumstances) the *de facto* period of patent protection (beyond the standard 20-year period), thereby delaying or even preventing totally the market entry of cheaper generic alternatives. There is currently an intense debate in India on whether to introduce data exclusivity, and if so, for how long, with different sections of the pharmaceutical industry taking different positions (Jain 2003; Sahai 2004). The IDMA represents domestic generics producers and opposes any provisions for data exclusivity. Nicholas Piramal, one of the leading companies, by contrast, advocates data exclusivity for five years. The government, in preparing the third amendment to the Patents Act, has signalled that a period of data exclusivity will be part of the legislation.

It is not as if the reverse engineering model did not entail innovation, a term that refers to the introduction of new products *or production processes*. The manufacturing of generics often requires considerable technological skills, particularly where based on reverse engineering. Only a small number of large developing countries (India, Brazil, China, Thailand, etc.) have the capacity to produce sophisticated drugs. In the Indian patents debate, the TNCs, supported by leading domestic companies and most business analysts, argue that after 2005 the Indian pharmaceutical industry will become by necessity more R&D intensive. The TNCs are expected to extend significantly their investments in research activities and clinical trials. Indeed, there have been many recent reports about the potential of Indian biomedical and pharmaceutical research (eg Dyer 2004). This expansion would draw on India's large pool of scientists and engineers and

low costs: "by some estimates, the cost of setting up a medium-sized chemistry research facility with about 50 scientists are 80%–85% lower in India than in the US or Europe" (Warmington 2003, p. 66).

Hyderabad-based Dr Reddy's Laboratories, a US\$500 million company in global terms, was the first Indian company in the early 1990s to initiate a basic research program. It now spends 10% of revenue on R&D, has three molecules in clinical development (one licensed to Novo Nordisk) and four in preclinical development. The company has launched eight generics in the US market and in March 2004 "had 35 applications for generic products and 56 filings for bulk products pending approval with the FDA" (Reddy 2004). Other firms with research of some significance include Ranbaxy, Wockhardt, Cipla, and Nicholas Piramal, all reported to be spending in the order of 5% of revenue on R&D. The research director of Nicholas Piramal claims: "The big pharmaceutical companies say it costs them at least \$800m to develop a new drug ... Well, we can do it for \$50m ... We are going to develop a cancer drug to prove it" (Dyer 2004). Indeed, it was reported recently that Indian researchers have discovered "the first new medicine to treat tuberculosis in more than four decades" as a result of a public–private project involving government research centres, universities, and the Mumbai-based company Lupin (Merchant 2004a).

India offers a range of support measures to encourage the industry to undertake R&D. For example, tax rebates of weighted deductions of 150% are provided for R&D expenditure, and drugs developed through indigenous R&D are exempted from price controls (though there would as yet seem to be few if any products in this category) (Government of India 2002a). The Council for Scientific and Industrial Research (CSIR), India's major public-sector research organisation, is now focusing strongly on interaction with the private sector on projects with a commercial potential (Merchant 2004b). The proactive role of the state in identifying and addressing the needs of the pharmaceutical

industry has increased India's prospects of emerging as a global R&D hub and manufacturing base (Ernst & Young International 2002). A reverse 'brain drain' is also working in India's favour as nearly 10% of US drug scientists of Indian origin have reportedly returned to work for Indian pharmaceutical companies (Nair-Ghaswalla 2004). R&D activities undertaken by both Indian firms and TNC subsidiaries have undoubtedly increased, and collaborations and joint research ventures involving firms of both types are reported regularly, such as the alliance between Ranbaxy and GlaxoSmithKline (Merchant & Dyer 2004).

Yet there is a conspicuous element of hype in many recent reports about Indian discovery-oriented pharmaceutical R&D. Its magnitude, in fact, is quite small, and it is heavily concentrated in fewer than ten firms. Across the industry, only 1.9% of revenue from pharmaceutical sales is reported to be expended on R&D compared with 10%–15% for the TNCs (Ranade & Basu Das 2003). According to the Financial Times, the research budget of Ranbaxy is around US\$60 million, and Dr Reddy's, US\$40 million. Other firms spend considerably less and "the entire revenue of the Indian drugs industry is less than the \$7bn a year Pfizer alone spends on research" (Dyer 2004). As noted, the same dollar amounts would buy 'more' research in India than in the US, but there can be no expectation that these discrepancies will diminish significantly. There are also major infrastructure problems and troublesome bottlenecks caused by lack of particular types of expertise (such as molecular biology) and access to expensive equipment. The research and higher education sector is very large (250 universities), but few of the 5000 PhDs produced annually are of 'global standard' according to the head of the CSIR (Dyer 2004). The R&D activities in India are noteworthy now, but commenced from a very low base. In the mid-1990s only Hoechst and Ciba-Geigy (both since merged with other firms) were doing any basic research in India (Lanjouw 1998, p. 25). It can also not be precluded that R&D undertaken by the TNCs in India will continue to be very marginal. With an

open market, big companies may focus mainly on imports (as before 1970) and they may decide to extend their market share through acquisitions of previously autonomous Indian firms. Notwithstanding India's competitive strengths, other countries are also bidding strongly for overseas R&D investments, from Ireland to Singapore to China. It is commonly suggested that India may have a ten-year head start for consolidation and upgrading of its pharmaceutical capabilities before China will have caught up. Finally, the literature on the socio-economic conditions for cutting edge biomedical research (the significance of established knowledge clusters, etc.) would suggest that very optimistic projections about pharmaceutical R&D in India and other developing countries are not warranted (see Benner in this issue, *page 161*).

Price controls and affordability

It is commonly asserted that drug prices in India are among the lowest in the world. As an example, in 2001 the price of a month's supply of Hydrochlorothiazide was US\$0.17 in India compared with US\$7.49 in Australia and US\$11.65 in the US (Lopert et al. 2002). Yet other analysts argue that only patented drugs are cheaper in India than elsewhere, and this is due to the absence of product patents. Off-patent drugs, accounting for more than 80% of the market, are often priced higher than in some developing countries such as Sri Lanka and Bangladesh (Ramachandran 2002). Around 85% of the population must meet all healthcare costs through private out-of-pocket expenses; thus even essential drugs at very low prices are not accessible to most people. With high levels of poverty and no general health insurance or pharmaceutical benefits, drug price controls take on particular significance.

Drug price controls were first imposed in 1962 in the context of fears that the war with China could trigger steep price increases. From 1966, manufacturers had to obtain government approval before prices on formulations could be increased. In 1970 drugs were brought under

5 Market share of drugs under the DPCO, 1979–2004

Year	Number of drugs	Approximate market share (%)
1979	347	80
1987	142	60
1995	74	> 40
2004	na	20

Compiled from sources cited in this article.
na=not applicable

the Essential Commodities Act, and the Drug Price Control Order (DPCO) mechanism was put in place. Initially, firms could set prices freely, but if pre-tax profits exceeded 15% of sales revenue the surplus was to be deposited with the government. This was a mild form of intervention with few negative effects on the growth of the industry, and the dominance of the TNCs was not threatened by this measure (Kunnapallil 2004; Shah & Patel 2004). More far-reaching regulatory controls were, however, contemplated in this period. The so-called Hathi committee in 1975 recommended wholesale nationalisation of the drug industry and that generic names should be used for all new single-ingredient products. This was “the high-point of social justice and pharmaceutical nationalism ... which made the little Indian’s access to medicinal justice the focus of state policy” (Krishna Iyer 2002). Intense industry lobbying ensued and most of the committee’s recommendations were not implemented. In 1978 brand names for only five products were abolished and even this modest step was ultimately stifled through industry court action. Recommendations to use generic names have since been largely ignored; brand marketing of combination drugs (of often questionable appropriateness) and products containing subtle adjustments to basic medicines (like paracetamol) are common (Mohan 2004).

The DPCO system for price ceilings for a basket of bulk drugs and their formulations introduced in 1979 is still in place. This arrangement is

supposed to encompass essential drugs in sub-markets where competition is inadequate but the criteria for determining inclusion and exclusion are often criticised as irrational. There are instances of truly life-saving and essential drugs not being controlled while some highly dubious drugs are covered (Narain 2004). The National Pharmaceutical Pricing Authority (NPPA) has responsibility for monitoring controlled prices, but it has little capacity to do this effectively. The NPPA does not have a field force and there are around 230 000 pharmacies in India selling about 60 000 medicines. To keep drug prices uniform throughout India, the Maximum Retail Price (MRP) including all taxes is printed on each pack and strip of all formulations (whether subject to price control or not).

Box 5 shows the number of drugs under the DPCO was reduced from 347 in 1979 to 74 in 1995 (Government Of India 2002a). As of 2004, about 80% of formulations are said to be outside the DPCO, and many prices are reported to have increased steeply in recent years (Shah & Patel 2004). Both the domestic industry and the TNCs have always opposed price controls and the issue remains highly contentious. Kunnapallil (2004) argues that the DPCO system severely affected profit margins during the 1980s; “the profits of the pharmaceutical industry plummeted over the period 1982–1991 and thereafter registered a stupendous increase”. Since the early 1990s, governments have become increasingly receptive to the industry’s point of view and critics assert that official pharmaceutical policy (pronounced in 1986 and revised in 1994 and 2002) assigns higher priority to trade and commercial objectives than public health.

The new Congress-led government elected in May 2004, however, has signalled a reversal of the trend of the past 25 years towards weakening the price control system. Its Common Minimum Program states that life-saving drugs must be available to consumers at reasonable prices and it has ordered the NPPA to track the prices of 300 ‘essential medicines’. According to media reports (in August–September 2004) a high-level government committee has been estab-

lished to revamp the price control mechanism, with a view to including therapeutic area as a criterion (that is, drugs of particular public health significance). The industry is reported to be “irked by the idea of more drugs being brought into the ambit of price control and that disease-specific drugs may be brought within its ambit” (Ghoshal 2004). A proposal to make it mandatory for companies to print the cost of production on packages (in addition to the maximum retail price) has also been flagged, causing industry alarm (Mudur & Sen 2004). The pharmaceutical industry now wields substantial influence in New Delhi, however, and it would seem unlikely that the government would impose regulatory measures that seriously impinge on industry growth and profitability.

Concluding discussion

The nationalist period of state-protected drug industry development in India has come to an end. At issue now is how the large domestic pharmaceutical industry which emerged after 1970 will be changed by integration into global markets — and how Indian firms may impact on the global industry. One scenario is that competition with the TNCs may escalate as Indian firms, building on the expansion of the past decade, drive global restructuring through large-scale exports of low cost, high quality generics. The generics market across the developed and developing countries will continue to grow, notwithstanding the TRIPS patents regime; most medicines on essential drugs lists (and formularies in the developed countries) are not under patent, and patents on many big-selling products will expire in the near future. Alternatively, the most advanced of the Indian firms may be substantially integrated into the global innovation and production networks of the TNCs and the threat posed to the ‘big pharma’ companies by relatively independent, highly efficient Indian generics manufacturers would thereby be defused. In both scenarios, domestic Indian infrastructure and regulatory arrangements will be progressively upgraded (better protection against counterfeiting, adulteration, etc.) and price controls weakened

further. Rightly or wrongly, the winding back of the DPCO system in conjunction with the new patent regime has stoked “a growing fear that the prices of medicines will skyrocket” (*Indian Pharmaceutical Reference Guide* 2003, section 1, p. 7).

There is more hype than realism in the contention that, in the foreseeable future, India is likely to have a research-based pharmaceutical sector of significant magnitude, as a consequence of a turn to R&D driven by the introduction of product patents and the capabilities of firms such as Ranbaxy and Dr Reddy’s. Although more R&D is undertaken than a decade ago and there is interest in locating more clinical trials in India, these are marginal activities set in the context of the Indian pharmaceutical sector as a whole and global R&D in the biosciences. It is also fanciful to suggest that developments in India’s pharmaceutical industry, alongside the IT sector, signal the commencement of a high-tech take-off that could lift the whole of the Indian economy. The pharmaceutical sector is large in absolute numbers, but all Indian high-tech industries are dwarfed by the overall size of the formal and informal economy.

The significance of 2005 for the TNCs is that India will again be an open market with no constraints on foreign direct investments. Soon it will be possible to look back at the period of state support for an autonomous domestic industry, at the expense of the TNCs, as an historical interlude. The TNCs are now reorganising their brand portfolios, distribution networks and marketing organisations and their overall market position will be reinforced. The chronic diseases of the rich countries provide the TNCs with their primary focus for R&D and marketing, but India, with a population exceeding one billion, will not be ignored. This may or may not mean that India will be chosen by the TNCs as a location for manufacturing, exports and research activities on a significant scale. A reversal to the pre-1970s practice of supplying the Indian market largely through imports is conceivable.

Analyses of industry developments tend to be largely divorced from considerations of public health. The forces that now reshape the Indian

pharmaceutical industry will not bring about an improvement in the health conditions of the vast majority of the population, around 70% of whom live in the countryside. India adds around 2.2 million people annually to the fifteen million patients suffering from TB. Communicable and infectious disease accounts for the deaths of 2.5 million children under five annually, and an equal number of adults. There are many millions of diabetics, AIDS and heart disease sufferers and, as noted, even essential drugs are beyond the reach of most people (Misra, Chatterjee & Rao 2003). It is striking that AIDS medications are not widely available to Indian patients notwithstanding the groundbreaking role of Indian companies in supplying relatively cheap generic AIDS drugs. Indian firms now undertake R&D of growing significance but its focus and direction is shaped by the imperatives of the profit- and market-driven model of drug development which manifestly does not meet the needs of the population in developing countries. The central government's Planning Commission posits that "priority needs to be given for the initiation of new drug development for diseases of relevance to the Indian population" (Government of India 2002b, p. 687), but needs-driven discovery research or, for that matter, the supply of essential drugs as public goods, will not be easily reconciled with success within a globally integrated pharmaceutical market.

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