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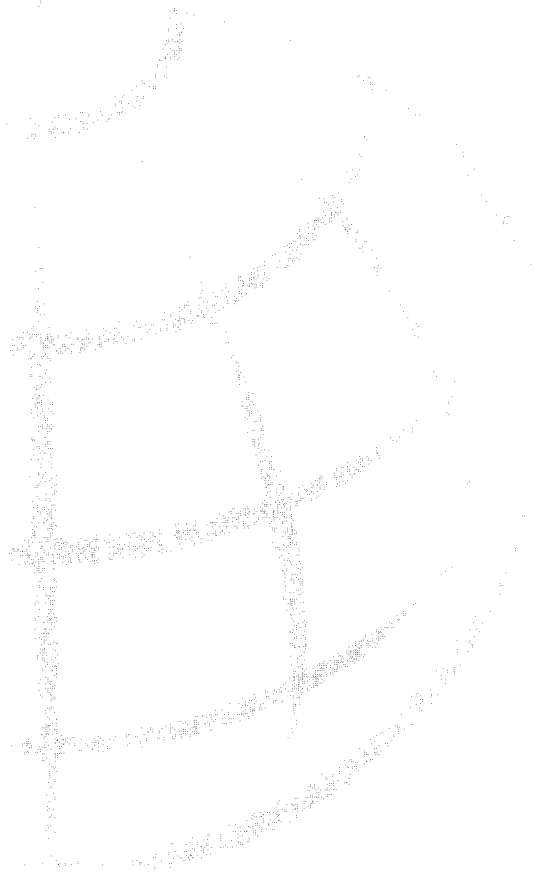
The Pharmaceutical Industry in India and Hungary

Policies, Institutions, and Technological Development



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Chapter I. Introduction - Pharmaceuticals

Greg Felker

The pharmaceuticals sector illustrates policy and institutional influences on technological development in science-based industries, where innovations are tied to advances in scientific knowledge, usually considered a quintessential public good. Pharmaceutical innovations are built upon and integrate discoveries in biology, chemistry, medicine, botany, and other scientific fields. They are less often related to technology innovations of process or to firms' operational know-how. The basis for such product innovations requires large and risky investments in scientific research, and an ability to live with failure. Much of the basic and even applied research is thus frequently carried out with public sponsorship and conducted in universities and government laboratories. Commercializing original drug products frequently involves even larger investments in product development, testing, and clinical research to demonstrate effectiveness and obtain official registration in major markets. Finally, selling brand-name drugs requires extensive marketing networks.

These formidable costs influence the sector's market structure. There are two major kinds of products: active substances (or bulk drugs), and formulations, the products sold to consumers. Active substances contain the core scientific and medical properties that are the focus of research. Their development involves isolating natural substances or synthesizing molecules with biochemical properties. The production of active substances may be simple, for the relatively low-margin market segment. Greater returns accrue to companies that hold patent rights for innovative active substances or formulations. Economies of scale in innovation and marketing have rendered the global market in final drugs oligopolistic. A few Western multinationals command the market partly by virtue of their massive investments in research, typically averaging 10 percent to 20 percent of sales.

Because they are science-intensive products rather than based on process technology, drug innovations are relatively easy to copy or reverse-engineer, and technology may leak as codified formulas or via the migration of staff. Intellectual property rights and patent laws are thus central to a company's ability to make profits and to followers' attempts to catch up with technological leaders. Patent laws vary from country to country. Many developing and socialist countries have been permissive toward imitators in order to stimulate local industry and hold down consumer prices. These countries may allow the patents for drug processes but not products; may allow only short patent lives, sometimes shorter than the period required between patent filing and final testing and marketing; and may have lax enforcement of patent infringements.

The Uruguay Round of GATT, however, includes commitments to raise many countries' protection of intellectual property rights to international norms. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, effective January 1, 1995, provides for all countries to make product and process patents available in a nondiscriminatory fashion for all inventions subject to normal tests of novelty, inventiveness and applicability. The term (or life) of the patent must be a minimum of twenty years from filing. Transition

arrangements, however, have been provided for. Specifically six year additional, (until January 1, 2000), is given for adopting the above norms to developing countries as well to countries like Hungary which are in transition from centrally planned to market economies. In developing countries like India which do not provide product patent protection in selected areas like pharmaceuticals and agro-chemicals, a further five years (until January 1, 2005) is provided for adopting product patents in those areas.

Coupled with broader market-oriented reforms, the new regulatory environment, even during the transition phase, challenges drug producers in countries accustomed to limited patent protection. The new property rights, as well as explicit research and technology policies, will influence technological development, although with time to adapt.

Pharmaceuticals have provided opportunities to countries with a strong base in related scientific fields. The mismatch between the theoretical orientation of public technology institutions and the applied-science needs of industry, which typifies many sectors, may be less of a hindrance to pharmaceuticals innovation. Scientific knowledge and research capabilities in chemistry and biology are often readily transferable to industry's product development efforts, whether aimed at original drugs or imitations. But industrial success still depends on accumulating process technology to support productivity and quality in drug production. Process technologies like chemical synthesis and fermentation are more science-based than those found in many other industries. The following cases illustrate that successful institutional support involves a strong focus on applied research and process technology.

Hungary and India have developed substantial pharmaceuticals industries whose performance is successful relative to their country's sector averages. Their governments have promoted development through direct investment, intellectual property and price regulation, and support for scientific research. In both countries public investments in R&D, education, and direct production have been more successful in fostering industrial technology development than is the case in many other promoted industries, for a number of reasons.

First is the nature of the product. Because advances are based more on science than firm-specific capabilities, public investments in research and training do not have to be so finely tuned to industrial and market needs to be useful to industry. Second, both countries have traditions of academic excellence in the sciences within public institutions and firms. Public institutions have had mixed success in providing formal services to industry, but research and engineering skills have benefited industry in both countries. And third, both countries' social policy commitments to inexpensive drugs led them to adopt lenient patent laws, affording firms important opportunities to innovate without having to shoulder the full costs of original product research or pay prevailing rates for international access to intellectual property. While accumulating substantial process technological capabilities, their industries have relied on sales of imitation drugs discovered by Western firms.

Hungary's role in the former East bloc's division of industry included the export of imitation Western drugs to the CMEA, the Soviet organized trading bloc. The industry was primarily composed of state-owned firms, each producing a broad range of products. Drug technology was often acquired through licensing from Western companies eager to enter otherwise closed markets in the East. Firms also developed research laboratories to support

production of imitation drugs, process improvements, and quality control. Their mastery of production technology is demonstrated by their success in standardization, adopting Good Manufacturing Practices and exporting active substances and other intermediate products to Western markets. Original-drug development was a lower priority, as reflected in R&D-to-sales ratios among Hungarian firms that were well below the international average. The country's universities and industrial institutes generally did not form effective research links with firms to support drug development. Central planners attempted to mandate coordination, and major firms held nominal ownership of most research institutes. But firms used them primarily for routine laboratory services and relied on foreign licenses for new products and on their own research for incremental process improvements. Important discoveries by local companies or research institutions, such as a drug used to treat Parkinson's disease, were sometimes licensed early in development to foreign companies, who reaped most of the returns in commercializing them.

India's pharmaceutical industry long focused on import substitution in a protected market. The industry is segmented, with a top tier of large local, foreign, and joint-venture firms, a few hundred medium-scale units, and several thousand small-scale producers. Public firms historically have been important. Though they now account for only 10 percent of output, they have been a training ground for technical staff and entrepreneurs who later entered the private sector. Drug formulas were acquired from Western and Soviet firms both informally and through licensing. India's patent laws long recognized only process innovations, which were protected for seven years. Multinationals nonetheless were players through local subsidiaries, particularly for formulations. As in Hungary, indigenous firms acquired process capabilities and exported active substances and generics. Larger firms had in-house research units that developed processes for manufacturing sophisticated products, including antibiotics and analgesics such as ibuprofen. Government price regulation reinforced the patent system, encouraging process innovations over the high costs and slim rewards of original-drug development. Research in public technology institutes also emphasized process technologies and adaptation of Western drugs, and several technology support institutions were oriented toward applied problem-solving. Formal links between industry and TSIs were strongest in education and training as well as standards and testing. Firms have used vocational institutions and industry associations for training workers.

Strong research in both countries contributed to development primarily through training and process technologies, rather than product innovation. Firms in both countries relied most often on links to suppliers, licensers, and customers for technology acquisition and on their own capabilities for process improvements.

Policy changes in the 1990s have altered the market for pharmaceuticals. Intellectual property reform and market liberalization will limit imitation-drug sales, presenting a strategic challenge for technology development. Although the boom in older drugs and generics as well as the transition period permitted under the TRIPS Agreement may provide breathing space to some companies certain countries, like India, and firms in both countries must decide to what extent they should pursue product innovation or the development and marketing of original drugs. The latter option is feasible because of the production and research capabilities in both countries. But translating underlying technological strengths into

competitive advantage entails major challenges. One obstacle is the financial resources required to assume the risks of research, which include vast long-term investments in a portfolio of R&D projects. Even the most successful companies in Hungary and India are much smaller than the Western multinationals that finance broad-based new-drug R&D. The expenditures and administrative burden of clinical testing and government certification in various countries take place between innovation and commercialization. Finally, selling brand-name drugs requires distribution and marketing.

In approaching long-term technology investments, Hungarian firms are constrained by inadequate access to capital and the uncertain progress of privatization. Most large drug companies have instead focused on expanding relations with foreign companies, acquiring licenses and serving as contract producers of intermediates. Firms and TSIs have also begun to profit from research agreements with multinationals, arrangements that bring short-term financial benefits but often surrender potential profits from long-term development of promising research.

The industry's structure has changed with economic reform. Established firms have contracted in the face of the loss of traditional export markets and intense competition from imports. New producers have grown by serving niche markets in specialized intermediates and formulations including traditional remedies. New firms frequently subcontract production to larger companies and often take advantage of weak intellectual property laws by hiring away key staff or commercializing their promising research. Small private firms have thus created means of exploiting the commercial potential of the capabilities built up in established companies. Though their flexibility enables more rapid commercialization, small firms still lack the capabilities to develop new drugs. And the new firms have not established formal service or research links with TSIs.

In India, reform has proceeded more gradually in both market liberalization and patent reform. Indigenous firms have continued to pursue exports of bulk drugs and active substances, but their investments in new-drug R&D remain low. With well-developed research capabilities and a large domestic market, some firms might produce modified imitation drugs that avoid patent infringement under the stricter standards of new rules. But as regulations tighten, the question of research for original drug development will become more pressing. India's public-sector TSIs, including universities, have developed strong capabilities in process-technology research, but have had limited success in commercializing new product innovations. Firms have relied on internal research for technology development, and external technology support has come primarily from long-term suppliers and customers. Links to TSIs remain largely limited to standards, testing, and information services. Firms have limited confidence in TSIs' ability to protect their intellectual property, a major inhibition to contract research. Achieving confidentiality will be critical if TSIs are to help firms compete on the basis of proprietary drugs.

As in Hungary, start-ups have grown through their ability to commercialize product technology rapidly, often drawing on the skills of the public sector and established firms. Many firms entered the market in the 1980s, when price-controls and licensing regimes were liberalized, and some have grown into large establishments with considerable technological capabilities. Some of them were built by entrepreneurs and technocrats trained by public-sector TSIs and enterprises.

These countries illustrate the potential and pitfalls involved in catching up to the technological frontier in science-based sectors. In such sectors, product and process capabilities often draw on the well-endowed research bases of some ex-socialist and developing countries. Protection of the local drug industry for social policy reasons created opportunities for learning-by-doing. The permissive patent regimes that accompanied pharmaceuticals promotion also enabled imitative learning. Despite the research infrastructure, however, drug companies in India and Hungary advanced far more in production capabilities than in original drug development. As economic reforms have altered market and intellectual property conditions, both industries are negotiating difficult transitions.

Chapter 2: The Evolution of the Indian Pharmaceutical Industry

Shekhar Chaudhuri

Introduction

Pharmaceuticals is one of India's most successful industries. State-owned enterprises, locally owned private firms, and affiliates of major multinational drug companies have enjoyed strong growth since the country's independence. The industry has achieved sufficient mastery over process and product technology to produce sophisticated antibiotics and synthetic drugs. India has also become a significant exporter of bulk drugs, or active substances. Success has come despite strict price controls and regulations and an intellectual property system that until recently recognized only process patents.

India created institutions to train researchers and technicians for the industry, enabling it to master pharmaceutical process technologies for high-quality production and to replicate foreign drugs efficiently. The government's early investments in state-owned enterprises further developed local capabilities and experience. Though industrial policies blunted competitive incentives for innovation, the development of state-owned firms resembled what Ergas (1986) calls a "mission-oriented" technology policy, and many of today's private sector managers and entrepeneurs gained earlier valuable experience in the state firms.

Local affiliates of multinationals have contributed to the industry's development. India's foreign investment regulations and permissive patent laws allowed the diffusion of technological knowledge and expertise from foreign firms. These factors might have led the multinationals to withdraw but for the lure of India's giant market and the availability of low-cost, quality labor, which enabled their affiliates to thrive. Loss of proprietary knowledge to Indian imitators incurred some costs, but the multinationals benefited from sales of brand-name products, and they retained control of export marketing.

The industry's development is based on scientific knowledge. That knowledge is embodied and can be transmitted in books or through the experience of technical personnel, even if government policies are heavy-handed and public institutions are bureaucratic.

This paper discusses the industry's growth and the institutions and policies that supported its technology development. Section 1 outlines the sector's origins and expansion. Section 2 describes the industry's structural characteristics. Section 3 examines patterns of growth and export competitiveness. Section 4 concerns government policy. Brief case studies in section 5 highlight the variety and roles of technology support institutions (TSIs) in the industry's success. Section 6 details the results of an industry survey. Conclusions are drawn in section 6.

The Indian pharmaceutical industry began in 1901 when the Bengal Chemical and Pharmaceutical Works was established in Calcutta by Professor P.C. Roy. Also at the turn of the century, the British set up several pharmaceutical research institutes for tropical diseases: the King Institute of Preventive Medicine, Madras, in 1904; the Central Drug Research Institute, Kasauli, in 1905; and the Pasteur Institute, Conoor, in 1907. During the First World War the

industry grew as local demand increased but imports were cut off (Singh pp. 97-98). Still the country depended largely on the United Kingdom, France and Germany for medicines until independence.

During the Second World War India began to produce conventional medicines, serums and vaccines. Manufacture of synthetic drugs for dysentery and leprosy also began. Since independence in 1947, with the government's emphasis on industrialization to achieve self-reliance, India has invested massively the public and private sectors and restricted imports (Singh p. 99). Pharmaceutical sales were Rs. 100 million in 1947, Rs. 540 million in 1954, Rs. 700 million in 1960, and Rs. 3.7 billion in 1973. Sales reached Rs. 12 billion in 1981 and Rs. 40 billion ($2.5 billion) in 1990, and growth has continued (Nayar, page 51; Exim Bank; Indian Pharmaceutical Guide [IPG]). Capital investment rose from Rs. 240 million (approximately US $30 million) in 1952 to Rs. 9.5 billion (US $400 million equivalent) in 1991 (IPG).

In the period soon after independence, India made little progress in the production of basic chemicals required for synthetic drugs, and it remained dependent on imports. To reduce imports of antibiotics, Hindustan Antibiotics Ltd., a public-sector firm, was set up in 1954. Indian firms started manufacturing sulpha drugs from indigenous raw materials. In the Second Plan (1955-60), the pharmaceutical industry was placed under the government's Directorate General of Technical Development to integrate development of allied chemicals-based industries. During the Third Plan (1960-65), the government invested heavily in the public sector (IPG).

Foreign multinationals entered the market as trading companies with small investments. They imported drug formulations in finished form and marketed them locally. At independence twenty-eight multinationals comprised a quarter of total investment and 38 percent of sales (Ahmad, p. 6). As there was no local substitute for the multinationals' technology, the government invited foreign investment and assured it of fair treatment. Foreign investment in chemical and allied industries grew from Rs. 123 million to Rs. 2 billion over the three decades ending in 1980. In the 1950s alone fifteen major foreign subsidiaries were established in India.

Because of government pressure the multinationals progressed to importing bulk drugs (active substances), which they processed into formulations (final products) in country. They did not have to invest in manufacturing plants, though they made good profits in the protected market. Within twenty years the multinationals achieved a strong foothold in India, thanks to several factors: patent law protection, their control of technology to develop antibiotics and synthetic drugs, their financial resources and management, and consumer preference for foreign brand names (Nayar, pp. 48-61). The multinationals, through high-pressure sales and massive advertising of world-wide brand names, created a market for simple medicines like cough syrups, tonics, and vitamins. They were often accused of price-gouging. Prices for broad-spectrum antibiotics, anveomycin, and achromycin, were among the highest in the world (Nayar). This situation has changed, as is explored below.

Industry Structure

The industry produces two kinds of products - bulk drugs and formulations. Bulk drugs are active chemical substances in powder form, the main ingredient in pharmaceuticals. Formulations are the final preparation, such as tablets, capsules, injectables, and syrups, sold as a brand or generic product. Eighty percent of industry sales are formulations. Major bulk drugs produced in India are antibiotics, sulpha drugs, vitamins, cortico steroids, analgesics, and those that address diseases like tuberculosis, dysentery, asthma, cardio-vascular ailments, diabetes, and malaria.

The industry includes large-firm, small-firm and informal (unorganized) sectors. Forms of ownership include public, private, and foreign firms. Production remains small compared to the industries in developed countries. The industry's total capital stock is about Rs. 9.5 billion (US $275 million equivalent at today's exchange rate), one-third of which is in the public sector (though it accounts for only 10 percent of the industry's production). Of 16,000 manufacturing units (IPG), 250 are large-scale and are monitored by the Directorate General of Technical Development. This group, also known as the organized sector, includes five public-sector firms and six companies with significant foreign shareholdings. The 250 large-scale firms account for more than 40 percent of total production and export. Of these, 155 produce basic bulk drugs. Industry production has had a compounded annual growth rate of 14.9 percent, according to the Export-Import Bank of India (Table 2.1)

Table 2.1 Production of Pharmaceuticals (Rs. Millions)

Year	Bulk Drugs	% Change Per Annum	Ofrmu-lations	% Change Per Annum	Total	% Change Per Annum
1950-51	-	-	210	-	210	-
1965-66	180		1,500	40.9	1,680	46.7
1975-76	1,130	52.7	5,440	26.0	6,570	29.1
1985-86	4,160	26.8	19,450	25.8	23,610	25.9
1986-87	4,580	10.1	21,400	10.0	25,980	10.0
1987-88	4,800	4.8	23,500	9.8	28,300	8.9
1988-89	5,500	14.6	31,500	34.0	37,000	30.7
1989-90	6,100	10.9	33,600	6.7	39,700	7.3
1990-91	6,750	10.7	35,600	6.7	42,350	6.7
1991-92	NA	-	NA	-	57,000	34.6
1992-93	NA	-	NA	-	71,500	25.4

Source: Adapted from EXIM Bank Paper, Pharmaceuticals: A Sector Study, 1991, and "India's Pharmaceutical Industry: A Presentation of Drug Manufacturers" in Monthly Commentary, May 1993, VI.

A leading public-sector enterprise, Indian Drugs and Pharmaceutical Limited (IDPL), was incorporated in 1961 and became an industry leader. Technology from the Soviet Union was used to establish plants making antibiotics, synthetic drugs and surgical instruments. The firm built five plants and established three subsidiaries in collaboration with state governments. IDPL's operations contributed to a geographic concentration of pharmaceutical companies in and around Hyderabad. Discussions with officials of medium-sized pharmaceutical firms there suggest that founders of perhaps a third of the two hundred-odd firms had at one time worked for IDPL's production or R&D departments. The owner of one of India's largest and most dynamic firms, Dr. Reddy's Lab, also worked for the company.

As a science-based industry, pharmaceuticals depends on research institutions for knowledge and human resources. Hyderabad has around forty institutions of higher learning, and is the home of one of the industry's most important TSIs, the Indian Institute of Chemical Technology. A second major institute, the Centre for Cellular and Molecular Biology, is also located in the city. Finally, Hyderabad has a number of pharmacy colleges with university (including advanced degree) programs.

The indigenous sector, including small firms, accounts for 90 percent of production. The remaining 10 percent is produced by the six companies covered by the Foreign Exchange Regulation Act. Their foreign-company equity ranges from 51 percent to 75 percent.

Locally owned firms have been greater producers of bulk drugs than formulations. In 1973, of total bulk production of 5,300 tons in the organized sector, Indian firms accounted for 4,700 tons (public-sector firms accounted for 1,500 tons). Still, the foreign firms' 11 percent of bulk-drug supply was 27 percent of sales. Local firms produced only 30 percent of sales in the market for formulations.

In 1992 most of the top twenty firms had foreign company equity (Table 2). The foreign exchange act required foreign companies to dilute their equity to no more than 40 percent in two years. Exemption was granted to companies employing high technology and those that were predominantly export-oriented. Such companies could retain foreign equity up to 74 percent. Firms with foreign equity holding of less than half were treated as Indian firms

Table 2.2 Top Twenty Pharmaceutical Companies (1992)

Rank	Company	No. of Product	Value (Rs. Millions)	Market Share
1.	Glaxo Pharma	116	187	5.5
2	Ranbaxy	42	129	3.8
3	Cadila Labs	135	129	3.8
4	CIPLA	79	98	2.9
5	Alembic	68	97	2.8
6	Ambalal Sarabhai	138	91	2.6
7	Pfizer	35	90	2.6
8	Hoechst	44	89	2.6
9	Lupin Labs	63	88	2.6
10	Boots	38	79	2.3
11	Burroughs Wellcome	54	75	2.2
12	Parke Davis	88	68	2.0
13	Torrent Pharma	98	67	2.0
14	Eskayef	63	50	1.5
15	Rhone-Poulenc	50	50	1.4
16	Hindustan Ciba Geigy	43	49	1.4
17	E. Merck	27	48	1.4
18	German Remedies	71	47	1.4
19	Wockhardt	68	46	1.3
20	Fulford India	29	46	1.3
	Total Market	5,748	3,424	100.00

Source: Jay Narayan Vyas, et al. (ed.), Pharmaceutical Data Book, 1993, p. 4

Multinationals have always been a significant part of the industry. They found India attractive because of its large market, rapidly increasing demand, mild drug control measures, lack of competition, and protection behind tariff walls and import restrictions. Because of the heterogeneity of the industry, multinationals can dominate specific market niches through extensive promotion and established brand names. The Indian market is a significant share of several companies' global sales. One study showed that for companies like Glaxo and Cyanamid, more than 10 percent of their foreign sales were generated in India (Singh, p. 128).

Until the early 1980s the industry was very profitable. It has been reported that the multinationals' returns may have been much higher because of transfer pricing and technology transfer payments (Lall, pp. 181-182). Despite foreign exchange mandates on the dilution of equity in subsidiaries, foreign parent companies have exercised control through restrictive clauses in technology and management contracts. In response to declining profitability in the 1980s, however, many subsidiaries diversified into

areas related and unrelated to their parent companies' main business lines. Some subsidiaries also severely curtailed their R&D in India because of poor returns.

India's New Economic Policy, adopted in 1991, relaxed controls on foreign ownership. It has attracted new multinationals and triggered others to increase their equity in their subsidiaries to more than 50 percent. With less protection and control and increased competition, a few multinationals have exited the country.

Growth, Competitiveness, and Technology Development

Sales have grown enormously in the last forty years. Imports too have steadily increased as the government has liberalized trade - an indication of latent demand for Exports include basic drugs, intermediates and fine chemicals, and finished formulations. Export sales have skyrocketed since 1980, increasing in some years 60 percent or more. India's costs are a major advantage. Manufacturing costs for bulk drugs are one-third of those in developed countries, and establishing a sophisticated drugs not produced domestically. Despite its growth, India's pharmaceutical industry holds only 1.6 percent of the world market (Ex-im Bank). Per capita consumption is about $2, compared to $40 in the developed countries Table 3, give some earlier comparisons with other developing and newly industrialized economies.

Direct employment in the industry is about 250,000, and employment in distribution and ancillary industries is about 750,000 (Ex-im Bank). Drug prices were among the highest in the world in the initial years of development, but today they are among the lowest. Prices increased 122 percent from 1971 to 1988, compared to inflation for all commodities of 300 percent (Ex-im Bank) comparable plant in the United States or Europe may cost five times more than it does in India. Operating costs are half, labor is one-tenth, and some important equipment is one-fifth the level of the developed world (Aggarwal).

Table 2.3 Annual Per Capita Drug Consumption (1988 - 89)

Country	Rupees
India	34 (Rural Rs. 8)
Pakistan	43
Indonesia	42
Nigeria	70
Philippines	95
Taiwan (China)	159
Turkey	165
Egypt	190
South Korea	346

Source: Ex-im Bank, Pharmaceutical: A Sector Study, p. 8.

Other factors that have contributed to exports are the greater marginal profits compared to domestic sales. Although profit margins have fallen in domestic sales because of increased competitiveness and price control, price controls do not apply to exports, nor do income taxes. Though the industry has made major strides in international markets, it has a long way to go. Exports remain less than a third of production, and India's share of the world market, whose total size is estimated at perhaps $125 billion, is around 0.3 percent. Analysts estimate that the industry has the potential to reap annual foreign exchange earnings of $1 billion to $1.5 billion by the year 2000.

Herbal drugs have tremendous potential. Exports of Ayurvedic and Unani medicines have been increasing, as major producers have built brand awareness.

Bulk drugs can be derived from plants or animals, minerals, and synthetic processes. Manufacture encompasses extraction, concentration, fractionation and crystallization, and complex, high-technology processes involving multi-stage reactions of organic synthesis and sophisticated formulation processes (Narayana, p. 87).

Formulations are diverse, ranging from pills and syrups to ointments, inhalants and injections and infusions. Though manufacture of bulk drugs is more complex than that of formulations, the latter pose technical problems that need careful investigation. Manufacture of enteric coated, sustained or delayed-action tablets requires sophisticated techniques, and parenteral and ophthalmic products require aseptic conditions and foolproof methods to avoid accidental contamination. Even packaging is challenging, as product stability must be assured during storage (Narayana).

The pharmaceutical industry world-wide is characterized by intense R&D. In 1989 sixty multinationals accounted for $89 billion in sales, 70 percent of the market. These companies spent $13.5 billion on R&D (Walker). Research is pursued in synthetic chemistry, chemical technology, bio-physics, medicinal chemistry, clinical pharmacology, bio-technology, and molecular biology.

In India there is a heavy reliance on foreign technology. While the turnover of the industry has increased considerably over the years, imports for the domestic market increased from 5 percent in 1965-66 to 23 percent in 1991-92. The importance of foreign know-how may be gauged from that fact that, of the top twenty firms, thirteen had foreign origins.

Table 2.4 R&D Expenditures, Selected Years (Rs. Million)

Year	R&D Expenditure
1965-66	30.0
1976-77	105.0
1978-79	120.0
1979-80	147.5
1981-82	293.0
1983-84	400.0
1985-86	480.0
1986-87	500.0
1991-92	700.0

Source: Monthly Commentary, p. xiii

R&D expenditures in India are quite low - 1.22 percent of sales - compared to 10 percent world-wide. R&D has grown at a compounded annual rate of over 12.8 percent (see Table 4), but production has grown much faster. Seventy-seven firms have in-house R&D departments approved by the Department of Scientific and Industrial Research. Much of the industry's R&D is done by the larger firms. Only a few pursue basic R&D to develop drugs.

Narayana (pp. 97-99) found that private-sector firms with foreign affiliations received up-to-date technology and technical assistance as required. Still, these companies made drugs by simple one-step or two-step processes from penultimates or late intermediates that were imported at prices much higher than those in the open market. On the other hand, public-sector firms' choice of technology was governed by ideological considerations, and they acquired obsolete technologies. Though they often made improvements through in-house R&D, these were not comparable to the improvements in developed countries.

The organized Indian sector (firms without any foreign collaboration) took up the manufacture of basic drugs slowly. They have acquired technological capability through a variety of methods, including in-house R&D, the national research laboratories and unreported and informal purchase of technology from abroad. Process research seems to be the forte of many large and medium sized manufacturers. Narayana found fifteen firms that had developed processes to manufacture bulk drugs.

The Government's Role

India's post-independence emphasis on industrial self-reliance and social welfare made the production of low-cost pharmaceuticals by domestically owned companies a primary policy goal. The government also has sought through regulation to prevent the marketing of poor quality products. The first drug safety law was enacted in 1919, and the Drugs Enquiry Committee was established in 1931 to recommend controls in the interest of public

health. The committee recommended a drug control bureau with branches in all provinces, a laboratory system, and the licensing of pharmacists. A 1940 law partly implemented the recommendations.

By independence India had a rudimentary industry, but newer drugs - including sulphas, antibiotics, vitamins, hormones, anti-histamines, tranquilizers, and psychopharmacological agents - were being imported in increasing quantities, straining the country's foreign exchange. The government responded by encouraging a comprehensive manufacturing base. It envisaged plants to produce basic organic chemicals and inorganic chemicals, manufacturing in the public and private sectors, technical and financial support for research in industry and in national laboratories, and training. India's rich plant life would provide some of the raw material to develop compounds.

During the second and third five-year plans, from 1955 to 1965, manufacturers began producing penicillin, streptomycin, chloramphenicol, and broad-spectrum antibiotics of the tetracycline group. Firms entered foreign collaborations to acquire technical knowledge. Firms in the United States, Switzerland, West Germany, Italy and the United Kingdom collaborated, and the Soviet Union supported the production of synthetic drugs and alkaloids. India also received funds and technical assistance from UNICEF and WHO to set up plants in the public sector. By 1993 Indians were consuming about 500 bulk drugs, of which about 350 were produced locally (IPG, 1993).

One government policy, the loan licensing system, permitted drug companies to meet emergency needs during war or natural calamities. It helped promote entrepreneurship and led to the development of the small-scale sector. About 8,000 loan licensees produce pharmaceuticals worth Rs. 9 billion. Some products, however, were spurious.

The government controls prices under the rationale that drugs are a basic social need that should be available to all at reasonable cost. Price controls began during the war between India and China in 1962. Beginning in 1966 manufacturers were required to obtain government approval to increase prices. Later orders fixed prices and markups, allowing greater profit for formulations involving R&D. In a 1987 price order, the R&D incentive was withdrawn, the span of price controls was reduced from 347 to 161 drugs, and the price mechanism for bulk drugs and formulations was adjusted to encourage greater production and better quality of essential drugs. Manufacturers responded to these governmental measures (Mittal, p. 130). A 1993 measure further reduced price controls to 143 drugs. Price revisions are based on government cost-cum-technical studies.

To encourage R&D, the government exempts from price controls for five years manufacturers that have developed production processes to produce drugs from the basic stage. Other reforms have been aimed at spurring formulation research. Until recently price orders did not provide for automatic increases for higher material costs. Firms had to prove that cost increases affected profits.

Table 2.5 Pharmaceutical Industry Profits

Year	Profit Before Tax (% of Sales)
1969-70	15.5
1974-75	10.7
1977-78	11.7
1980-81	8.8
1982-83	7.5
1983-84	6.7
1984-85	5.8
1985-86	4.5
1986-87	3.4
1987-88	3.5
1988-89	2.8
1989-90	3.5

Source: Chemical Weekly Annual, 1992 as quoted in Pharmaceutical Data Book, 1993.

Table 5 shows the erosion of profits. Successive price orders in 1970, 1979 and 1986 corresponded to decreasing profitability. The decline is considered a major factor preventing investment in manufacturing and R&D. A 1994 drug policy freed from price controls all but the most popular drugs. It allowed greater profit and encouraged R&D and the development of Ayurveda and Unani. Controls on foreign investment were loosened. The policy also created an independent body to consider prices and a National Drug Authority to monitor practices in drug promotion and use.

The Indian Patents and Design Act of 1970 reflected greater concern for firms that adapted products than for inventors. The law recognized only process patents, and patent lives of five to seven years; placed the onus of proof of infringement on the patentee, and set a ceiling on license fees. This encouraged innovation of drugs at costs much lower than those of inventors. With GATT, however, India recognized product patents, extended patent life to twenty years, shifted the onus to the alleged patent infringer to prove innocence, and abolished the ceiling on license fees.

R&D and Technology Institutions: An Overview

Drug research is carried out in firms, six labs of the Council for Scientific and Industrial Research (CSIR), several units of the Indian Council of Medical Research (ICMR), and nearly fifty universities.

Firm R&D Department

The R&D departments of medium and larger pharmaceuticals firms undertake to master, improve and innovate product and process technologies, as well as to reduce costs and improve product quality.

Although R&D investments have been traditionally low in the private sector, they have risen in the 1990s.

Table 2.6 Private Sector R&D Expenditures

Year	Expenditures (Rs. million)
1991-92	800
1992-93	950
1993-94	1,250

One of the industry's fastest growing companies is Dr. Reddy's Lab (DRL), headed by Dr. Anji Reddy, a chemical engineer. The company was founded in 1984, when the drug alphamethyldopa was in short supply (Shenoy). Today DRL is the largest producer of several drugs in India and the second largest manufacturer of norfloxacin and ibuprofen in the world. Ninety percent of its sales comes from bulk drugs.

The key to Dr. Reddy's success is its operation outside international patent law, a consequence of the shelter provided by India's patent act of 1970. The company's strategy has been to develop and patent indigenous processes to make drugs to capture the market. It also exports formulations to countries that do not honor international patent laws. Its senior chemists scan the international market for best-selling drugs whose patents are soon to expire. The company's focus is expected to change, with India joining the Dunkel Agreement, which is to be implemented by 2005. The company plans to concentrate on basic research rather than process research.

Central Drug Research Institute

CDRI is a laboratory under CSIR that develops drugs and drug technology, investigates disease processes, evaluates natural resources for potential development, disseminates research, and provides technical training. CDRI offers consultancy in technological development of drugs and animal laboratories to industry, R&D institutions, and others, and it undertakes contract research and grant-in-aid projects. Its clients include firms in India and elsewhere.

The institute provides analytical and testing services to academia and industry, and supplies laboratory animals, including pathogen-free animals, cell lines, and parasites and parasite products. The National Information Centre for Drugs and Pharmaceuticals, located at CDRI, provides access to international databases. It also offers short-term ad hoc training in research techniques to academic organizations and industry. It conducts training in laboratory animal science.

Indian Institute of Chemical Technology

IICT, another laboratory under CSIR, undertakes R&D in chemical technology and develops process/products/design and engineering know-how based on the use of indigenous raw materials. It carries out applied research in chemistry and chemical technology. IICT helps industry improve efficiency through technical consultancy and testing services. Its specialties are pesticides, drugs, organic intermediates and fine chemicals, catalysts, polymers, organic coating, low-grade coals, and value-added products from vegetable oils. Process design and mechanical engineering design form an integral part of technology development and transfer.

IICT has transferred more than seventy technologies in various chemical areas (including pharmaceuticals) to industry, of which fifty are being used in commercial production. It offers technologies, particularly for bulk products, and basic and detailed design for

commercial plants with guarantees on raw material consumption, product quality and plant capacity. A significant share of its work is sponsored by industry.

Services include development of technologies on contract; basic and detailed design of commercial plants along with assistance for commissioning; analysis and testing facilities; simulation, optimization and control of process plants; hazard and risk analysis of chemical and petrochemical plants; and toxicity evaluation of pesticides. Pharmaceuticals is one of its most important areas of work.

National Chemical Laboratory

Established immediately after independence, NCL also is under CSIR. Its mandate is to conduct research in chemistry, develop technologies to use natural resources, help expand import substitution and exports, and assist industry's technological development. Its research involves catalysis, biotechnology, organic chemical technology, polymers and other high performance materials, and basic research in chemistry and biochemistry.

Important drugs independently developed by NCL are ibuprofen and an intermediate for ranitidine. NCL has developed a method for producing Vitamin B6. Technologies for drugs and pharmaceutical products have been transferred to industry. NCL has developed a water-absorbing polymer of importance for wasteland development, forestry, and edible oil programs. It has developed a fibre-reinforced thermoplastic material to produce critical components of vehicle engines.

NCL has developed instruments to study chemicals, a catalyst testing unit, and facilities for fabricating engineering polymer components. The laboratory offers consultancy to industry, R&D units, and project engineering organizations in India and abroad. The laboratory's international clients include Du Pont, Eastman Kodak, Rohm and Haas, and Toray. Pharmaceutical work is less important in NCL.

Formal TSIs focusing on drug development are very few - perhaps CDRI is the only one. TSIs like the Indian Institute of Chemical Technology and the National Chemical Laboratory have worked on pharmaceuticals as part of their portfolio. Other publicly funded TSIs related to the industry focus on areas like vaccine development and biological and toxicological studies. As there are so few TSIs, they cannot serve all the firms in the industry. Only a few firms in the survey had worked with them, though the TSIs had served a number of firms that were not covered in the sample.

The India Institutes of Technology have not trained graduates and post-graduates in pharmacy, though some of them do have programs in pharmaceutical engineering. Universities have traditionally performed the educational role for the industry but have not generally provided other services.

Survey Results

Mail surveys and interviews were conducted to evaluate firms' sources and development of technology and use of technology institutions. Thirty-eight firms responded to the surveys. Large firms - those with at least 500 employees - comprised nearly all of the respondents to the mail survey.

Of the fourteen firms that had achieved "significant" product changes, four had used TSIs and one had collaborated with a foreign partner. The others relied on in-house development. Of ten firms that reported "incremental" product changes, two had used TSIs and eight had no outside support. Concerning "significant" process changes, eleven of fourteen firms had used no outside support; none of the eleven reporting "incremental" process changes had outside support.

TSIs were not involved in organizing links among companies to pursue innovation. Three firms said they had established their own links that had strongly contributed to improvements. It may be supposed that the intense competition discouraged firms from working together for fear of loss of trade secrets.

Firms used vocational institutions and, less often, industry associations to provide outside training to workers, but the associations were found to be more helpful. Several firms relied on universities, but they were not fully satisfied. A few firms used suppliers; only one sought out buyers for training.

Mail survey respondents drew on outside support most often for standards/testing (because of the exacting standards required of products), trouble shooting, formation of technical networks, and information services. They also took advantage of their commercial advice and training courses. TSIs were used least often, for contract and collaborative R&D among surveyed services, perhaps because of the firms' fear of leakage of technical know-how and their lack of confidence in the former's capabilities. Long-term customers were used for information services and technical networks. Consultants were used for one-time jobs like trouble shooting, commercial advice, and training.

The preferred methods of acquiring technological services were in-house laboratories and long-term suppliers, which constantly communicate with firm decision makers. Long-term contacts - suppliers, customers, foreign investors - were rated more important for technological development; short-term contractors like consultants and private laboratories were less so. Universities and academic and research associations were least regarded, perhaps because they were thought to lack practical perspective. It also may indicate firms' lack of regard for basic research.

The most important benefits of TSIs were their ability to solve problems, provide quick access to information and technology, provide product development, and enhance technical and business contacts. On the other hand, their defects included slow response, inadequate confidentiality, and expensive fees.

On the importance of government policies, firms rated export incentives useful, particularly with the surge in exports since 1987. Fiscal incentives were popular, though they tended to be concentrated in better off firms. Other government supports have included grants, technology loans, standards/testing, government procurement, and training.

Firm's technology management

A few examples illustrate how firms acquire and use technology.

Company A, established in 1907, is a reputable manufacturer of antibiotics. It is credited with having been India's first

private-sector producer of penicillin and the second company in the world to produce roxithromicin, a semi-synthetic macrolide antibiotic. Recent innovations include a state-of-the-art fermentation technology. It exports to Germany, the Netherlands and Switzerland. The company has a modern laboratory and a comprehensive library. Some of its scientists have done research in national laboratories; they now work in applied research, focusing on industrial needs.

The company runs a technical school in its factory for workers and students, including a foreign candidate under WHO's sponsorship. A six-month course for recruits from universities involves lectures and practical work, and it is followed by on-the-job training for another six months. The company is a member of thirty-three scientific/technical, commercial and professional associations, with which it mainly exchanges knowledge. Consulting firms have been used for energy and environmental audits and in engineering, laboratory services, and R&D. Government policies of which it has taken advantage include technological loans, apprentice schemes, market protection policies, and export incentives.

Company B was founded in 1982 by an organic chemist with research and teaching experience in India and the United States. It makes bulk drugs and drug intermediates. Its growing export markets include the Commonwealth of Independent States, Western Europe, and Southeast Asia.

The company has continuously expanded its R&D and has developed processes for the manufacture of several drugs, including pyrazinamide, which fights tuberculosis. In 1987 it started manufacturing ampicillin from a process developed in-house, enabling it to reduce costs. It developed a process for the manufacture of zinc picolinate and picolinic acid, and it is the only exporter of this product from India.

Of thirty-three employees in R&D, six hold doctorates and twelve are post-graduates. The company uses the Indian Institute of Chemical Technology to train its employees. It also conducts in-house classroom and on-the-job training. The company says it has benefited enormously from its memberships in industry organizations, particularly by obtaining information on industry developments, exports, and standards and testing.

It uses private consulting firms and individuals for process design and engineering, product development, plant layout, and Good Management Practices (GMP) audits. It has, however, expressed dissatisfaction with consultants for slow work, inadequate testing facilities, and poor equipment. The company believes R&D and product development services can be provided by national laboratories and its own facilities

Company C was established in 1924. In 1950 the company, originally incorporated in India, became a wholly owned subsidiary of the parent multinational. To comply with Indian law, the parent diluted its holdings to 40 percent.

The company was the first in India to manufacture drugs, including steroids and vitamin A, from basic stages. It is a leading manufacturer of advanced steroids, anti-ulcerants, broad spectrum antibiotics, infant foods, and diabetic foods. Export markets include Germany, France and Bangladesh.

Innovations have included an indigenous process for bethamethasone disodium phosphate. Product changes include development of suspension coating for tablets and elimination of chloroform from expectorants and larger batches of ointments.

The company trained 600 management staff in 1992-93 through in-house programs. About 1,000 workers received on-the-job training in GMP, safety, and productivity.

The company has not approached any TSI for services, but it employs private consultants for effluent treatment and process technology. It expects to obtain services and technology from the parent company's research group.

Company D, part of a multinational, was established in India in 1958. Until 1984 it was a closely held company, when like other multinationals it had to dilute its holdings to 40 percent. Its research laboratory works closely with other laboratories of the group abroad.

The company's Bombay research center, which employs 200 including fifty Ph.D.s, was set up in 1972. It is the only one of its kind in the pharmaceutical sector that is working at an international standard in basic research, modifications, product development, and process development. It is searching for biologically active substances from plants and microbial sources as leads for potential drugs. The Indian subsidiary is the multinational's leader in target-oriented natural product research. Its laboratory is one of the few in India pursuing basic research.

The company research director said GATT would push Indian companies to do research. Furthermore he asserted that with its strength in scientific manpower India could become a global player in pharmaceuticals.

Finally, Company E, established in 1987 by two brothers, is the largest producer of intravenous fluids in India, with thirty-five million bottles annually. One-third of its production is exported - 90 percent of Indian IV-fluid exports.

The company considers technology crucial to achieving quality and cost advantages. Its low prices depend on efficient operations. Its laboratory equipment is of a standard seen in few companies in the country, and its advanced manufacturing machinery was imported from one of the world's leading pharmaceutical machinery manufacturers.

It is certified to be following WHO's GMP norms. The company has taken measures to keep abreast of technological developments. It is a member of the U.K. Parenteral Society and the Parenteral Drug Association of the United States. It has deputed its senior personnel for training and participation in international conferences and invited internationally reputed scientists to talk to its technical staff.

Company E's in-house training offers capsule programs to employees, from top management to shop floor personnel. During 1991-92, about 1,000 persons attended fifty in-house training programs. Fifteen employees have gone to Switzerland for training in machinery operation and maintenance, and to be exposed to another culture.

The company has had no formal tie with any TSI, though it is exploring the kind of interaction it wants to have.

Conclusions

The pharmaceutical industry in India is considered a life-line industry, as its products help alleviate the suffering of diseased people. It was designated as part of the core sector by officials who launched economic growth plans in 1951, subjecting it to a host of government policies. The policies have been important in the phenomenal growth of the industry, though some of them have had an adverse effect on technological development.

The industry is characterized by a large number of firms - small and large, technologically dynamic and stagnant. Exports have become a salient feature of the industry, especially bulk drugs. India benefits from low production costs compared to developed countries. The industry's technological status is mixed. Each of its major sectors - public, multinationals and indigenous organized and small-scale - has its strengths and weaknesses.

R&D expenditures, though high for India, are very low compared to developed countries. Technological development has occurred mainly through in-house efforts. State laboratories have worked closely with some firms for product and process development. Most R&D, however, is concentrated on process development, and large companies perform the most significant in-house R&D.

Two major developments have affected the industry. First, cuts in government financial support to TSIs have forced them to become more industry-oriented, and they are seeking collaboration with firms and marketing their services. Second, the recent GATT agreement is expected to trigger stringent enforcement of product patents. In anticipation the industry is examining the technological innovation necessary for development. Many companies realize the importance of basic research and are creating in-house research facilities. An increasing number intend to take advantage of TSIs.

The analysis indicates the need for the industry, TIs and government to redefine their relationships. Suggestions for each follow.

Recommendations for industry

Most firms lack the resources to conduct product research. They should therefore concentrate on process research, which has become a strength. It would allow them to pursue innovation in drugs that are off patent, a market that could be worth $20 billion by 2000. Similarly firms can focus on "me-too" drugs - devise products by manipulating their molecular structure, as Japanese industry did two decades ago (Yamamoto). Firms that are relatively resource-rich may pursue both product and process research. Even so, the Japanese experience shows that product research requires many years to reap commercial benefits. Gradually, firms should move into product research once they accumulate resources and develop their technological competence.

To overcome the scarcity of resources, firms may consider a variety of options:

- mergers with other Indian firms;
- collaboration with foreign firms;
- joint ventures with foreign firms in third countries, leveraging thelow-cost home base;
- collaboration on R&D with TSIs;
- joining R&D consortia centered around TSIs like the Central Drug Research Institute, Lucknow or the Indian Institute of Chemical Technology; or
- joining industry-oriented research organizations sharing expensive facilities.

The strength of the industry - its ability to develop cost-effective processes for products patented abroad - cannot remain a competitive advantage in the post-GATT world. The industry must therefore create training facilities and an environment supporting basic research. Young, creative individuals have to be encouraged to pursue research to ensure the industry's long-term success.

Firms that pursue basic research may consider focusing on tropical diseases (not a strength of the multinationals) and herbal drugs, which would exploit India's variety of plants and its tradition of indigenous medicine. The failure to use publicly funded TSIs is a lost opportunity. TSIs should be involved in seminars and conferences, training programs, and joint research designed around mutual strengths.

Boosting expenditures on R&D and technical training is an imperative, though it will not ensure success. Managing these activities consistent with a firm's strategy also is important. For instance, the survey found that firms considered increasing product quality, reliability and development to be important means of competitiveness. R&D and training must be linked to firm strategies.

Recommendations for TSIs

Support institutions should set up extension centers where firms are clustered. There are too few TSIs to cater to the industry, but separate departments could address the needs of small-scale firms and firms in the unorganized sector, which need to improve their product quality. They lack expertise in designing, implementing and maintaining manufacturing systems according to GMP norms. The price of these services should be appropriate to the firms' limited resources.

The continuing high growth of the industry indicates its dynamism. The government's 1994 drug policy, the Dunkel Agreement, and changes in patent law indicate a growing need for technological services, management consultancy, technical training, and basic research capability. Some of these needs are short term, some are long term. Even TSIs that want to offer the sophisticated capabilities that can only be developed over time may benefit from serving some of the short-term needs that would help them build relationships with firms.

As noted in the survey results, firms turn to TSIs to solve specific problems, provide quick access to information, help develop products, and enhance their contacts. TSIs should be aware of the trade-offs in providing these services. Solving problems implies an organization that has close relationships with clients, is aware of

their needs and can respond quickly, and can work on problems that are likely to be of short duration. These problems are not likely to require basic or applied research, and customers are likely to be small firms. On the other hand, helping develop products requires a long-term focus, applied research, and perhaps basic research. Customers likely would be medium and large firms.

The skills required to pursue these two courses differ. TSIs should analyze their organizational imperatives to clarify the trade-offs. TSIs also need to be aware of their weaknesses as perceived by the firms: slow response, inadequate confidentiality, and high fees. Market-rate fees are a recent development, often triggered by the need to generate revenue that the government had previously provided.

Networking and collaboration among TSIs and between TSIs and engineering consultants may help meet industry's needs. It would enable basic-research-oriented TSIs to strengthen their core competence and respond to industry's need for practical technology, and it would save resources that otherwise would have to be devoted to acquiring facilities and capabilities.

Government policy

Few Indian TSIs have the capability to perform drug research. Given the growth of the industry, the government must support the expansion of services for diverse firms. It should urge industry to be a partner in institutions, which could be oriented toward applied research. At the same time, the government should maintain support for existing TSIs, and it should urge them to develop strategies to help the large number of technologically laggard firms to produce better quality drugs.

Until recently the government has behaved like a regulator. It must do more to promote and sustain the industry. Its 1994 drug policy is a beginning. Other measures that would help industry move into the world market include funding of R&D, concessional loans to build research facilities, export incentives, and progressive removal of price controls and restrictions on mergers where possible without harming the public interest.

The survey found that export incentives were considered important. Fiscal incentives were also important. Firms took little advantage of other government programs; they reported ignorance of them and bureaucratic problems in obtaining support.

Government should encourage cooperation among applied-technology institutions, universities, higher level scientific TIs, and industry. One avenue could be collaborative R&D, partly funded by the government, to develop drugs to treat tropical diseases. Other government-led mechanisms might be deputation of university professors to work in applied TSIs or pharmaceutical firms, founding of chairs in universities and TSIs to work on applied R&D, creation of advisory boards with industry representation to advise educational institutions regarding their research and curriculum, and deputation of scientists and executives from pharmaceutical firms to the policy making bodies of government. The government may also explore partially funding these endeavors.

The government should actively support alternative medicine - Ayurveda, Siddha, Unani, and homeopathy. These alternatives may be more cost-effective

given the country's huge natural resources, and they do not have many of the side effects of allopathic medicines. The alternatives have suffered because they do not have the same scientific rigor as the allopathic medicine. This lacuna can be reduced if scientific research in these fields is pursued.

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1 Indian Pharmaceutical Guide figures differ: production in 1989–91 was Rs. 6.4 billion, Rs. 7 billion, and Rs. 7.9 billion respectively for bulk drugs, and Rs. 3.4 billion, Rs. 3.8 billion, and Rs. 4.2 billion for formulations.

Chapter 3. Institutions and Technological Innovation in the Hungarian Pharmaceutical Industry

Katalin György

Introduction

Pharmaceuticals is one of Hungary's most successful and outward-oriented manufacturing industries. Some observers say it is the country's only technologically advanced industry with competitive potential in global markets. The country's transition from socialism to a market economy, including trade liberalization and privatization, has naturally affected the industry. Privatization has been largely accomplished. The industry has continued to perform reasonably well, maintaining exports though losing ground domestically to foreign competitors. It is unclear whether the industry will prosper in the long run, having adapted to the new environment, or whether its present relative success is only temporary.

Key to the industry's long-run competitiveness is innovation, capitalizing on the country's underlying capabilities in related technology and research. Hungary's leading role in the defunct East bloc's Cooperation for Mutual Economic Assistance (CMEA) system built upon the country's tradition of pharmaceuticals production and research in chemical and biological fields. Although technological innovation lagged behind major Western multinational drug companies during the socialist era, the industry developed substantial research capabilities within firms and in designated branch research institutes. The industry's ability to draw on its strengths is hampered, however, by certain institutional legacies of socialism. Even the larger established firms are small and insufficiently specialized by international standards, while the branch research institutes remain isolated from the needs of industry. Above all, economic restructuring has created acute financial difficulties for the industry and its support institutions, weakening their ability to invest in development and commercialization. Changes are required within the industry and in the relations between firms and research institutions. Resources must be invested in modernization and innovation.

This report is based on a 1992-93 survey conducted as part of a World Bank study on technology development institutions and policies. Since then important changes have occurred, particularly in the degree of industrial privatization, and these later developments are discussed.

With respect to the cooperation between technology support institutions (TSIs) and manufacturers, we cannot offer an update. Our impression is that the conclusions of the 1992-93 survey remain valid.

Section 1 provides an overview of the historical and technological development of the industry, emphasizing the changing relationship between the state and industry. Section 2 profiles the industry, its growth, market performance, finance, and structure. Section 3 describes innovation strategies of various types of firms. Section 4 analyzes tfhe effect of government policies on the industry's technological development. Section 5 examines TSIs and their relationships with industry. Three case studies of industrial innovation are presented in section 6. The final section draws

conclusions concerning the industry's technological development.

Industry History

Hungary's pharmaceutical industry began more than eighty years ago. Five of the seven largest firms were founded before the Second World War, the first and largest in 1908 and the second-largest in 1910. Its early development was supported by chemical and pharmaceutical research in Hungarian universities. Growth in the 1920s was spectacular, and the industry's volume ranked sixth in the world. By the 1930s these companies had built substantial international marketing networks and established several foreign subsidiaries. After the war, however, the socialist regime nationalized the industry. Lucrative export markets in the West were cut off, and new links to East bloc economies were formed.[1]

In the 1950s the industry was managed by a centralized control system, much like a single, M-form corporation. All strategic decisions regarding product selection, investment, and R&D were made by supervising ministries, and established firms were reduced to production units with only operational independence. Even marketing was separated from production, with one monopoly handling domestic sales and another carrying out foreign trade. Basic research was assigned to academic institutions, and applied R&D was carried out by the new industrial branch research institutes.

In the 1960s and 1970s, Hungary implemented modest though important decentralization of some decision-making authority to manufacturers. Pharmaceutical firms used their increased autonomy to rebuild in-house research capabilities, giving them greater control over product decisions. They also received additional central government financial support for research. Still the institutional system for technological innovation performed poorly. The branch institutes continued to expand but remained isolated from the needs of industrial firms, resulting in redundant manpower and R&D. The institutes concentrated on scientific research, but firms used them primarily for routine tasks like testing and laboratory services.

Socialism provided industry with guaranteed markets and limited autonomy in exchange for state control over prices, profits, and production. The government assured a profitable CMEA export market, a protected domestic market, subsidized loans, and relaxed patent laws under which firms imitated Western drugs. Firms paid a tax on CMEA exports, lived with low fixed domestic prices, and complied with requirements to supply certain specific drugs. All industrial enterprises paid a special tax to finance the Central Technological Development Fund (KMUFA).

In 1991 the industry-government relationship was shattered with the collapse of the Soviet bloc. With the dissolution of the CMEA, Hungarian firms lost trade with Eastern Europe, while import liberalization challenged their domestic markets. However, by 1993 pharmaceuticals was one of the few manufacturing industries to show an apparent recovery.

Profile of the Industry

Growth and exports

Throughout the socialist period, the pharmaceutical industry enjoyed strong growth, driven largely by exports to the East bloc. Because of its substantial pre-war research and development tradition, Hungary's pharmaceutical industry was chosen to supply CMEA countries under CMEA's international division of industry. By the 1960s, exports had recovered to pre-war levels, and by the 1980s

Hungary was the world's tenth largest drug exporter, with $330 million in exports between 1982-83. Exports represented 41 percent of pharmaceutical sales in 1991, well above average for all industries.

The drug sector's growth was higher than the industrial average in the 1980s, and its share of Hungary's GDP increased from 2.4 percent in 1980 to 3.5 percent in 1990. In 1992 the industry accounted for 3.1 percent of manufacturing employment, 5.5 percent of manufacturing sales, and 10 percent of manufacturing exports. These achievements were largely due to Hungary's role as drug supplier to the Soviet Union, which accounted for 80 percent of the industry's CMEA exports in the late 1980s. Exports to Western European and other hard-currency markets, which began in the 1970s, continued to grow through the 1980s. CMEA exports were primarily finished drugs, whereas the smaller volume of exports to the West, most importantly the United States, Japan and West Germany, were almost entirely active substances, the less lucrative intermediate products.

Table 3.1 Distribution of Industry Sales (percent)

Market	1980	1990	1991	1992
Domestic	41.5	40.0	49.7	43.3
Export	58.5	60.0	50.3	56.7
Eastern Europe	36.1	27.0	15.6	20.2
Other countries	22.4	33.0	34.7	36.5

Source: Pharmaceutical Manufacturers' and Wholesalers' Association

With the collapse of the CMEA, exports dropped after 1990 (Table 2), but they quickly stabilized, and exports to the post-Soviet Commonwealth of Independent States actually increased. CIS exports are dominated by the established firms who held positions in the former Soviet market, and they consist of a few top products. Still, retaining markets required adaptation and effort. The former export monopoly, which became a company owned jointly by four manufacturers, was able to exploit international aid programs in the CIS countries. The company used its relationships to gauge consumer needs, and through quick action it consolidated its marketing channels before Western competitors entered. It has remained competitive by virtue of its lower prices.

Table 3.2. Domestic, Export, and Total Sales, 1990-1994 (million $)

Sales	1990	1991	1992	1993	1994
Domestic	378	437	344	393	398
Export	522	394	385	390	375
Total	900	831	729	783	773

Note: Data for the seven largest companies. Converted at annual average HUF/$.
Source: Pharmaceutical Manufacturers' and Wholesalers' Association

Domestic sales and import liberalization

The Hungarian drug market is relatively attractive because the country spends about 7 percent of GDP for health care, a ratio somewhat below the world average of 8 percent but significantly higher than the 3.6 percent average of ex-socialist countries (Merrill Lynch). After 1990 import liberalization has caused a steady loss of domestic market share (see Table 3).[2] Apart from the quality gap between foreign and local drugs, other factors are significant in the industry's domestic failure despite long success abroad. One is marketing. Unlike ordinary goods, drugs are usually not chosen by customers but by the prescribing physicians, the primary targets of drug companies' marketing. Hungary's over-the-counter trade is only 12 percent to 13 percent of drug sales, low by international standards. Multinational firms typically spend almost as much on marketing, including lavish conferences for physicians, as on R&D. Superior marketing has enabled foreign companies to invade the Hungarian market by convincing physicians and even government

authorities that their products are better than similar locally produced drugs. Hungarian firms, by contrast, had little need for marketing under socialism, as sales were channeled through a government monopoly.

Table 3 - Production by market share (percent)

Sales	1990	1991	1992	1993	1994
Domestic production	74	71	62	53	47
Imports	26	29	38	47	53

Source: Pharmaceutical Manufacturers' and Wholesalers' Association

A second issue is the established firms' unfamiliarity with market competition, stemming from oligopolistic practices and government control. Before liberalization, the six leading companies divided the market through the Association of Hungarian Pharmaceutical Manufacturers so that each therapeutic and research field was occupied by a single company. Government regulations also placed local firms in a poor competitive position. Chief among these were statutory supply obligations. Once it had registered a drug with the Ministry of Health, a company needed permission to withdraw from distribution. In practice, that was impossible to obtain, and the company had to continue production even if demand was negligible. The policy resulted in firms having a wide range of products, up to 200 to 300 each, and the lack of specialization hurt efficiency.

In 1991 Hungarian firms welcomed the lifting of supply obligations, as well as price controls and import restrictions (Borszéki). Prices rose steadily and firms shed unprofitable product lines.[3] But industry managers were quickly shocked by the flood of imports.

The loss of share has been cushioned by strong market growth, as foreign firms have introduced new products, monopolies in therapeutic fields have been replaced by a wider choice of medicines, and old domestic products have stayed competitive because of their lower prices. According to a recent study the four largest domestic manufacturers still control at least a third of the market, and their share has been increasing slightly (Merrill Lynch).

Profitability, investment, and finance

As industry has adjusted to a market system, its financial health has become a central issue. Reforms under socialism had allowed firms to accumulate accounting profits, but they were long depressed by the tax on CMEA exports. In the wake of restructuring, industry profits rose from HUF 3.4 billion in 1989 to HUF 6.7 billion in 1991, a performance in striking contrast to the overall manufacturing sector, whose profits fell from HUF 87.9 billion to HUF 23 billion in the same period. After losses in 1992, all drug firms returned to profitability in 1993, and margins continued to rise in 1993-1994[4] to around 10 percent, lower than the international industry average, but well above other Hungarian manufacturers.[5] The revival of exports to ex-Soviet markets in convertible currency also boosted profit margins, as did the lifting of domestic price controls. The elimination of supply obligations has allowed companies to rationalize product lines and discontinue unprofitable drugs.

Even with its relative profitability, the industry's share of manufacturing and gross domestic investment has declined. From 1989 to 1991, overall manufacturing investment grew by more than 55 percent and economy-wide investment grew more than 21 percent, but nominal pharmaceutical investment declined slightly, a substantial reduction in real terms. Declining investment raises concern about the industry's ability to renovate its production and product technologies to secure its long-term competitiveness. In recent decades the industry has had two waves of investment, 1977-81 and,

supported by World Bank loans, 1984-87. Both were aimed at building capacity for hard-currency exports. World Bank loans were given to TSIs as well as firms. The financing of these investments resulted in the sector having a long-term to short-term debt ratio of 66 percent in 1989, well above the industrial average of 25 percent. As investment declined, the ratio fell to 45 percent in 1991. Access to investment capital was constrained in the early 1990s, threatening the industry's future. There are signs, however, that recent acceleration of privatization has led to better financing opportunities, and firms have again begun to make substantial investments.

Industrial structure

Through the 1980s the pharmaceutical sector was dominated by five firms, which together made up the predecessor of the Hungarian Pharmaceutical Manufacturers Association (HPMA).[6] In 1990 the top seven companies accounted for 95 percent of domestic sales. Since then the industry has changed significantly. It now has several distinct segments: six established producers of human medicines, a few veterinary producers, and a fine-chemicals producer involved in pharmaceuticals; new small manufacturers, including foreign joint-ventures and makers of traditional home remedies; and the representatives of foreign drug companies.

Small firms making a few products have grown dynamically, while some of the large, over-diversified, state-owned firms have contracted. The HPMA's formal membership has grown to eighty-six companies, including forty-four in pharmaceuticals trade, as well as representatives of foreign drug companies. For instance, the seven new manufacturing firms included in the sample are all small and medium-scale enterprises, whose owners are predominantly private or foreign. Some small and medium firms base their activities on process innovation, introducing improved production and management techniques to established product lines. One group of firms makes paramedical drugs or traditional remedies. Sales of paramedical drugs have increased dramatically since 1990. Entering this market segment is easy for small firms, as paramedical remedies do not require rigorous and time-consuming clinical trials. However, this huge growth in demand may be temporary, resulting from their novelty after their virtual absence from commercial distribution during socialism.

Only one company specializes in generic drugs, and it has been successful in applying modern production technologies. The firm based its strategy on incremental process improvements, an area neglected by the larger firms under socialism. Smaller enterprises compete by producing original drugs. Such firms have usually drawn on former staff of large companies in entering the market. (The role of these firms in commercializing product innovations is discussed in the next section.) One firm produces in-vitro drugs (compounds used in diagnostic testing) for laboratory customers who demand only small quantities but require high purity and hygiene. Unlike the retail drug market, this segment does not require expensive marketing networks or complicated clinical trials.

Small and medium companies have several other advantages over the large firms. They do not suffer from overemployment, they have smaller overhead, and they specialize in a few profitable drugs. Many of them, established at the end of the 1980s, have foreign equity. Their modern facilities are also an advantage over most older firms. Foreign joint-venture firms have better access to foreign financing, both equity and loan rates. New firms have received generous tax relief. Free from the legacy of

socialism, some have registered spectacular growth. Even heightened import competition has affected them only slightly, given their concentration in niche markets.

Even more spectacular changes have occurred in trade. Before 1990 a monopoly wholesaler handled all marketing. Today several dozen companies, including all the manufacturers, are involved in large-scale commerce. Integrated marketing and production allows greater profit margins. Representatives of foreign drug companies have also acquired wholesaler licenses for their own products.

R&D and Innovation Strategies

Hungarian companies were neither large nor innovative by international standards.[7] They typically spent only 5 percent to 8 percent of gross sales on R&D, compared to the international norm of 12 percent to 18 percent. Within Hungary, however, the industry ranked high in terms of R&D; four firms were among the top ten companies in R&D spending, despite their lower net sales (see Figyelõ). The six largest pharmaceutical companies spent about HUF 3 billion on R&D in 1990 and HUF 5 billion in 1993 (albeit in nominal currency; this was a 13% increase in U.S. dollars, from $47.5 million to $54.1 million).

Established firms' strategies

Before 1970 firm research and product strategy was based largely on imitation of Western drugs, eased by permissive domestic patent laws. In the 1970s, however, when the government sought to increase hard-currency exports to Western markets, the industry began to form links with Western companies and obtain product licenses. Western companies are generally reluctant to license drugs but were willing in Hungary's case to enter the otherwise closed CMEA market. As former East bloc markets have opened, Western companies now prefer to enter them on their own rather than through Hungarian licensees. Thus new agreements typically confer on Hungarian firms only the right to sell in the domestic market. The current 20 percent share of licensed products in total industry output (34 percent in domestic sales) will probably continue to fall (Concorde).

Since the 1980s firms have sought to rely on their own R&D for product development to complement foreign product licensing. The lack of capital and marketing networks has precluded an independent strategy based on exporting proprietary drugs to Western markets. Most firms have entered into agreements with foreign principals either to sell active substances or to collaborate in drug development. All of the largest firms regard R&D with foreign companies as more significant than collaboration with Hungarian institutions or other firms. The five largest firms have had R&D agreements that confer exclusive rights to their foreign (mostly Japanese) partners to market Hungarian innovations in certain regions in exchange for royalty payments. While the large companies see external R&D agreements as a way of bolstering their financial viability, they appear to be neither a long-run solution to the industry's problems nor an alternative to full privatization. The foreign partners covet promising Hungarian R&D results that they can develop and market independently and so reap the largest share of the profits. They are reluctant to shoulder much of the risks of capital investment, research, and management renovation that the Hungarian industry needs.

Together, the expiration of former licenses, the tightening of domestic patent laws, and the collapse of the former R&D financing system challenge firms to reconsider their product and innovation strategies. They must decide

whether to continue R&D or concentrate on less risky generic drug production. Past investments in R&D were large, and though inefficient they did yield some internationally recognized results. Internal R&D capabilities represent a significant asset that could be exploited by developing and producing higher-margin original drugs. R&D can also bring short-term financial benefits in cases where foreign firms agree to finance collaborative projects. A product-innovation strategy is riskier and requires formidable capital and marketing. The alternative is to reduce the number of research projects or sell research findings early in development.

Most firms have reviewed their projects and abandoned many of them to concentrate their resources. Contracting out research tasks to TSIs has declined sharply. The most drastic changes have occurred at Chinoin, a large firm privatized in 1991, where R&D projects have been scrutinized more carefully than before and very few new projects have been launched. As a result its R&D staff has been halved. Survey respondents said the organization of R&D had improved significantly with the introduction of Western laboratory and management norms.

Hungarian firms have barely begun to consider the revolution from chemistry-based to biotechnology-based research. The traditional mode of discovering new drugs is largely based on chemistry, wherein molecules are screened for their pharmacological properties, a procedure known as molecule roulette. Experience with particular compounds and sheer serendipity are critical to breakthroughs. Biotechnology allows more deliberate and precise manipulation of biological processes at the molecular level, for example by influencing the activity of enzymes or proteins, known as protein engineering (Kovács). While bio-molecular research is more efficient overall, it is more costly in its early stages, requiring dedicated equipment and more specialized science. Most Hungarian biotechnology plants have outdated facilities. Two biotechnology companies had been started, but they failed and were closed or absorbed by larger firms. A few firms have had successful biotechnology projects, and at least one academic institute is pursuing research.

Strategies of new companies

New small and medium sized private enterprises have used more modern technology, and many of them are internationally competitive in specialized niches. Others produce active substances or laboratory compounds, requiring strict quality control. Unlike established firms, most of these entrants compete on quality or product differentiation in addition to price.

Under Hungary's intellectual property rights system, before 1994, migrating staff could carry innovations from their employer to start-ups and other small companies, which frequently could offer better compensation than state enterprises. (It should be noted that the state-owned companies were slow to exploit technological opportunities, thus the transfer of knowledge might have meant avoiding the loss of it.) Small-company managers are almost always former employees of large firms. Some kept a watch on promising research of their former companies and tried to acquire results without investing in R&D. The start-ups also have had official channels with the older firms. Sometimes they contracted out excess production to the large firms. In other cases, lacking production and R&D capacity, they relied on large firms for all but marketing and management functions. In a sense these firms serve as venture capitalists by identifying and commercializing promising research.

Large firms may have begun to use the new patent laws to control their intellectual property. And some small firms have begun independent development. After years of high growth they aim to become "large enterprises."

Government Policies

The Ministries of Industry, Trade, Finance, and Health exercised authority over the industry during socialism. Government intervention was particularly important in three areas: price controls, drug registration and statutory supply obligations, and finance through grants or loans. In the transition privatization policies have become equally important.

Price regulation

Drug prices are regulated in many countries, commonly by subsidizing prices to consumers. In these cases governments must balance public health objectives against other budget priorities. Before 1989 Hungarian prices were fixed for long periods, and companies had to secure permission from the Finance and Health ministries to make price "corrections." Because the authorities preferred stable low prices, companies usually looked for ways to bargain for financing or other favors from the government. Since the transition prices have been set free, but price negotiations have continued between manufacturers and the Social Welfare Administration (SWA). A specific drug is assigned to a product category, each of which receives predetermined subsidies. During the registration process, the National Institute of Pharmacy recommends a category for the drug to SWA. The welfare agency thus has discretion over subsidization and must reconcile fairness in classification with economy of government subsidy expenditures.[8]

Some Hungarian manufacturers contend that classification has not always been fair. SWA automatically put imported drugs into the highest subsidy classes, 95 percent and 100 percent. Because of industry complaints and the growth in subsidy outlays, a new system was introduced in 1992, under which subsidies were made fixed amounts rather than percentages of the retail price. This meant that among the drugs with the same active substance, the cheapest determined the subsidy.[9] The new mechanism was thought to make manufacturers more sensitive to changes in demand, and coupled with the privatization of pharmacies and competition among wholesalers, inflationary pressure would be reduced. The system seemed to create an incentive to produce cheaper generic drugs, but subsidy expenditures continued to grow because of the sharp increase in subsidies for imported drugs.[10] Another change in the system in 1995 put the more important medicines into higher-subsidy categories. Its effect remains to be seen.

Finance for innovation

Government finance for technological innovation in pharmaceuticals has come from several agencies. The main actor has been the National Committee for Technological Development (OFMB). The committee had a substantial role in the tenders for World Bank restructuring loans in 1984 through 1987. It was a cofinancier of the Technology Development Project loans, which sought to help Hungarian firms escape their reliance on low-margin exports of active substances to Western markets, and market final drug products abroad. Loans backed by the World Bank could be used only for acquiring licenses, equipment, technical know-how, or technological services, and borrowers were required to match financing. Loans were used for toxicological and pharmacological projects closely related to drug development, as well as production equipment. The industry's export

potential in final drugs was limited by firms poor marketing skill and inability to achieve international manufacturing practice and quality standards. As a result their usual export options were to sell rights to promising research findings.

Between 1990 and 1994, OMFB's main device to promote technological development was its right to distribute money from the Central Technological Development Fund. The long-established fund was derived from a tax levied on all industrial enterprises. OMFB, giving priority to "applied research projects," provided special loans to both industry and research institutions to finance projects that would yield short-term returns.[11] But OMFB has largely shied away from pharmaceutical research as long-term and risky. Between 1991 and 1994, HUF 930 million was allocated to applied research in pharmaceuticals, one-third of which went to one research institute. The firms themselves spent several times that amount but received almost no government money.

Owing to OMFB's conditions, companies rarely bothered to apply for research loans except for collaboration with research institutions. Interviews indicated that pharmaceutical managers thought OMFB's requirements were too stringent and demanded confidential information. Thus internal financing or even foreign loans were preferred alternatives for funding research. Even the managers of the TSI that received the largest part of OMFB allocations were dissatisfied. They said the loan maturity was too short compared to the time required for development of a drug in the best case.

The development fund aimed to promote cooperation in research by giving priority to industry projects involving both firms and TSIs. Research institutes and enterprises applied jointly for funds. The applications included a letter of intent that enterprises would apply the research findings in practice, and assume partial responsibility for the repayment of debt. They were not bound to use the TSIs, however, and not surprisingly this method failed to promote genuine commercialization of technology. For instance, one academic institute received funding for twelve projects, ostensibly in partnership with industry, but drug firms have not used them. After 1994, following complaints from several industries including pharmaceuticals, the industry tax that financed the development fund was replaced by a direct government allocation, and then the fund was was abolished. The government made the OMFB subordinate to the Ministry of Industry and Trade. The reform represented a return to centralized allocation of research finance, in contrast to the broader trend toward decentralization. The change also cut off TSIs' most important channel of financing.

Privatization

The ownership of state enterprises did not change significantly until 1995. After the early sale of one firm, Chinoin, to a multinational in 1991, privatization in pharmaceuticals came to a standstill. Foreign investors' early interest had been based on the industry's unique access to the huge Soviet market, but the collapse of the East bloc trading system made them more cautious. Nonetheless, since 1993 a new wave of transactions has taken place. First, individuals have acquired blocks of shares floated on the Budapest Stock Exchange. Pharmaceuticals were among the most actively traded stocks, but their prices fluctuated greatly along with the broader market, and it appeared unlikely that the swings reflected changes in the fundamental health of the firms. Two firms issued new equity, benefiting the capital structure of these highly leveraged enterprises.

According to the mandate of the State Asset Holding Company and its successor, the State

Privatization and Asset Holding Corporation, the state must retain at least 25 percent of shares in large pharmaceutical companies. The policy was justified by the high research intensity of the industry and the need to maintain it to a degree that supposedly short-sighted private investors, especially foreigners, might otherwise forego. Some (outside) critics pointed to Chinoin as evidence of the harmful consequences of foreign ownership for technological development. It was alleged that some promising research was transferred to the parent company for development and commercialization, that few new R&D projects had been launched, and that contracting to local TSIs had been decreased. The firm's position is that Western management norms, particularly project monitoring, have improved the organization of research (Chinoin). Assets were rationalized and many wasteful and unpromising projects were abandoned, while new projects were launched in fewer fields to focus efforts and improve efficiency. Employees no longer own the patents for drugs discovered during working hours, another tightening of management preventing losses of inventions to the company(György-Vincze). One institute that provided technical services to Chinoin maintained that, even though its volume of business had declined, new contracts with the firm provided better commercial terms.

It is unclear how the troubles surrounding privatization, frequent organizational changes, little consensus on principles and methods, and its prolonged process affected firms' technology decisions. Managers seemed to believe that increasing technological investments would put them in a better bargaining position, and some companies (like Chinoin) shuffled their organizations along Western management lines (see György-Vincze). Managers said privatization was slower than necessary, and that the required government equity participation makes investment unattractive to foreigners.

In the second half of 1995 the government radically changed its attitude toward privatization. First, the long-term involvement of the state was almost eliminated. In only one firm does the government maintain a 25 percent (plus 1) share, on grounds of the sensitivity of one of the company's main products. Next followed a series of transactions that resulted in an ownership structure diametrically opposite to the structure that had prevailed in 1991. By 1996 the state had a majority stake in only one among the seven biggest companies, and in three it had no share at all. In most cases strategic investors became the majority stakeholders, though usually the share of other stakeholders was insignificant (see Merrill Lynch). The effect of these changes remains to be seen, but there are indications that investment has increased, and that may bring technological development, a question for further research.

Patent law and drug registration

The 1994 patent law was intended to encourage R&D. After three years of negotiations, American and Hungarian delegations agreed that Hungary would recognize not only process innovations but also product patents. The agreement averted the American threat to withdraw most-favored-nation status. Automatic patent protection in Hungary was retroactively extended to U.S. patents granted beginning in 1987. The U.S. had asked for retroactive protection of patents granted in the past twenty years; the seven years to which Hungary agreed is longer than U.S. terms with any Western European nation. Similar intellectual property agreements have been reached with the other Eastern European countries, though none of them have Hungary's level of development in pharmaceuticals. Opinions on the consequences of the U.S.-

Hungary agreement vary. Some experts say that no ongoing research would be impeded. The Hungarian Pharmaceutical Manufacturers' Association declared that seventy-two projects could be affected by patent protection retroactive to 1987. It seems that enterprises will be affected differently, as some firms have prepared for the changes for several years. An important caveat is that loopholes in the agreement will allow Hungarian companies to continue copying and selling reproduction generics. Estimates of the agreement's full effect range from the year 2000 (Concorde), to ten years following the final agreement (Merrill Lynch). The negotiations appeared to affect managers' propensity to detail their R&D strategies, and some were suspicious of this project's entire questionnaire.

The agreement has several major implications. Licences will be required for domestic production of imitation drugs, and if these are not obtained, imports will be allowed to increase. Either outcome will result in higher domestic prices. Second, certain exports of imitation drugs will be lost. Third, imitative research projects must be abandoned. Some government experts tentatively estimate losses to the industry of as much as $300 million per year.

The number of drugs registered increased sharply after 1990, because of import liberalization, and slowed in 1994 mainly because of satiation. There is evidence that foreign producers sought to register drugs in Hungary that were subject to increasingly strict regulation or whose patents were expiring in Western European markets.

Other policies

Established firms blame the old economic system for their current economic difficulties. The government had appropriated a high proportion of their profits, though some of it was channelled back. Thus, few managers identified any government policy as being beneficial to development. World Bank loans at preferential rates were cited, but respondents usually also noted the consequent increased interest burden. Managers of established firms seem most to regret the loss of domestic market protection, which they regard as harmful to technological development.

The Structure and Evolution of TSIs

Hungary's socialist government established the independent branch research institutes to conduct applied industrial R&D, and assigned basic R&D to academic institutions. The country's independent industrial and academic institutions carried out a far larger proportion of national R&D (70 percent) than in any OECD country (Pavitt). The institutional separation of production and R&D frustrated collaboration. Firms were unwilling or unable to adopt inventions originated in research institutes, as they would have to assume the risks of failed innovations brought to market but would have to share the profits of successful products with the institutes. The branch institutes, lacking pilot plants, let alone production capacities, were unable to demonstrate or exploit their innovations commercially.[12] As a consequence, firms typically contracted out only simple technical and laboratory services to the branch institutes. Contrary to the goal of close cooperation between industry and the branch institutes, the two remained distant, resulting in duplication of effort. Firms began to rebuild their R&D departments, using manpower and capital, even as the institutes conducted basic research while performing simple tasks for industry.

Three branch institutes were dedicated to serving the pharmaceutical industry (a fourth, discussed in a case study below, was assigned to the chemicals industry but performed research

relevant to pharmaceuticals). The biggest of these (with 450 employees) was set up in 1950 after being spun off by a major company. It was intended to develop technologies for producing major known drugs, but by the 1960s it had shifted toward original research and invested heavily in facilities. It became a research and development center rather than an institution catering to the needs of manfacturers. A second institute dealt mostly with the technology of drug production on a large scale, and companies moved away from using it because they believed that an outside institution had little understanding of their working conditions. A third institute specialized in herbs and occupied a modest place in the industry. Its signficance increased with the advent of paramedicines, though not especially for the traditional companies.

With its desire to reduce expenditures and make firms finance technological development, the government in 1983 transferred ownership of the branch institutes to the six member companies of the HPMA. The change did not result in management coordination, and the problems inherent in the divided institutional structure, including the misallocation of scientific and research personnel, the redundancy of institute and company research capabilities, the under-specialization of institute activities, and limited interaction with industry, remained unresolved. The government's reforms of the central funding mechanism for R&D, which were intended to promote greater industry/TSI collaboration, also met with little success.

The difficulties of fostering industry/TSI collaboration may be illustrated by a case involving the most important branch institute and the largest manufacturer. In the early 1980s, during a centrally financed research program, institute researchers invented a molecule that appeared to prevent heart attacks. Consistent with its obligation to offer promising research findings to industry, the institute entered into negotiations with the manufacturer for development and marketing. One obstacle to an agreement was informational: the manufacturer could not evaluate the institute's incurred expenses, remaining development costs, nor the potential market value of the compound. Finally the two parties decided simply to divide the patent rights, with the firm acquiring rights to export markets while the institute retained rights to the domestic market. The agreement conferred responsibility for further development of the chemical compound to the firm, which was to keep the institute updated. But the institute was unable to assess the additional development work and grew suspicious that the firm was devoting insufficient attention to the project. In 1988 new government regulations allowed the branch institutes to conclude their own foreign collaboration agreements. By 1990 the compound had interested several foreign companies, but they could not come to an agreement with the Hungarian company. To seize the opportunity, the institute bought out the foreign patent rights from its erstwhile partner and entered into a cooperation agreement with a multinational drug company to market the drug. The moral of the story is unclear. It may have been that in the still-public company, no one had sufficient interest in the compound, which seems to have been a prerequisite to innovation in the socialist era. And the institute must have been eager to exploit an opportunity that was significant to its portfolio, whereas the company found it of trifling importance.

Despite various difficulties, the branch institutes have had more business links than have the academic institutions (AIs). Among AIs, university institutes have been more active than the Hungarian Academy of Sciences. AIs

are even less business-oriented than the branch research institutes. They cannot enter into direct relationships with firms but must contract through their parent institutions, universities or the Hungarian Academy of Sciences. In practice, this means that a large part (usually 80 percent) of their contract revenue is retained by the universities or the academy. Some AIs have striven for greater autonomy, but because their main mission is education and basic research, their prospects for contract research have been limited.

Hungary's pharmaceuticals-related TSIs regard themselves as organizationally different from Western corporate research departments. Before the transition, they were affiliated with state industrial combines or groups of companies, and they engaged in a range of research disciplines with little specialization. (An exception was one large fine-chemical firm's research unit, which was established in the 1980s with World Bank loans. The company, however, was unable to use the facilities fully or to commercialize its research. The rising interest rate on the foreign-currency loan forced the company to spin off the unit.) Notwithstanding their lack of specialization, TSIs typically have more modern facilities and laboratory equipment than the manufacturing companies they are to serve.

Firm managers' views of the TSIs varied. Among established firms, a few managers were very satisfied with their performance, but others viewed them as of little use. The main complaints were that TSIs lacked practical capabilities and had little awareness of industry's needs and limitations. Indeed, some enterprise managers regarded their ownership shares in institutes, vested in them by the government in 1983, as a liability. A second criticism is the branch institutes lack of specialization. Manager did comment that companies would work with an institute focusing on pharmaceutical production and process technology, which could help them adapt foreign-licensed drugs and other acquired technologies. Historically most formal cooperation between industry and TSIs was encouraged by government programs and earmarked funds. Because formal projects did not stem from industry needs, they were largely uncoordinated, commissions were given without clear objectives, and projects lacked timetables. The principal goal seems to have been to spend government money.

While critical of TSIs, some firms do report using some of their services. Firms have maintained close contacts with universities, other academic institutions, and hospitals for clinical research and testing. The main contact with branch institutes involved testing and laboratory services. As they increased R&D investments in the 1980s, firms initiated two- to three-year contracts with applied and academic TSIs. In all relationships personal contacts were decisive, especially because of the inadequate formal protection for intellectual property. Contacts were made with persons rather than the institutes. Equally, TSI researchers turned to friends or acquaintances in industry when looking for partners to commercialize research findings, since in this way they could avoid yielding most of the royalties to their employers. As the case studies below illustrate, these relationships sometimes produced excellent results. Even so, disputes were endemic, and attempts to regulate industry-TSI contacts did not resolve the problems.

Economic reform and the restructuring of the branch research institutes

In the transition, branch institutes have come under severe financial pressure because of the loss of government funding. Employment in many TSIs has fallen. Researchers have emigrated. Government subsidies and contracts from traditional clients have declined, while

new private companies have commissioned little work. Despite the difficulties, most institute managers do not fear being shut down, as they are owned jointly by manufacturing companies, whose managers in turn are not much afraid of closing. TSI managers expect that orders from the dynamic small companies will increase in due time even as those from larger firms wane. They regard informal, personal relationships with industry as all-important to generating contracts.

Despite wrenching adjustments in the industry and renewed pressure on TSIs to find clients, there is little evidence that TSIs and companies are more inclined to cooperate. Rather, both appear to be in search of foreign partners. The branch institutes are seeking research contracts with foreign companies, which have far more resources to spend on outside research. They also offer better terms than domestic companies, which remain accustomed to a system under which the institutes were bound to offer their research to local firms in exchange for government funding. Hungarian firms paid one-fourth of development costs, but foreign firms finance up to 100 percent. Also in line with previous practice, domestic firms insist on retaining intellectual property rights for all export markets; foreign firms negotiate for rights to sell in specific markets. In the benefit-sharing contract system set up in the early 1980s, local firms paid royalties to the branch institutes only after a drug was marketed, requiring the institute to bear up-front expenses. Foreign firms typically pay maintenance fees from the time the contract is concluded, along with royalties on sales. Finally, contracts with domestic firms usually do not include joint research, whereas foreign firms allow the institutes valuable exposure to state-of-the-art research through collaboration.

Case Studies

Jumex

Jumex, a medication used to treat Parkinson's disease, is the first Hungarian drug sold in the U.S. market. Its history began in 1961, when Chinoin synthesized the molecule on which it is based. Semmelweis University of Medicine in Budapest examined it as an anti-depressant in pre-clinical testing and found it to be a MAO-B inhibitor, without the dangerous side effects found in other MAO-B inhibitors. Further investigations by institutions in Hungary and Austria resulted in the discovery of its anti-Parkinson's effect; paternity for the discovery is unclear. A Czechoslovak institute, commissioned by Chinoin, later found that Jumex could be used to treat Alzheimer's disease.

A Finnish company bought the marketing rights to Jumex in 1984 and sub-licensed it throughout Europe and engaged in further clinical testing. Chinoin licensed Jumex to the Canadian and U.S. markets, drawing the attention of the U.S. National Institutes of Health (NIH). NIH trials, involving up to 800 patients annually, were far beyond the Hungarian firm's capabilities. The drug has proved a commercial success in the U.S., but Chinoin has received little of the profits. It supplies the active substance at a small fraction of the finished product's price. Though Chinoin hoped to repurchase U.S. rights in 1986, the price (about $30 million) would have required Hungarian government financing, in hard currency (Chinoin). Still, Jumex, now sold in many countries, is Chinoin's most important product.

Ypriflavon

Ypriflavon, another Chinoin product, also is based on a molecule synthesized in the 1960s. The compound was discovered in 1964 at

Budapest Technical University, during research commissioned by Chinoin to develop veterinary drugs. Research eventually led to establishing the compound as a human medicine. In 1979 a Japanese company, Takeda, became aware of Ypriflavon and directed research toward the compound's use as a medicament for osteoporosis (Chinoin). Takeda licensed it, completed clinical investigations in Japan, and in 1988 began to sell the product in Japan and throughout Asia. Since then it has been marketed in Italy, Argentina, and Belgium. Takeda's role in the drug's development is reflected in lower-than-average royalties to Chinoin, though its supply of the active substance makes it a profitable line.

Curiously, the drug acquired only partial registration in Hungary, in 1988, which means that a restricted circle of physicians can prescribe it but it cannot be sold widely in pharmacies. Several explanations have been offered why full approval has not been given. One is that its therapeutic effect is difficult to establish because of the particulars of osteoporosis. Some Chinoin managers claimed that certain officials were opposed to approval because neither the Japanese nor the Italian clinical trial results were accepted. The lack of domestic recognition was an obstacle to international registration. In the meantime, Chinoin was privatized to a foreign investor, which is waiting for new clinical trials before deciding whether to market the drug.

These two cases show the capability of Hungarian researchers to produce top-level innovations. Their histories also exhibit inefficiency in the socialist system, specifically in the long time between the original invention and commercialization. Contract terms might have been better if Hungarian managers had not been isolated from world markets by decades of socialist policies. The cases also show the relationship of parties all over the globe in the development of a drug, and perhaps that in a small country like Hungary purely domestic development of drugs may be unviable.

Toxi

Toxi, a laboratory within a branch institute in the chemical industry, was founded in the 1980s with World Bank financing. The institute foundered in 1990, the same year Toxi began functioning, in the wake of rising interest rates and capacity under-utilization (because of declining contracts from chemical firms). Though owned by the branch institute, Toxi was a separate entity specializing in toxicological testing and analysis. It resembled TSIs in industrial countries rather than the Hungarian pattern of broad research. Following the institute's bankruptcy, Toxi prepared for privatization and was finally acquired in 1995 by the First American Fund (FAF) (for one-fifth of its 1992 value). FAF transferred Toxi's ownership to a new Hungarian pharmaceutical firm in which it held a majority stake. Toxi's role in the new firm is under review.

Toxi's brief history illustrates the ownership-rights mayhem that has characterized the transition. Physically valuable assets like a modern institute with good capabilities may have had low market value because it happened to be in the "wrong" hands.

Conclusions

The Hungarian pharmaceutical industry entered the post-socialist era with significant technological resources and production capabilities, dating from the substantial academic research institutions and industry before the Second World War. These capabilities were deepened during the socialist era, particularly as firms rebuilt in-house technical units following the limited reforms of the 1960s and 1970s. With licensing and the

reproduction or imitation of molecules, made possible by relaxed patent laws, Hungarian producers were able to pursue fast-follower strategies in competition with leading drug producers in the West. But while they were able to produce sophisticated imitations and supply quality active substances to Western markets, they failed to become competitive in the production and export of proprietary final drugs, by far the most profitable market segment.

Recognizing the industry's technological strengths, the socialist government attempted to drive innovation from the top down, mandating cooperation between industry and state-run research institutes and financing research through centralized mechanisms. Its efforts produced limited results. The industry's focus on East bloc markets did not pressure firms to improve quality, and the state's branch research institutes were unresponsive to industry needs. Formal industry/TSI collaboration was thus largely confined to routine tasks. The central government's control over the profits from innovation, either within industry or the branch institutes, also discouraged efficient innovation. Still, the industry has had some developments that have been marketed internationally, and the public investments in research have produced a large reserve of research and engineering personnel upon which the industry has drawn. Informal personal networks within industry, and between industry and the TSI community, did enable technological ideas and information to circulate. Many firms modernized their production technologies in the mid-1980s, using World Bank loans. But the investments were never enough to achieve a complete updating of technology, and companies remained technologically outmoded.

In the transition, financial constraints and the difficulties of institutional reform have prevented the industry from capitalizing on its technological potential. Commercializing pharmaceutical research requires major investment in clinical trials and marketing networks, and these pose major obstacles to financially strapped Hungarian firms. Privatization, viewed as a way to recapitalize the industry, has only recently accelerated, and initially foreign direct investment waned for several years. Domestic finance is scarce, and market instability makes internal financing of major technology investments all but impossible. Caught between their immediate financial difficulties and the potential long-term value of their research capabilities, Hungarian firms turned to international R&D agreements in which foreign drug companies funded specific projects or research-related investments. These contracts usually reflected firms' short-term financing needs and entailed selling research findings at an early stage of development, without long-term commitments on the part of the foreign partner.

Recent reforms have been even more traumatic for the research institutes. Government funding has shrunk dramatically, and contract revenues have also fallen as their main clients, the large state-owned companies, have limited their research and production. At the same time, institutes have been unable to supply specialized services that might attract the rapidly growing smaller firms. Finally, institutional obstacles discouraged industry from collaborating with TSIs: there were substandard documentation of research, delays in project completion, and disputes over patent rights growing out of joint research. Unable to raise revenue by increasing services to industry, the institutes have turned to selling their research to foreign firms. As their activities have diminished, they have lost staff to industry and emigration.

Government policies have been largely ineffective in helping the industry respond to the new competition. The central system of

research funding was reformed, and competitive tenders became the main vehicle of distributing government research funds. But technological development has not noticeably increased. A bureaucratic shift in authority over pharmaceuticals, involving a change from drug price controls to government subsidies of production, has been controversial in implementation. The industry views government policy as hampering their effort to become competitive, particularly by removing import protection, but also by disproportionately subsidizing the sale of foreign drugs in Hungary. Case histories show that the industry has developed drugs of international renown. (The successes originated in the 1960s, and thus it may be that quality work stemmed from the industry's traditions.) But they also reveal failures, through lack of capabilities to develop and market innovations, poor institutional performance, and a lack of industry/government cooperation. Financial and institutional weaknesses could jeopardize Hungary's technological capabilities as economic restructuring continues. Chief lessons from the Hungarian experience are the importance of strong support for research and the necessity of effective financial and regulatory mechanisms (patent law, drug registration, and price regulation) to link innovation to the market.

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Notes

1 While the division of Europe into rival blocs cut off access to Western markets and technology, it also resulted in a one-time boon to the industry after the disclosure of patents of leading German pharmaceutical firms.

2 A jump in domestic sales in 1991 resulted from speculative buying by the then-monopoly drug distributor in anticipation of the relaxation of price controls.

3 Data supplied by the PMWA show that the average price of imported drugs was about four times higher than the price of domestically made medicines in 1994.

4 The two firms exhibiting the poorest financial condition specialize in fine chemicals/diagnostic agents, and veterinary drugs, respectively.

5 Dispersion around the average is significant, however, with profit ratios ranging from 2.6 percent to 16.8 percent.

6 A sixth member of the association primarily produced fine chemicals.

7 The largest Hungarian company's 1992 sales were about $160 million.

8 Drug subsidies amounted to HUF 18 billion in 1990, HUF 61 billion in 1994.

9 A similar system is in force in Germany.

10 Measured at producer prices, sales of domestic drugs doubled and imports grew quintupled from 1990 to 1994.

11 Loan maturity was usually five years, with a two-year grace period and a proviso that research institutions were obligated to pay back only 50 percent.

12 In-house research is particularly critical among firms that compete globally, and firm competitiveness depends on the generation and protection of proprietary knowledge. (See Sharp.)

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