

**Working Paper
No: 2007/02**

**NEW POLICY REGIME AND
SMALL PHARMACEUTICAL FIRMS
IN INDIA**

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January 2007

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Abstract

Small firms dominate the Indian pharmaceutical industry with significant contribution to the national drug production and employment. They had played an important role in enhancing domestic technological capabilities in drugs production and have been instrumental in keeping drugs prices affordable for the Indian populace in remote rural areas. This rise of small firms in this sector has been facilitated by a set of strategic government policies implemented in the past decades like adoption of a process patent regime, relaxation granted from price control and industrial licensing requirement, reservation of items for exclusive production and preference in government procurement, etc. Since 1990s the regulatory regime for small firms underwent dramatic changes with withdrawal of most of the favorable policies and implementation of regulations like a long-term product patent regime, withdrawal of exemption from price controls, implementation of good manufacturing practices, etc. These new policies have a number of implications for the survival and growth of small pharmaceutical firms today.

Keywords

Small Firms; TRIPS; Patent

JEL Classification

L11; F13; O34

Acknowledgements

This paper is prepared for 30th Indian Social Science Congress, December 27- 31, 2006, Karaikudi, Tamil Nadu, India.

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NEW POLICY REGIME AND SMALL PHARMACEUTICAL FIRMS IN INDIA

*Jaya Prakash Pradhan**

1. Introduction

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

While there is a growing appreciation about the role of strategic government policy on the competitiveness of Indian pharmaceutical enterprises, the issue is less analyzed 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 have clearly contributed in enhancing indigenous capability in the sector. In fact, the available data for 1985–86 suggested that small firms had a higher share of basic drugs (i.e. bulk drugs) production over foreign firms in India (Kumar and Pradhan 2003, Table-1, p. 17). These small scale units like their large domestic counterparts have grown around a soft patent regime that India had adopted in the early 1970s. Under the process patent regime, these firms had effectively utilized the technological imitation, reverse engineering, and process development as means of advancing their firm-specific competitive capabilities. They made rapid technological advances in developing own cost-effective processes and successfully competed with foreign firms in the domestic and overseas markets.

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Apart from enjoying a favourable patent regime, small producers of pharmaceutical products in India had received special policy focus in 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 skill, etc. have been well recognized and from the very beginning of industrial policy like the first Industrial Policy Resolution (IPR) 1948, these firms have been accorded protection from large firms as well as provided with various support measures and incentives. Several policy measures like provision of finance, training, 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 pharmaceutical sector, small firms have been facilitated by various favourable policies like exemption from the Drug Price Control Order (DPCO) and drug policy parameters, reservation of drugs for exclusive production in small scale sector¹, 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 small Indian private sector in the production of bulk drugs has gone 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 (Kumar and Pradhan 2003, Table-1, p. 17). Over the years 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, etc². Further, this sector has been a source of meeting substantial demand from the Government Health Care Programme. This vibrant SME sector functioning on very low profit margins, thus, has played an important role in keeping the essential life saving drugs at affordable prices and in remote rural areas, ensuring health security of the Indian masses.

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

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.

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

widespread reduction in import duties, etc. have radically changed the overall business environment. Along with these changes in the domestic policies, the global policy environment also has undergone rapid transformation with the emergence of the World Trade Organization (WTO) and the implementation of liberalization measures at various global levels—individual countries, bilateral, regional and multilateral level. This large-scale policy liberalization has resulted in intense competition for the survival and growth among firms. Small firms, eventually, face a globalized competition with urgency like never before.

The liberalization of policy regime with respect to the pharmaceutical sector in the 1990s poses many challenges for the small enterprises. With the progressive reduction of list of drugs under the DPCO, the relaxation granted to the small scale sector's products has been effectively reduced overtime. Finally the 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 since DPCO 1987. The permission of 100 per cent foreign direct investment (FDI) and removal of the restriction on large-size firms required that small firms have to enlarge their market focus and competitive strategies. The adoption of product patent regime and emphasis on quality and good manufacturing practices are likely to demand higher technological efforts from small firms (Das and Nair 2004). As small firms, often are constrained by their size limitation in sales, investment, or employment, and with small financial resources, meeting these new challenges may not be assumed to be as smooth as in the case of large enterprises.

In the above backdrop, the study examines the performance of small pharmaceutical firms relative to large pharmaceutical firms. This involves comparative analysis of productivity, technology and skill performance of SMEs vis-à-vis large firms. The study also explores the implications of new policy regime for small pharmaceutical firms.

2. Database, Definition and Size of Small Pharmaceutical Units

As of now, there is hardly any accurate estimation about the size of SME sector in pharmaceutical industry. Most of the official statistics simply rely on the estimates provided by private industry associations like the Organization of Indian pharmaceutical Producer of India (OPPI) and the Indian Drugs Manufacturers Association (IDMA). However, estimates from these sources are not reliable at all. For example, the OPPI has estimated that there are about 20,053 units in the pharmaceutical sector in 2000–01, of which just 250–300 units are large units. But in 2003–04, it is estimated that there are just 10,000 units of which 300 units are large units. It's not clear as to how the total number of units halved just within a four-year period. Although the information about the

organized sector is available from the Annual Survey of Industries (ASI), 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, has also faced a problem regarding data on small scale sector in 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” (p. 9).

This study has made an attempt to provide estimates on the size of pharmaceutical small scale sector in the organized manufacturing sector. This sector only consists of those units that are registered under the Factories Act, 1948 and employing 10 or more workers using power and those employing 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 informal/un-organized small scale segment producing traditional systems of medicines like Ayurveda, herbal, Siddha, Unani and naturopathy.

The study had collected unit level unpublished data from the Annual Survey of Industries for the year 2000–01. Since we have just one year data, the study can only address the static differences between small and large pharmaceutical units in efficiency and on other performance indicators. In spite of this limitation, the study can provide the exact size of small scale sector and its contribution to domestic pharmaceutical production and employment.

The official definition of small pharmaceutical units has been adopted in the study. 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. Then the investment limit was reduced to Rs. 10 million in 1999 and later raised to 50 million for some industries including pharmaceuticals since October 2001 (Das 2006). Following this criterion, those pharmaceutical units are classified as small whose net value of plant and machinery is up to Rs. 50 million and units that exceeded this limit were 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 2872 organized units operating in the pharmaceutical industry, 2623 units were small units as

compared to just 249 large units (Table-1). The small scale units are playing an important role in the domestic sector, contributing 65 per cent of employment and 42 per cent of total pharmaceutical production. This suggest that small firms have grown significantly over the past decades since 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 drugs production and job creation.

Table-1
Size of Small Scale Sector, 2000-01

<i>Characteristics</i>	<i>Small Units</i>	<i>Large Units</i>	<i>All Units</i>
No. of units (numbers)	2623 (91)	249 (9)	2872 (100)
Employment (numbers)	162487 (65)	86559 (35)	249046 (100)
Net Fixed Investment (Rs. Lakhs)	28573 (29)	68469 (71)	97042 (100)
Total Output (Rs. Lakhs)	1511366 (42)	2128004 (58)	3639370 (100)
NVA (Rs. Lakhs)	199337 (44)	254911 (56)	454248 (100)

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

Note: Percentage shares are in the parenthesis.

Indian pharmaceutical enterprises, in general, tend to be regionally concentrated in a few states. Out of every 100 pharmaceutical units, 40 units are located in just two states such as Maharashtra and Gujarat (Table-2). Andhra Pradesh and Uttar Pradesh respectively had about 12 and 7 units. These top four states together accounted for about 60 per cent of total pharmaceutical units in India. They are also major hosts for small units, hosting about 60 per cent of total number of small pharmaceutical units. Interstate 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 relatively higher intensity to host small units as compared to large units. In terms of total pharmaceutical production, similar feature of geographical concentration in Indian pharmaceutical sector can be noticed. Maharashtra and Gujarat, together account for about 43 per cent of total production. Top four states like Maharashtra, Gujarat, Andhra Pradesh and Uttar Pradesh contributed about 55 per cent of total production.

Table-2
State-wise Distribution of Pharmaceutical Sector in India, 2000-01

State	No. of units (Number)			Total Production (Rs. Lakhs)		
	Small Units	Large Units	All Units	Small Units	Large Units	All Units
Andhra Pradesh	288 (11.0)	49 (19.9)	338 (11.8)	108617 (7.2)	312514 (14.7)	421130 (11.6)
Assam	6 (0.2)		6 (0.2)	696 (0.0)		696 (0.0)
Bihar	21 (0.8)		21 (0.7)	2766 (0.2)		2766 (0.1)
Chandigarh	3 (0.1)	1 (0.5)	4 (0.1)	165 (0.0)	2778 (0.1)	2943 (0.1)
Chhatisgarh	11 (0.4)		11 (0.4)	1390 (0.1)		1390 (0.0)
Dadra And Nagar Haveli	17 (0.6)	4 (1.5)	21 (0.7)	42330 (2.8)	13866 (0.7)	56196 (1.5)
Daman & Diu	24 (0.9)	7 (2.8)	31 (1.1)	37023 (2.4)	0 (0.0)	37023 (1.0)
Delhi	66 (2.5)		66 (2.3)	26744 (1.8)		26744 (0.7)
Goa	42 (1.6)	12 (4.8)	54 (1.9)	44902 (3.0)	61053 (2.9)	105955 (2.9)
Gujarat	534 (20.4)	33 (13.1)	567 (19.7)	247309 (16.4)	324450 (15.2)	571759 (15.7)
Haryana	115 (4.4)	2 (0.8)	117 (4.1)	104430 (6.9)	52333 (2.5)	156763 (4.3)
Himachal Pradesh	22 (0.8)	13 (5.2)	35 (1.2)	19080 (1.3)	93455 (4.4)	112535 (3.1)
Jammu & Kashmir	5 (0.2)		5 (0.2)	288 (0.0)		288 (0.0)
Jharkhand	4 (0.1)		4 (0.1)	1959 (0.1)		1959 (0.1)
Karnataka	94 (3.6)	15 (5.9)	108 (3.8)	66446 (4.4)	143044 (6.7)	209489 (5.8)
Kerala	89 (3.4)	8 (3.0)	97 (3.4)	28171 (1.9)	2222 (0.1)	30393 (0.8)
Madhya Pradesh	102 (3.9)	19 (7.6)	121 (4.2)	92072 (6.1)	123555 (5.8)	215627 (5.9)
Maharashtra	548 (20.9)	59 (23.6)	607 (21.1)	451475 (29.9)	542386 (25.5)	993862 (27.3)
Orissa	44 (1.7)	1 (0.4)	45 (1.6)	3051 (0.2)	4290 (0.2)	7341 (0.2)

contd...

State	No. of units (Number)			Total Production (Rs. Lakhs)		
	Small Units	Large Units	All Units	Small Units	Large Units	All Units
Pondicherry	10 (0.4)	1 (0.4)	11 (0.4)	10989 (0.7)	10250 (0.5)	21239 (0.6)
Punjab	65 (2.5)	7 (2.8)	72 (2.5)	16957 (1.1)	170507 (8.0)	187464 (5.2)
Rajasthan	59 (2.3)	3 (1.2)	62 (2.2)	31875 (2.1)	35517 (1.7)	67393 (1.9)
Tamil Nadu	136 (5.2)	7 (2.8)	143 (5.0)	78072 (5.2)	66434 (3.1)	144506 (4.0)
Uttar Pradesh	195 (7.4)	7 (2.8)	202 (7.0)	52959 (3.5)	166241 (7.8)	219199 (6.0)
Uttaranchal	31 (1.2)	1 (0.4)	32 (1.1)	3378 (0.2)	2465 (0.1)	5843 (0.2)
West Bengal	92 (3.5)	1 (0.4)	93 (3.2)	38221 (2.5)	646 (0.0)	38867 (1.1)
All India	2623 (100)	249 (100)	2872 (100)	1511366 (100)	2128004 (100)	3639370 (100)

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

Note: Percentage shares are in the parenthesis.

In the context of new policy regime, technology and productivity are most important determinants of survival and competitiveness of pharmaceutical firms. Small firms are required to urgently upgrade their internal sources of technology like expanding in-house R&D activities, employing more skilled labour, investing in modern machinery and information and communication technologies (ICTs), providing training to their technical manpower, etc. 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 be certainly predicted that small pharmaceutical firms considerably lagged behind their large counterparts in undertaking innovative activities. A study on R&D intensity of 223 Indian pharmaceutical firms for 1999–2000, has found that 139 firms had zero value of R&D intensity and another 47 firms had R&D intensity of less than 1 per cent of sales (Pradhan 2002). Together these firms account for 83 per cent of total firms under study and thus suggesting that a large number of Indian pharmaceutical firms do not engage in any R&D activity and the majority of those engaged spent a very small proportion of their turnover.

Since capital goods and machinery are often acknowledged to contain new technologies in embodied form, fixed capital stock per labour may indicate inter-firm differences in employing embodied innovation in production activities. Table-3 presents the capital-

labour ratio measured as the invested capital per manday of work done by the 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. 1404 as compared to Rs. 5,468 of large units. Clearly resource-constraint small firms have a tendency to employ more labour-intensive techniques of production than large firms and thus are characterized by a relatively lower capital-labour ratio.

Table-3
Factor and Skill Intensities, 2000–01

<i>Indicators</i>	<i>Small Units</i>	<i>Large Units</i>	<i>All Units</i>
Capital-Labour Ratio (Rs.)	1404	5468	2896
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 in a factory.

In terms of investments in ICTs, which is 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 one per cent of net value of 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 total non-residential investment of the business sector in 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 in 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-3). Typically white-collar workers have relatively higher level of human capital, skills and knowledge than blue-collar workers. White-collar workers are involved in planning and establishing production targets, 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 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

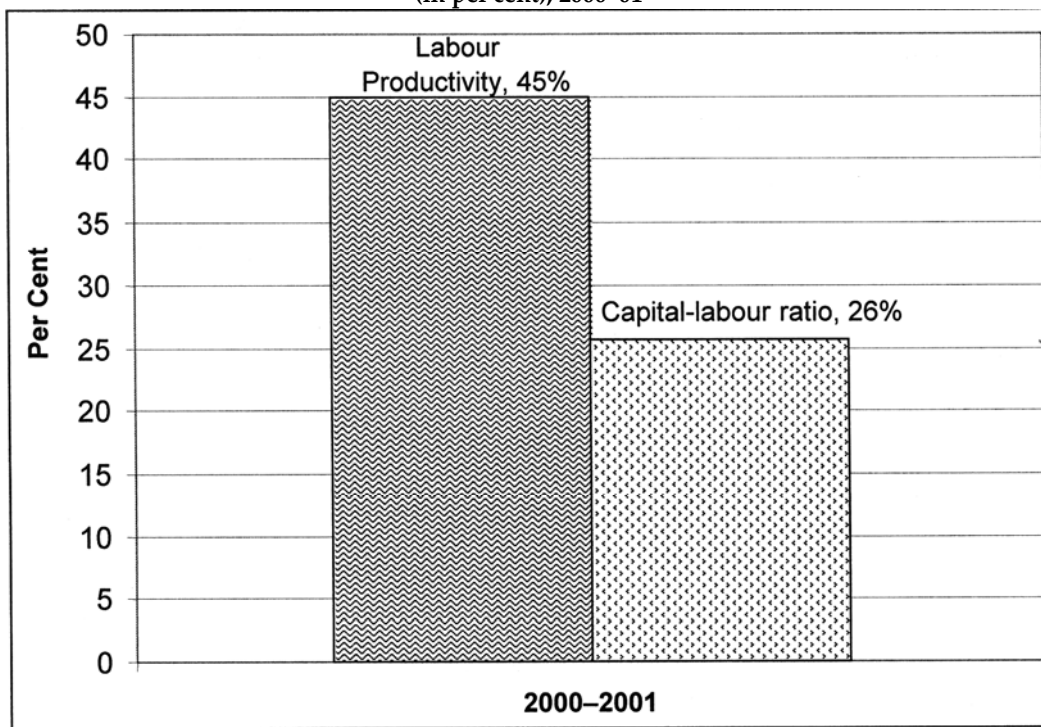
relatively better than large firms. The estimated partial productivities for small and large firms are presented in Table-4. Small pharmaceutical firms' labour productivity, measured as net value added per manday of work by employee, is about Rs. 405 compared with Rs. 893 of large pharmaceutical units in 2000-01. This lower productivity of small firms relative to large firms as mentioned earlier is partly due to a relatively lower capital-labour ratio implying reliance on more labour-intensive techniques of production than large firms (Figure-1). However, a large part of the productivity gap between small and large units still remain and other factors like R&D and skill may explain the productivity differences.

Table-4
Partial Factor Productivities, 2000-01

<i>Indicator</i>	<i>Small Units</i>	<i>Large Units</i>	<i>All Units</i>
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.

Figure-1
Small units labour productivity and capital-labour ratio relative to large units
(in per cent), 2000-01



In summary, the section shows that small pharmaceutical units constitute the bulk of the pharmaceutical sector in India with significant contribution to the 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 a relatively lower level of capital to labour ratio, skill-ratio and innovative activities than large firms whereas 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 corner-stone of competitiveness in the market place.

3. New Policy Regime and Implications for Small Pharmaceutical Units

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

3.1. 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 World Trade Organization (WTO) agreement on the Trade-Related Intellectual Property Regime (TRIPS) had 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 has been carried out to bring Indian patent regime in harmony with the requirements of TRIPS. This new IPR regime had extended patent protection to products in drugs, food and chemicals sectors, besides increasing the duration of patent term to 20 years. The burden of proof has been reversed in the case of a process patent and patent owner may not produce the product locally. The flexibility of granting compulsory licensing has been reduced greatly.

Therefore, under the new IPR regime, 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 reverse engineering strategy

in the case of drugs patented internationally after January 1, 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 technology strategy. However, they definitely require strong technology supports because unlike large firms, small firms do not have huge resources to expand their internal sources of knowledge. Government can play a major role in providing external sources of technology to small firms and linking their innovative activities with 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 government, universities and research institutions, small firms must upgrade their internal R&D activities. Hence, strengthening of internal R&D efforts with provision of external sources of technology is the most crucial strategy for small pharmaceutical firms to remain competitive. The role of 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 research needs of the small pharmaceutical units.

The government should carefully interpret and implement the data protection requirement under the 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 (NCE) and not to the complete set of variations of the same drugs submitted by a patent holder. The demand for ever-greening of a patent by foreign firms by submitting different derivatives of the same drug as NCE and having no therapeutic advantage must be resisted. Data protection should not be granted to different derivatives and changes in the process of drug delivery of an existing drug which is going off-patent in near future. Otherwise a blanket grant of data protection and extension of 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 of reducing their transaction and search cost 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 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, input suppliers, and interaction with government agencies.

Hence, ICT can be a strategic strategy for small firms to improve their productivity and reduce costs.

3.2. 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, domestic and overseas markets. There has been a clear tendency among small firms under the Confederation of Indian Pharmaceutical Industry (CIPI) to delay implementation of Schedule M that contains good manufacturing practice norms set by WHO. Under their pressure, the government had extended the deadline for implementation of Schedule M from December 31, 2003 to December 31, 2004 and then to June 30, 2005. While majority of the large units have already taken steps to bring in the manufacturing standards mandated by highly regulated market places like US, Europe, and Australia, small firms have been adopting a reluctant approach. As GMP is considered as the benchmark of product quality, it is important not only for maintaining market share in domestic market, but also for accessing extremely competitive export markets. The only factor that is inhibiting the small firms in adopting GMP criterion is their limited resources. Therefore, government should set up a special fund with the help of financial institutions, credit agencies and industry bodies in line with pharmaceutical R&D fund to support small firms to comply with quality standard norms. Given their valuable contribution to domestic drugs production and employment in the country, small firms need serious policy supports from government.

3.3 Trade Liberalization and Small Firms

With increasing emphasis on reduction of custom duties on imports in 1990s, the pharmaceutical sector had also witnessed drastic cuts in tariff barriers. In 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 Act 1975 (CT), custom duty was reduced to 20 per cent from 50/25 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 were slashed from 25 per cent to 20 per cent. In Union Budget 2002–03 the peak customs duty on raw materials and

bulk drugs was cut from 35 per cent to 30 per cent. The Union Budget 2003–2004, has further accelerated trade liberalization with respect to 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 customs duty on specified life-saving equipment has been reduced from 25 per cent to 5 per cent and exempted from CVD (countervailing duty). 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 down from 15 to 10 per cent. The Union Budget 2005–06 has reduced peak custom duty from 20 per cent to 15 per cent on bulk drugs.

This policy of trade liberalization has, however, disproportionately affected small pharmaceutical firms in India. Specifically, the impact of import duties reduction on bulk drugs has negatively affected small firms since they are mostly active on bulk drugs production than in formulation. The 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 cheap bulk drugs imports from China (Business Standard 2006). It is estimated that over 35 per cent of the products manufactured by Indian bulk drug small scale units 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 azithromycin, clarithromycin, ciprofloxacin, norfloxacin, roxycomycin, cephalosporins and anti-quinolones are on the verge of halting the production. On the other hand, large pharmaceutical units that are un-affected by reduced custom duties on bulk drugs are shifting their inputs requirement to imported Chinese bulk drugs because of cost-advantage. Since many of these drugs like paracetamol are reserved item for the small scale sector, this shows that the reservation as a policy tool for promoting small firms has no relevance in a liberalized trade regime.

This import competition and inability of Indian small firms to stay competitive suggests that radical measures have to be taken. Small firms have to upgrade their manufacturing practices, quality standards, cut down cost, improve organizational efficiency and marketing strategy. Government can help these producers by a variety of green-box incentives including 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 bulk drugs importers from other countries are demanding stricter quality compliance, implementation of revised Schedule M is important. Small firms can also focus on emerging generic markets in overseas and home markets with a number of drugs going off-patent in the coming years (Table-5). In this case export and contract manufacturing of generics can be a growth strategy for small firms provided they have

required technology support programme. Presently, very few small firms have the capability to meet growing outsourcing demands of foreign firms. Innovation clustering for small pharmaceutical firms with strong support from Technology Upgradation Funding Scheme can help small firms to catch-up the rapidly emerging outsourcing trends in global pharmaceutical industry. Establishing Special Economic Zones (EPZs) for pharmaceutical small firms can also be helpful from the exporting point of view.

Table-5
Drugs going off-patent during 2005–13

<i>Name of Drugs</i>	<i>Patent expiry date</i>
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
Risperidone	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 August 11, 2005.

3.4. Tax Free Zones, MRP-based Excise and Small Scale Units

With the objective of providing impetus to the industrialization process in the backward regions, the government has been adopting area-based tax holiday scheme. As a part of this strategy, specified areas in selected states like Himachal Pradesh, Uttaranchal, Sikkim, Jammu & Kashmir and Gujarat have declared a number of tax incentives like ten-year excise holiday and full income-tax waiver for the 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, Uttarakhand, and Sikkim has been extended up to March 30, 2010.

This area-based tax holiday had 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 was strongly negative. It is estimated that about 1000 pharmaceutical units have either migrated or shut down in Maharashtra alone in the last couple of years (Pharmabiz 2006). The number of pharmaceutical units in Mumbai has decreased by 50 per cent within the last 3–5 years. In Punjab and Haryana not a single pharmaceutical unit was set up and nor has expansion of any existing units taken place (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 and are either forced to migrate or close down. Since regional location of small scale sector is important for meeting requirement of health security at 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 the MRP-based excise duty for the pharmaceutical units in the country. As per this policy, government had levied a 40 per cent excise duty on maximum retail price (MRP) of drugs and not on the manufacturing expenses (i.e. on 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 and thus effectively defeating the basic purpose of small scale exemption limit (Express Pharma Pulse 2005). Under the earlier ex-factory price based excise duty structure majority of small units had a turnover of about Rs. 50 lakhs and now based on MRP that 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 SSI exemption limit for excise from existing Rs. 1 crore of turnover to Rs. 2 crore.

4. Conclusion

Indian pharmaceutical industry is home to a large number of small units that contribute significant proportion of pharmaceutical production and employment in India. The growth of small firms can be seen through the strategic policy interventions undertaken in the past and covering a soft patent regime, relaxation in 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 adoption of the provisions of WTO, the regulatory regime governing small scale units became more stringent in terms of product patent and quality emphasis. In India small pharmaceutical firms are characterized by a lower level of labour productivity than large pharmaceutical firms because of their reliance on more labour-intensive techniques of production. They had also employed, disproportionately, more unskilled workers relative to skilled workers as compared to their large counterparts. Given the resource constraint they incur a limited internal budget for innovative activities unlike large scale units. As a result of low skill, limited investment in capital goods and R&D, their productivity is much lower than their large counterparts. Although small firms have a tendency to spend more on ICT than large firms but that is just about one 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 on quality direction.

The challenge for survival is quite formidable for small firms under the new regime. Inadequacies of capital, technology and skills are prohibiting small firms to stay competitive and government can help this sector in several ways. A special fund can be created to enable the small scale units to adopt the strict quality standards and help the sector to 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 keeping prices of life-saving drugs at affordable level, it is important that they should be given strong policy supports in enhancing their competitive capabilities.

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