Interventions and Experiences

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New Policy Regime and Small Pharmaceutical Firms

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Introduction

Since the 1970s the Indian pharmaceutical industry has been experiencing rapid growth and significant advancement in its domestic technological capabilities. Many Indian pharmaceutical companies have emerged as global players, with India experiencing an ever-increasing trade surplus in pharmaceutical products (Pradhan 2006). An industry that was almost nonexistent at the dawn of independence is now a global competitor. The main factor responsible for this transformation of the pharmaceutical industry is a host of strategic government policies aimed at promoting indigenous technology and production (Pradhan and Alakshendra 2006). The starting of public-sector companies which could assume a leading role in enhancing local capabilities in the production of bulk drugs, the adoption of a process patent regime, and regulation of the activities of foreign firms were some of the important policy initiatives.

While there is a growing appreciation for the role of a strategic government policy with regard to the competitiveness of Indian pharmaceutical enterprises, this issue is analyzed less in the case of small pharmaceutical producers. The Indian pharmaceutical industry is strongly represented by a large number of small firms that are essentially producers of technology-intensive bulk drugs and which have clearly contributed in enhancing the indigenous capability of the sector. In fact, data available for 1985–86 suggested that small firms had a higher share of the production of basic drugs (i.e., bulk drugs) over foreign firms in India (Kumar and Pradhan 2003: 17, Table 1). These small-scale units, like their larger domestic counterparts, have grown under a soft patent regime that India had adopted

in the early 1970s. Under the soft patent regime, these firms had effectively utilized technological imitation, reverse engineering, and process development as means of advancing their firm-specific competitive capabilities. They made rapid technological advances in developing their own cost-effective processes and successfully competed with foreign firms in the domestic and overseas markets.

Apart from enjoying a favourable patent regime, small producers of pharmaceutical products in India also received special focus with regards to industrial, trade and pricing policies. The social relevance and the pivotal role of small firms in employment generation, regional and economic de-concentration, local resource utilization, and mobilization of skills, etc., have been well recognized, and from the very beginning of the industrial policy, as in the first Industrial Policy Resolution 1948, these firms have been accorded protection from large firms as well as provided with various support measures and incentives. Several policy measures, like the provision of finance, training, and technical, marketing and other support measures; access to raw materials; preference in government procurement; and reservation of products for exclusive development in the sector, have also been implemented.

In the case of the pharmaceutical sector, small firms have been helped by various favourable policies like exemption from the Drug Price Control Order (DPCO) and drug policy parameters, reservation of drugs for exclusive production in the small-scale sector,[1] preferential procurement by government health programmes, etc. As a result of these strategic interventions, small firms, in spite of their resource disadvantage, were able to respond to the changing business environment and emerged as significant market players. The share of the small Indian private sector in the production of bulk drugs went up to 21 per cent in 1985–86 from 7.7 per cent in 1975–76, and in the case of formulations their share rose to 26 per cent in 1985–86 from 17 per cent in 1976–77

[1] Drugs such as Paracetamol, Parabenes, Calcium Gluconate, Benzyl Benzoate, Pyrazolones, Lanolin Anhydrous, Halogenated Hydroxy Quinolines, Nicotinic Acid/Amide, Glycerophosphoric Acid & Glycerophosphate, Citrates, and Aluminium Hydroxide gel were reserved for exclusive development in the small scale-sector.

(Kumar and Pradhan 2003: 17, Table 1). Over the years the small-scale sector has diversified its production base to produce many important bulk drugs/intermediates like Ampicillin Trihydrate, Amoxycillin, Trimethoprim, Sulphamethoxazole, Analgin, 6-APA, Chloramphenicol, etc.[2] Further, this sector has been a source of meeting substantial demand from the Government Health-care Programme. This vibrant Small and Medium Enterprises (SME) sector, functioning on very low profit margins, has thus played an important role in keeping essential life-saving drugs at affordable prices and in ensuring the health security of the Indian masses in remote rural areas.

However, since the early 1990s, the macro policy regime in India has undergone dramatic changes. The dismantling of the industrial licensing system, de-reservation, increasing openness to foreign investment and technology, removal of non-tariff barriers and widespread reduction in import duties, among other things, have radically changed the overall business environment. Along with these changes in the domestic policies, the global policy environment has also undergone rapid transformation with the emergence of the World Trade Organization (WTO) and the implementation of liberalization measures at various global levels — bilateral, regional, multilateral and at the level of individual countries. This large-scale policy of liberalization has resulted in intense competition for survival and growth among firms. Small firms are now facing competition at a global level with an urgency like never before.

The liberalization of the policy regime with respect to the pharmaceutical sector in the 1990s poses many challenges for small enterprises. With the progressive reduction in the list of drugs under the DPCO, the relaxation granted to the small-scale sector's products has been effectively reduced over time. Small-scale units are no more granted exemption even from the diluted DPCO under the new policy regime, reversing the provision granted to the sector under DPCO 1987. The allowance of 100 per cent foreign direct investment (FDI) and the removal of the restriction on large-sizes firms requires that

[2] Report of the Working Group on Drugs and Pharmaceuticals, Eighth Five Year Plan Period, pp. 9.

small firms enlarge their market focus and competitive strategies. The adoption of the product patent regime in January 2005 and the emphasis on quality and good manufacturing practices are likely to demand higher technological efforts from small firms (Das and Nair 2004). Because small firms are often constrained by their size in sales, investment, and employment, as well as due to their inadequate small financial resources, meeting these new challenges cannot be assumed to be as smooth as in the case of large enterprises.

In the above backdrop, this article examines the performance of small pharmaceutical firms relative to their larger counterparts. This involves a comparative analysis of the productivity, technology and skill performance of Small and Medium Enterprises (SMEs) vis-à-vis large firms. The study also explores the implications of the new policy regime for small pharmaceutical firms.

Database, Definition and Size of Small Pharmaceutical Units

As of now, there is hardly any accurate estimation about the size of the SME sector in the pharmaceutical industry. Most of the official statistics simply rely on the estimates provided by private industry associations like the Organisation of Pharmaceutical Producers of India (OPPI) and the Indian Drugs Manufacturers' Association (IDMA). However, estimates from these sources are not reliable at all. For example, the OPPI estimated that there were about 20,053 units in the pharmaceutical sector in 2000–01, of which just 250–300 units were large units. But in 2003–04, it was estimated that there were just 10, 000 units, of which 300 were large units. It's not clear as to how the total number of units halved just within a four-year period. Although information about the organized sector is available from the Annual Survey of Industries (ASI) of the Central Statistical Organization (CSO), it does not provide information separately for small and large units. The Working Group on Drugs and Pharmaceuticals, Eighth Five Year Plan Period, also faced a problem regarding data on the small-scale sector in the year 1989: 'Small scale units contribute substantial share to the indigenous production. It is

estimated that the contribution of small scale units may be around 30%. However, no authentic data is available' (*Report of the Working Group on Drugs and Pharmaceuticals* 2006: 9).

In this article I have made an attempt to provide estimates on the size of the pharmaceutical small-scale sector in the organized manufacturing sector. This organized sector consists of only those units that are registered under the Factories Act 1948 and which employ 10 or more workers using power or 20 or more workers without using power. This sector can be taken as the modern small-scale sector in the pharmaceutical industry, which is different from the informal/unorganized small-scale segment producing traditional systems of medicines like Ayurveda, Siddha, Unani, naturopathy as well as herbal medicines.

I collected unit-level unpublished data from the ASI for the year 2000–01. Since that is just one year's data, this article can only address the static differences between small and large pharmaceutical units in terms of efficiency and some other performance indicators. Despite this limitation, this article provides the exact size of the small-scale sector and its contribution to domestic pharmaceutical production and employment.

The official definition of small pharmaceutical units has been adopted in this article. Since 1966 the Indian classification of small enterprises is based on the historical value of the investment in plant and machinery, whether held on ownership terms or on lease or hire–purchase basis. In 1966 the investment limit for a small unit was fixed at Rs 0.75 million, irrespective of the industry it belonged to. Subsequently, there has been a continuous upward revision in the investment limit — to Rs 3.5 million in 1985, Rs 6 million in 1991, and Rs 30 million in 1997. Thereafter, the investment limit was reduced to Rs 10 million in 1999, and later raised to 50 million for some industries, including pharmaceuticals, in October 2001 (Das 2006). Following this criterion, pharmaceutical units whose net value of investment in plant and machinery is up to Rs 50 million are classified as small and units exceeding this limit are tagged as large scale.

The estimated figures on the size of small pharmaceutical units for 2000–01 confirmed that they comprise the bulk of the pharmaceutical sector in India. Out of a total of 2,872 organized

units operating in the pharmaceutical industry, 2,623 units were small units as compared to just 249 large units (Table 10.1). The small-scale units are playing an important role in the domestic sector, contributing 65 per cent of the employment and 42 per cent of the total pharmaceutical production. This suggests that small firms have grown significantly over the past decades, since the 1970s, and as emphasized earlier, the main factor responsible for their growth is a host of strategic policies employed by the government. Small firms have not only made the industrial structure more competitive, but also contributed substantially to the production of drugs and job creation.

Table 10.1: Size of the Small scale Sector, 2000–01

Characteristics	*Small Units*	*Large Units*	*All Units*
Number of units (numbers)	2,623 (91)	249 (9)	2,872 (100)
Employment (numbers)	1,62,487 (65)	86,559 (35)	2,49,046 (100)
Net Fixed Investment (Rs Lakhs)	28,573 (29)	68,469 (71)	97,042 (100)
Total Output (Rs Lakhs)	15,11,366 (42)	21,28,004 (58)	36,39,370 (100)
NVA (Rs Lakhs)	1,99,337 (44)	2,54,911 (56)	4,54,248 (100)

Source: Computed from unit-level data of ASI, 2000–01, CSO, India.
Note: Figures in parentheses represent the proportion in percentage terms.

Indian pharmaceutical enterprises, in general, tend to be regionally concentrated in a few states. Out of every 100 pharmaceutical units, 40 units were found to be located in just two states, Maharashtra and Gujarat (Table 10.2). Andhra Pradesh and Uttar Pradesh had about 12 and 7 units, respectively These top-four states together accounted for about 60 per cent of the total pharmaceutical units in India. They are also major hosts for small units, hosting about 60 per cent of the total number of small pharmaceutical units. Inter-state differences in the ratio of the number of small to large units suggest that states like West Bengal, Haryana, Orissa, Uttaranchal, and Uttar Pradesh had a greater incidence of hosting small units as compared to large units. In terms of total pharmaceutical production too, a similar feature of geographical concentration in the

Table 10.2: State–wise Distribution of the Pharmaceutical Sector in India, 2000–01

	No. of Units (Number)			*Total Production (Rs Lakhs)*		
State	*Small Units*	*Large Units*	*All Units*	*Small Units*	*Large Units*	*All Units*
Andhra Pradesh	288 (11.0)	49 (19.9)	338 (11.8)	1,08,617 (7.2)	3,12,514 (14.7)	4,21,130 (11.6)
Assam	6 (0.2)		6 (0.2)	696 (0.0)		696 (0.0)
Bihar	21 (0.8)		21 (0.7)	2,766 (0.2)		2,766 (0.1)
Chandigarh	3 (0.1)	1 (0.5)	4 (0.1)	165 (0.0)	2,778 (0.1)	2943 (0.1)
Chhatisgarh	11 (0.4)		11 (0.4)	1,390 (0.1)		1,390 (0.0)
Dadra and Nagar Haveli	17 (0.6)	4 (1.5)	21 (0.7)	42,330 (2.8)	13,866 (0.7)	56,196 (1.5)
Daman & Diu	24 (0.9)	7 (2.8)	31 (1.1)	37,023 (2.4)	0 (0.0)	37,023 (1.0)
Delhi	66 (2.5)		66 (2.3)	26,744 (1.8)		26,744 (0.7)
Goa	42 (1.6)	12 (4.8)	54 (1.9)	44,902 (3.0)	61,053 (2.9)	1,05,955 (2.9)
Gujarat	534 (20.4)	33 (13.1)	567 (19.7)	2,47,309 (16.4)	3,24,450 (15.2)	5,71,759 (15.7)
Haryana	115 (4.4)	2 (0.8)	117 (4.1)	1,04,430 (6.9)	52,333 (2.5)	1,56,763 (4.3)
Himachal Pradesh	22 (0.8)	13 (5.2)	35 (1.2)	19,080 (1.3)	93,455 (4.4)	1,12,535 (3.1)
Jammu & Kashmir	5 (0.2)		5 (0.2)	288 (0.0)		288 (0.0)
Jharkhand	4 (0.1)		4 (0.1)	1,959 (0.1)		1,959 (0.1)
Karnataka	94 (3.6)	15 (5.9)	108 (3.8)	66,446 (4.4)	1,43,044 (6.7)	2,09,489 (5.8)
Kerala	89 (3.4)	8 (3.0)	97 (3.4)	28,171 (1.9)	2,222 (0.1)	30,393 (0.8)
Madhya Pradesh	102 (3.9)	19 (7.6)	121 (4.2)	92,072 (6.1)	1,23,555 (5.8)	2,15,627 (5.9)
Maharashtra	548 (20.9)	59 (23.6)	607 (21.1)	45,1475 (29.9)	5,42,386 (25.5)	9,93,862 (27.3)

(*Table 10.2 continued*)

(*Table 10.2 continued*)

State	*No. of Units (Number)*			*Total Production (Rs Lakhs)*		
	Small Units	*Large Units*	*All Units*	*Small Units*	*Large Units*	*All Units*
Orissa	44 (1.7)	1 (0.4)	45 (1.6)	3,051 (0.2)	4,290 (0.2)	7,341 (0.2)
Pondicherry	10 (0.4)	1 (0.4)	11 (0.4)	10,989 (0.7)	10,250 (0.5)	21,239 (0.6)
Punjab	65 (2.5)	7 (2.8)	72 (2.5)	16,957 (1.1)	1,70,507 (8.0)	1,87,464 (5.2)
Rajasthan	59 (2.3)	3 (1.2)	62 (2.2)	31,875 (2.1)	35,517 (1.7)	67,393 (1.9)
Tamil Nadu	136 (5.2)	7 (2.8)	143 (5.0)	78,072 (5.2)	66,434 (3.1)	1,44,506 (4.0)
Uttar Pradesh	195 (7.4)	7 (2.8)	202 (7.0)	52,959 (3.5)	1,66,241 (7.8)	2,19,199 (6.0)
Uttaranchal	31 (1.2)	1 (0.4)	32 (1.1)	3,378 (0.2)	2,465 (0.1)	5,843 (0.2)
West Bengal	92 (3.5)	1 (0.4)	93 (3.2)	38,221 (2.5)	646 (0.0)	38,867 (1.1)
All India	2,623 (100)	249 (100)	2,872 (100)	15,11,366 (100)	21,28,004 (100)	36,39,370 (100)

Source: Computed from unit-level data of ASI, 2000–01, CSO, India.
Note: Figures in parentheses represent the proportion in percentage terms.

Indian pharmaceutical sector could be noticed. Maharashtra and Gujarat together accounted for about 43 per cent of the total production. The top-four states with respect to production—Maharashtra, Gujarat, Andhra Pradesh and Uttar Pradesh—contributed about 55 per cent of the total production.

In the context of the new policy regime, technology and productivity are the most important determinants of the survival and competitiveness of pharmaceutical firms. Small firms need to urgently upgrade their internal sources of technology like, among other, expanding their in-house Research and Development (R&D) activities, employing more skilled labour, investing in modern machinery and information & communication technologies (ICTs), and providing training to their technical manpower. Although the ASI unit-level dataset does not provide information on R&D, other indicators of technological activities can be compiled. As far as R&D intensity is concerned, it can certainly be said that small pharmaceutical firms considerably lagged behind their large counterparts in undertaking innovative activities. A study on the R&D intensity of 223 Indian pharmaceutical firms for 1999–2000 found that 139 firms had zero value of R&D intensity and another 47 had an R&D intensity of less than 1 per cent of sales (Pradhan 2002). Together these firms accounted for 83 per cent of the total firms under study, thereby suggesting that a large number of Indian pharmaceutical firms did not engage in any R&D activity, and the majority of those that did spent a very small proportion of their turnover on R&D.

Since capital goods and machinery are often acknowledged to contain new technologies in an embodied form, the fixed capital stock per labour may indicate inter-firm differences in employing embodied innovation in production activities. Table 10.3 presents the capital-labour ratio measured as the invested capital per man-day of work done by an employee for small units as well as large firms. Unsurprisingly, small firms, defined on the basis of a limitation of investment in plant and machinery, had a capital-labour ratio of Rs 1,404 as compared to Rs 5,468 for large units. Clearly, resource-constrained small firms have a tendency to employ more labour-intensive techniques of production than large firms, and are thus characterized by a relatively lower capital–labour ratio.

Table 10.3: Factor and Skill Intensities

Indicators	*Small Units*	*Large Units*	*All Units*
Capital–Labour Ratio (Rs)	1,404	5,468	2,896
ICT Intensity (%)	1.17	0.83	0.91
Skill-Intensity (%)	23	33	27

Source: Computed from unit-level data of ASI, 2000–01.
Note: ICT intensity is the percentage share of computer hardware and software in net fixed assets; skill intensity denotes the ratio of white-collar workers working in clerical, supervisory, managerial, marketing divisions to blue-collar workers who typically do manual labour factories.

In terms of investments in ICTs, which comprise the core technology of a knowledge-based industry, Indian pharmaceutical firms have performed poorly across firm sizes. It has been estimated that the cumulative net investment in computers and computer software accounted for even less than 1 per cent of the net value of the fixed assets of these firms in 2000–01. This is pathetically low when compared to the above-15 per cent share of ICT hardware and software in the total non-residential investment of the business sector in Organisation for Economic Co-operation and Development(OECD) countries in 1999 (OECD 2001). In comparison to large units, small units had a higher ICT intensity, suggesting that small firms are relatively more inclined to adopting ICT as a new business strategy. However, small firms had lower skill intensity than large firms. They had employed just 23 white-collar workers per 100 blue-collar workers employed, whereas large firms employed 33 white-collar workers (Table 10.3). Typically, white-collar workers have a relatively higher level of human capital, skills and knowledge than blue-collar workers. The former are involved in planning and establishing production targets, organizing materials and inputs, training and assignment of work to employees, coordinating work with different departments, personnel management, adjusting and testing machinery, marketing of the product, R&D activities, etc. Their functions play a major role in the enterprise-level technological and innovative efforts.

Given that small pharmaceutical firms utilize less machinery and capital goods per employee, have a lower proportion of

skilled workers, and undertake relatively lower levels of R&D than large pharmaceutical firms, these differences may translate into lower productivity levels for them. It is only on the use of ICT that small firms have performed relatively better than large firms. The estimated partial productivities for small and large firms are presented in Table 10.4. Small pharmaceutical firms' labour productivity, measured as the net value added per man-day of work by employee, was recorded to be about Rs 405, compared with Rs 893 for large pharmaceutical units, in 2000–01. This lower productivity of small firms relative to that of large firms, as mentioned earlier, is partly due to a relatively lower capital–labour ratio, implying small firms' greater reliance on labour-intensive techniques of production vis-à-vis large firms (Figure 10.1). However, a large part of the productivity gap between small and large units still remains to be filled, and other factors like R&D and skill may explain the productivity differences.

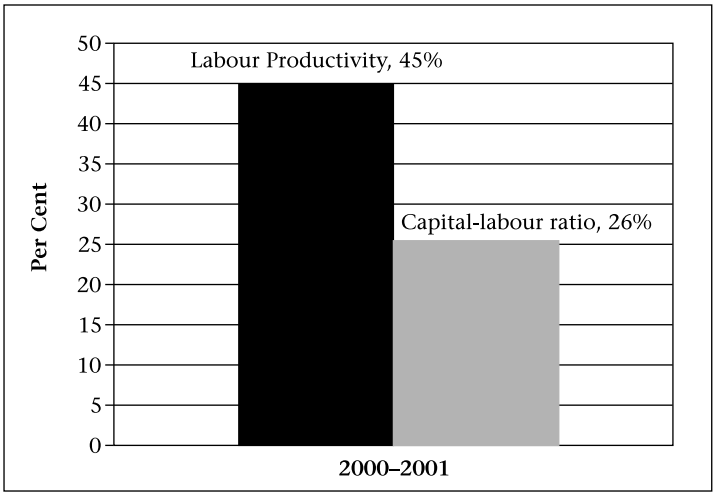
Table 10.4: Partial Factor Productivities, 2000–01

Indicator	*Small Units*	*Large Units*	*All Units*
Labour Productivity (Rs)	405	893	585
Capital Productivity (Rs)	0.29	0.16	0.20

Source: Computed from unit-level data of ASI, 2000–01.

In summary, this section shows that small pharmaceutical units constitute the bulk of the pharmaceutical sector in India, with significant contribution to total pharmaceutical production and employment. Overall, the industry is regionally concentrated in a few states like Maharashtra, Gujarat, Andhra Pradesh, and Uttar Pradesh. Small firms are characterized by relatively lower levels of capital-to-labour ratio, skill ratio and innovative activities than large firms, although on ICT intensity they have performed relatively well. Because of these factors the level of small units' labour productivity remains well below that of large firms in India. A continuing gap in the levels of productivity is not conducive for the survival of small firms under the new policy regime, where productivity and technology form the cornerstone of competitiveness in the marketplace.

Figure 10.1: Small Units' Labour Productivity and Capital–Labour Ratio Relative to Large Units (in percentage terms), 2000–01



Source: Based on the feeling of Table 10.4.

New Policy Regime and its Implications for Small Pharmaceutical Units

The new policy regime for the pharmaceutical industry covers a number of areas like intellectual property rights (IPR), trade, industrial and pricing policy, foreign investment, among other things. Following are the important implications of the new policy regime that can be deduced for the small pharmaceutical units:

New IPR Regime and Innovative Activities of Small Firms

Under the new IPR regime, the challenge for Indian small pharmaceutical firms is to remain innovative, as they were under the earlier regime. Under the Indian Patent Act 1970, small firms with their resource limitation had relied primarily on outside sources of R&D, like products of foreign firms, and effectively invested their limited internal R&D fund for reverse engineering and developing cost-effective processes.

However, the implementation of the WTO agreement on the Trade-related Intellectual Property Rights (TRIPS) led to a number of radical changes in the Indian IPR regime. Three amendments — in March 1999, June 2002 and April 2005 — on the Patent Act 1970 have been carried out to bring the Indian patent regime in harmony with the requirements of TRIPS. This new IPR regime extended patent protection to products in drugs as well as the food and chemicals sectors, besides increasing the duration of the patent term to 20 years. The burden of proof has been reversed in the case of a process patent, and a patent owner may not produce the product locally. The flexibility in granting compulsory licensing has also been greatly reduced.

Therefore, under the new IPR regime, the earlier technological strategy of imitation, reverse engineering and adaptation is not feasible. Small firms are now de-linked from a substantial source of technical innovation that comes from a reverse engineering strategy in the case of drugs patented internationally after 1 January 1995. Resource-constrained small firms are thus discriminated in favour of large domestic and foreign firms that can afford the massive research investment required for product development. For the existing and emerging generic segments consisting of drugs patented before 1995 and drugs going off-patent, small firms are still free to pursue their strategy with regard to technology. However, they definitely require strong technology-related support because, unlike large firms, small firms do not have huge resources to expand their internal sources of knowledge. The government can play a major role in providing external sources of technology to small firms and linking their innovative activities with the resources of R&D institutions and universities. As firms that do not undertake innovative activities in-house are those that have failed to absorb learning from external sources like the government, universities and research institutions, small firms must upgrade their internal R&D activities. Hence, the strengthening of internal R&D efforts, along with the provision of external sources of technology, is the most crucial strategy for small pharmaceutical firms to remain competitive. The role of the government in creating a Pharmaceutical Research and Development Support Fund as a follow-up of the Mashelkar

Committee Report is certainly appreciable, but part of that fund must be directed towards the research needs of small pharmaceutical units.

The government should carefully interpret and implement the data protection requirement under Article 39.3 of the TRIPS. Marketing approvals and limited data protection can be given to only those pharmaceutical products which utilize a new chemical entity (NEC), and not to a complete set of variations of the same drugs submitted by a patent holder. The demand for the evergreening of a patent by foreign firms which submit different derivatives of the same drug as an NEC, but which have no therapeutic advantage, must be resisted. Data protection should not be granted to different derivatives and to changes in the process of the drug delivery of an existing drug which is going offpatent in the near future. Otherwise, a blanket grant of data protection and an extension of the protected period would not only delay the entry of small and large domestic pharmaceutical firms into the emerging generics, but also hurt domestic innovative activities.

Small pharmaceutical firms can use ICT as a tool for reducing their transaction- and search-related costs and to improve their efficiency. This is an alternative strategy which can allow them to survive in the existing generics segment and to meet the competitive challenges from large firms. Small firms should increase their information technology (IT) investment to at least 5 per cent of their fixed assets. ICTs have been playing a major role in a number of global industries by offering an effective and cheaper information system and management between producers and customers, and producers and input suppliers, as well as interaction with government agencies. Hence, ICT can be a strategic strategy for small firms to improve their productivity and reduce costs.

De-reservation and Shrinking Government Procurement Preferences

Many small pharmaceutical firms in India have grown in response to the policy of reservation and guaranteed market offered by government procurement. However, such favourable policy treatment is fast disappearing. In this case, small

firms must strengthen their niche businesses with increased technological activities, improved qualities, etc. The implementation of good manufacturing practices may be costly for small firms in the short run, but it is surely going to enhance their market competitiveness in government healthcare procurement, and in domestic and overseas markets. There has been a clear tendency among small firms, under the Confederation of Indian Pharmaceutical Industry (CIPI), to delay the implementation of Schedule M that contains norms for good manufacturing practices set by the World Health Organization (WHO). Under their pressure, the government had extended the deadline for the implementation of Schedule M from 31 December 2003 to 31 December 2004, and then to 30 June 2005. While a majority of the large units have already taken steps to bring in the manufacturing standards mandated by highly regulated marketplaces like the US, Europe and Australia, the small firms' approach in this regard has been reluctant. As good manufacturing practices (GMP) are considered the benchmark of product quality, it is important not only for maintaining the market share in the domestic market, but also for accessing extremely competitive export markets. The only factor that is inhibiting small firms in adopting the GMP criterion is their resources limitation. Therefore, the government should set up a special fund with the help of financial institutions, credit agencies and industry bodies in line with the Pharmaceutical Research and Development Support Fund R&D fund to help small firms in complying with quality standard norms. Given their valuable contribution the to domestic drugs' production and employment in the country, small firms need serious policy support from the government.

Trade Liberalization and Small Firms

With an increasing emphasis on the reduction of custom duties on imports in the 1990s, the pharmaceutical sector also witnessed drastic cuts in tariff barriers. In the Union Budget 1996–97, for a group of specified drugs falling under Chapter 30 and specified bulk drugs falling under Chapter 29 of the First Schedule to the Customs Tariff (CT) Act 1975, custom duty was reduced to 20 per cent from 25–50 per cent. On codeine

phosphate and narcotine, it was reduced from 25 per cent to 20 per cent, and for specified veterinary drugs and other products, from 15 per cent to 10 per cent. The Union Budget 1997–98 granted full exemption from customs duty on specified life-saving drugs/medicines and diagnostic kits, and customs duty on homoeopathic drugs was slashed from 25 per cent to 20 per cent. In the Union Budget 2002–03, the peak customs duty on raw materials and bulk drugs was brought down from 35 per cent to 30 per cent. The Union Budget 2003–04 has further accelerated trade liberalization with respect to the drug industry: Drugs and materials imported or produced domestically for clinical trials are being exempted from customs and excise duties. The list of life-saving drugs attracting zero customs duty stands expanded, and the customs duty on specified life-saving equipment has been reduced from 25 per cent to 5 per cent, even as these have also been exempted from CVD (countervailing duty). The basic customs duty on glucometers and glucometer strips has been reduced from 10 per cent to 5 per cent, and veterinary drugs saw customs duty come down from 15 to 10 per cent. The Union Budget 2005–06 has reduced the peak custom duty on bulk drugs from 20 per cent to 15 per cent.

This policy of trade liberalization has, however, disproportionately affected small pharmaceutical firms in India. Specifically, the impact of reduction on import duties on bulk drugs has negatively affected small firms, since they are more active in the production of bulk drugs than in formulation. Evidence suggests that the Indian bulk drugs' industry, dominated mostly by small firms, is incurring a loss of business worth Rs 2,500 crore a year due to imports of cheap bulk drugs from China (*Business Standard* 2006). It is estimated that over 35 per cent of the products manufactured by Indian small-scale units of bulk drugs are available from China at a much lower price. As a result, small units making conventional bulk drugs like paracetamol and analgin have already stopped production, and small units producing bulk drugs like Azithromicin, Clarithromycin, Ciprofloxacin, Norfloxacin, Roxycomycin, Cephalosporins, and Anti-quinolones are on the verge of halting their production. On the other hand, large pharmaceutical units that are unaffected by reduced customs duties

on bulk drugs are shifting their input requirement to imported Chinese bulk drugs because of the cost-advantage offered by the latter. The fact that many of these drugs, like paracetamol, are reserved items for the small-scale sector shows that reservation as a policy tool for promoting small firms has no relevance in a liberalized trade regime.

This competition offered by imports and the inability of Indian small firms to stay competitive suggests that radical measures have to be taken. Small firms have to upgrade their manufacturing practices and quality standards, cut down costs, and improve organizational efficiency and marketing strategy. The government can help these producers by a variety of green-box incentives, including offering support for innovation and upgradation of quality. Besides that, small firms must focus on export activities to counteract their declining share in the domestic market. Since importers of bulk drugs from other countries are demanding stricter quality compliance, implementation of the revised Schedule M is important. Small firms can also focus on emerging generic markets, overseas and at home, with a number of drugs going offpatent in the coming years (Table 10.5). In this case, export and contract manufacturing of generics can be a growth strategy for small firms, provided they have the required technology-support programme. Presently, very few small firms have the capability to meet the growing outsourcing demands of foreign firms. Innovation clustering for small pharmaceutical firms with strong support from the Technology Upgradation Funding Scheme can help them catch up with the rapidly emerging outsourcing trends in the global pharmaceutical industry. Establishing Special Economic Zones (SEZs) for small pharmaceutical firms can also be helpful from the export point of view.

Tax-free Zones: MRP-based Excise and Small-scale Units

With the objective of providing impetus to the industrialization process in the backward regions of the country, the government has been adopting an area-based tax-holiday scheme. As a part of this strategy, specified areas in selected states like

Table 10.5: Drugs Going Off-Patent in the period 2005–13

Names of Drugs	*Patent Expiry Date*
Azithromycin	1-11-2005
Pioglitazone	17-01-2006
Tiludronate disod.	24-10-2006
Sumatriptan	28-12-2006
Terbinafine	29-12-2006
Ibadronate Sod.	9-7-2007
Budesonide	13-03-2007
Dofetilide	25-09-2007
Resperidone	29-12-2007
Riseperidone	29-12-2007
Amlodipine	1-8-2008
Levofloxacin	1-10-2008
Salmeterol	12-2-2008
Natritriptan	12-8-2008
Paroxetine	24-09-2008
Valporate SemiSod.	29-01-2008
Rosiglitazone	30-08-2008
Losartan Pot.	11-8-2009
Zafirlulkast	26-09-2009
Risedronate	10-12-2013

Source: Confederation of Indian Pharmaceutical Industry, Circular No. 4, dated 11 August 2005.

Himachal Pradesh, Uttaranchal, Sikkim, Jammu & Kashmir, and Gujarat have declared a number of tax incentives, including a 10-year excise holiday and full income-tax waiver for specific years. In August 2006, the excise-free zone status for new units coming into production or taking up substantial expansion in specified areas of Himachal Pradesh, Uttaranchal, and Sikkim was extended to 30 March 2010.

This area-based tax holiday has created two groups of states — the tax-exempt and non-tax exempt states, with a 40 per cent tax gap between them (*Tribune* 2006). The impact of such a policy on small pharmaceutical manufacturers outside such tax-free zones has been strongly negative. It is estimated that about 1,000 pharmaceutical units in Maharashtra alone have either migrated or shut down in the last couple of years (*Pharmabiz* 2006). The number of pharmaceutical units in Mumbai has decreased by 50 per cent within the last three to five years. In Punjab and Haryana, neither did existing units

expand their production capacity in 2005–06, nor did any new pharmaceutical unit get established (*Tribune* 2006). Small pharmaceutical units situated in southern states like Tamil Nadu have also suffered seriously. This policy has discriminated against small pharmaceutical units situated in other non-tax free areas in the country too, which have been either forced to migrate or close down. Since the regional location of the small-scale sector is important for meeting the requirement of health security at the local level, forced concentration of these units in a few tax-free zones is clearly undesirable; it is better to do away with area-based tax exemption for the pharmaceutical sector.

Since January 2005 the government has introduced MRP-based excise duty for the pharmaceutical units in the country. As per this policy, the government levies a 40 per cent excise duty on the maximum retail price (MRP) of drugs and not on the manufacturing expenses (i.e., on the ex-factory price), which was the practice earlier. Under the new excise scheme, most small-scale units are likely to cross the excise exemption limit of Rs 1 crore, thereby effectively defeating the basic purpose of the small-scale exemption limit (*Express Pharma Pulse* 2005). Under the earlier ex-factory price-based excise duty structure, a majority of small units had a turnover of about Rs 50 lakh, and now, based on MRP (which includes marketing and distribution expenses), their turnover is likely to reach Rs 1 crore. As small units are operating at low profit margins and are incurring additional expenses to upgrade their manufacturing facilities to be GMP compliant, this MRP-based excise regime is going to affect them negatively. In this context, the government should increase the small-scale industry's exemption limit for excise from the existing Rs 1 crore of turnover to Rs 2 crore.

Conclusion

Indian pharmaceutical industry is home to a large number of small units that contribute a significant proportion to pharmaceutical production and employment in India. The growth of small firms can be seen through the strategic policy interventions undertaken in the past, which included a

soft patent regime, relaxation in the industrial licensing and pricing policy, reservation of items for exclusive development, and preference in government procurement. Regionally, the industry is concentrated in a few states in India such as Maharashtra, Gujarat, Andhra Pradesh, and Uttar Pradesh.

With the implementation of economic reforms in India and the adoption of the provisions of the WTO, the regulatory regime governing small scale-units became more stringent in terms of product patent and emphasis on quality. In India, small pharmaceutical firms are characterized by a lower level of labour productivity (vis-à-vis that of large pharmaceutical firms) because of their reliance on more labour-intensive techniques of production. They also employ, disproportionately, more unskilled workers relative to skilled workers as compared to their larger counterparts. Given the small firms' resource constraints, they incur a limited internal budget for innovative activities unlike large-scale units. As a result of low skills and limited investment in capital goods and R&D, their productivity is much lower than that of their larger counterparts. Although small firms have a tendency to spend more on ICT than large firms' that amount is just about 1 per cent of their fixed assets. Further, small firms are more reluctant in adopting good manufacturing practices, whereas large units have already gone much ahead in this direction.

The challenge for survival under the new regime is quite formidable for small firms. Inadequacies of capital, technology and skills are prohibiting small firms from staying competitive, and the government can help this sector in several ways. A special fund can be created to enable small-scale units to adopt strict quality standards and to help the sector create clustering for innovation and skill enhancement. Encouraging these firms to improve productivity and participate in the international markets may partly negate the unfavourable impact of cheap Chinese bulk drugs imports into the country. Given the role that small firms had played in achieving self-sufficiency in technology-intensive bulk drugs and raw materials, and in keeping the prices of life-saving drugs affordable, it is important that they should be given strong policy support to enhance their competitive capabilities.

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