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Global Regulatory Imperatives and Small Firms: Case of the Indian Pharmaceutical Industry

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Abstract

With a clear accent on competitiveness, globalisation exercises significant pressure upon those enterprises long protected and assured of much of the domestic market. As it is becoming increasingly difficult to survive and grow essentially on price competition, the very participation in the global market would entail adhering to quality through substantial investment in R and D. Emphasis on intellectual property protection and the impending WTO have been a cause of much concern especially for the Indian small firms. Through a case study of one of highly regulated industries, that of the pharmaceuticals, this paper enquires into the implications of the technological paradigm shift for small enterprises. Those who would not consider conforming to the regulatory framework (specifically enlisted under the good manufacturing practices of the World Health Organisation) worthwhile, may diversify or exit business. But for those who would, the options are several; the most important being collective action, especially, if the aspiring firms are part of an industrial cluster. Joint business promotion through networking holds much hope for enterprises, despite their small size, to be active players in the global market within the framework of regulations. In any case, the overwhelming presence of MNCs and large domestic firms would continue to influence the behaviour of small firms.

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1. INTRODUCTION

At the root of the process of globalisation, early nineties onwards, lies a fundamental technological paradigm shift which is reflective of the changes in the global technology system. An increasing demand for intellectual property protection especially from the developed nations has been forthcoming largely because "introduction of new generic technologies is closely intertwined with a new wave of internationalization of the economy" and it tends "to blur social boundaries" (van Wijk and Junne, 1993: 4). This is especially so in case of the so-called knowledge industries. Although developing nations are affected differently, depending upon the degree of their assimilation in the global market, globalisation does exercise significant pressure upon those players protected for long and enjoyed much of the domestic market. Whereas it is no longer possible to survive and grow essentially on price competition, thus compromising quality, the very participation in the global market would entail adhering to quality through substantial investment in R and D, either in-house or through collaborative arrangement. `Rules of the game' thus changed would evoke varying responses from the individual firms depending upon their capabilities and preparedness to adjust to the changing production and marketing specifications. The small firms, in all likelihood, will be caught between the horns of dilemma, and such a state would be the most real.

This paper addresses the aforesaid issues through a case study of the drugs and pharmaceuticals industry (called pharma industry, henceforth) in the Indian context. With the World Trade Organisation (WTO) looming large over the Indian industry, the pharma sector is under tremendous pressure to act fast; or to languish, in the least. Being a highly regulated industry, much of the firm response would also be shaped by what the governmental (both provincial and central) regulatory authorities and other domestic competitors propose to do. It is in this relatively uncertain policy environment context that we discuss the case of pharma industry in globalising India.

The pharma industry in India, especially in the small sector, is going through the travails of major transformation, as the global leaders in drug manufacturing are readying themselves for one of the fiercest market wars to be waged in the current decade. The former is faced with challenges on many fronts, the most important ones being an imminent change in the laws concerning intellectual property rights (IPRs) and the government's resolve to enforce stricter manufacturing practices and reference standards so that the domestic industry becomes more acceptable in the international market place. The purpose of this paper is to explore the likely implications of the ongoing efforts at globalising the Indian pharma industry for producers, particularly, the small enterprises.

The paper is organised thus. In Section 2, we describe the salient structural features of the pharma industry and examine the pattern of growth of Indian pharma firms over the two decades spanning the 1980s and 1990s. This is followed, in Section 3, by a detailed exposition of the major changes in the global market scenario and the nature of the regulatory environment that is emerging. Also discussed here are the Indian Patent regime and the likely implications the global policy initiatives might have on it. Section 4 discusses the options available and likely strategies to be adopted by small firms in response to the substantial changes that would concern them. Concluding observations are presented in the form of summary of major findings.

2. PHARMA INDUSTRY: GROWTH AND STRUCTURE

By virtue of the very nature of its product, the pharma industry is highly fragmented (SPJIMR, 1998). The disease profiles vary widely across geographic locations and so are therapeutic categories. Further, in the pharma industry, there is a greater scope for alternative configurations of the value chain. Typically, the pharma industry consists of firms that (a) produce chemical intermediaries for manufacturing bulk drugs; (b) produce bulk drugs, the inputs for formulations; (c) produce formulations, the drugs that finally reach the consumer; and (d) engage in integrated operations like manufacturing bulk drugs and intermediaries, or bulk drugs and formulations or bulk drugs, formulations and intermediaries. In addition, there are specialised marketing firms, distribution units and contract manufacturers, who undertake manufacturing on behalf of other units under a loan licensee agreement. There are also related industries like medical disposables producers and machinery manufacturers.

Ideally, the fragmented structure of the industry should facilitate an environment quite akin to monopolistic competition where many firms can coexist by resorting to product differentiation and diversification. According to information provided by the Organisation of Pharmaceutical Producers in India (OPPI) there were about 20053 units engaged in the production of pharmaceuticals in 1998-99 as against 2257 in 1960-70 and 5156 in 1979-80 (OPP1, 1998-99). Of these, around 8000-9000 are manufacturers and the rest loan licensees. It is estimated that about 40 per cent of the total production in the sector is generated in organised sector that consists of nearly 250 units. The top 400 companies account for 80 per cent of the drug production in the country, while the small and tiny manufacturing units produce the rest 20 per cent. Interestingly, it is the small and tiny sector that caters to about 70 per cent population (Venkateswarlu, 2000). The multinational firms number around 50 and are located mostly in Gujarat, Andhra Pradesh and Maharashtra (IPG, 1998). In other words, the bulk of the pharmaceutical producers in India are in the unorganised sector, most of them being small enterprises, which generates about 60 per cent of drug production.

As shown in Table 1, there was above ten-fold increase in the value of production of drugs in the country between 1980-81 and 1997-98. Though formulations continue to dominate production figures with a share of more than 80 per cent, the indices in Table 1 suggest that the increase in the 1990s was much sharper in the case of bulk drugs.

An estimate made by OPPI shows that the pharma industry employed about 29 lakh people by 1998-99 (OPPI, 1998-99). Interestingly, according to this estimate, nearly 58 per cent of this employment is generated in the distribution trade (Table 2). Ancillary industry accounts for about 26 per cent of the employment. The share in employment of direct production activities comes to 16 per cent - 10 per cent in the organised sector and 6 per cent in the unorganised sector.

In the sphere of trade, compared to the 1980-81 level, the increase in value of exports of both bulk drugs and formulations was phenomenal (Table 3). Notably, there has been a progressive decline in the share of bulk drugs in total imports (Table 4) and a corresponding increase in its share in overall exports of drugs and medicines, while the reverse has been the case with formulations. When expressed as a proportion of domestic production, the export of bulk drugs shows a definite improvement in the 1990s over the 1980s (Table 5).

Thus, the Indian pharma industry has come a long way through the last century to become a fast growing knowledge industry that holds promise for the country both in terms of meeting the domestic demand for medicines as also earning valuable foreign exchange for the exchequer. But in the process, it has come to demonstrate a clearly dichotomous structure, with a few large firms and MNC subsidiaries coexisting with a large number of small firms, largely in the unorganised sector. This has also led to a clear division in the positions held by the small and large firms in matters that concern the governance of business. The Indian Drug Manufacturers Association or IDMA and the OPPI have come to represent this ideological division within the industry. The former (established in 1961) has 500-odd Indian small and medium companies as its members, while the latter (founded in 1965) are comprised of about 70 companies, majority of that are foreign owned.

It seems, however, that the industry cannot just rest complacent on the record of its past performance. The 1990s have seen a few such developments that could completely wipe the gains made so far by this sector, largely, under the protective industrial policy regime as prevailed during the 1950s through the 1980s and an apparently non-interfering international economic order. The package of corrective measures introduced in 1991 (aimed at mending the distortions as resulted from the overindulgence of the state) had a clear accent on trade and industry liberalisation, economic reform and macroeconomic stabilisation as their principal edifices. Internationally, the mid-nineties proved to be a watershed with the release of the Dunkel proposals at the 1994 GATT summit as it envisaged drastic changes in the intellectual property laws and investment policies of countries like India which were known to have lenient rules and laws and weak enforcement mechanisms. The developed countries were insistent that IPRs were trade related and, hence, to be negotiable at the multilateral trade fora. The domestic programme of liberalisation coupled with the global pressure for stricter regulatory norms have redefined the contours of business environment for many industries, including pharmaceuticals.

3. CHANGING GLOBAL MARKET SCENARIO AND REGULATORY MPERATIVES

The market scenario for the pharma industry the world over is fast changing due to a variety of reasons. To begin with, the post-GATT environment has compelled the manufacturers to place "quality" at the centre of all business planning and strategy formulation exercise. Secondly, the generics market in the US and Europe is poised for a boom, as a large number of molecules are going off patent in a couple of years. Thirdly, with new product introductions expected to take a beating in the

product patent era, the generics market in the Indian countryside lies open to the raid of MNCs and large Indian companies. Fourthly, with the amendment of the patent law, the pharma firms will have to commit massive investments to develop new drugs and to put in place an adequate and efficient sales force to market them successfully. Fifthly, other developing countries, especially China, will put up tough competition for Indian manufacturers in the coming years. China, in fact, has been dumping bulk drugs at prices lower than that of Indian manufacturers. The existence of huge production capacities and an inherent strength to deliver large quantities at short notice, are its major advantages. Of late, the Chinese manufacturers have also been rapidly upgrading their technology base. Finally, internationally, the pharma industry is facing sluggish growth in sales and increasing R and D costs. It is shown that in order to maintain an estimated 7 per cent growth, R and D costs are to be slashed by at least 20 per cent. The choices in front of pharma leaders are only two: make R and D more productive, or make each of the drug, a `blockbuster'. The industry forecast suggests that the pharma industry structure would change dramatically by 2005 with only a few producers reigning the market.

In this section, we will examine how the proposed changes in the Patent law and the directives of the World Health Organisation (WHO) to firms to follow good manufacturing practices (GMP) could influence the expectations and growth experience of the pharma industry in India.

3.1 Reforming the Patent Regime

The Indian Patent Act of 1970 succeeded the similar Act – Patents and Designs Act - passed in 1911 during the colonial rule. The growth of the Indian pharma industry in the post-1970s owes a lot to the 1970 Act, which allowed the domestic marketing of patented products without a license. In a number of cases there was no need to discover a new process as the inventor might not have filed an application in India. Even in cases where applications were filed in the country, the patents would normally have expired given their short duration of validity - seven years - under the Act. Importantly, by following a process patent system, the pharma industry has sharpened its competence in applied research for developing process technology for production, especially, of synthetic bulk drugs. It has been argued that the production of pharma products increased several times between the early 1970s and early 1990s, and the country could attain near self-sufficiency in bulk drug production. Also, the time lag between new product introduction in the world market by the inventor and in the Indian market by domestic producers was found to be only about 4.5 years on an average (Keayla, 1994). For most Indian companies

more than 20 per cent of sales came from products those were less than two years old.

The new international trade norms promoted under the aegis of the WTO have put the Indian pharma industry at the threshold of a major transformation. First and foremost, under the new law, the patents are granted for products and not for processes. Also, all patents will have a much longer duration, i.e., 20 years. Other proposed changes in the existing Patent Act include:

- compulsory licensing on the merits of each case, but the patent holder will have to be heard;
- *sui generis* for the protection of plant varieties;
- patenting of micro-organisms;
- no discrimination between imported and domestic products; and
- the burden of proof is on the alleged infringer.

Considering that these changes are to be put in place before 2004, the Government of India has already taken the first step towards incorporating the proposed changes by notifying the Patents (Amendment) Rules 1999. This would enable the grant of exclusive marketing rights (EMRs) for items, which qualify under the eligibility criteria set out in the proposed Act.

The operationalisation of the new patent regime in 2005 is likely to bring about fundamental changes in the composition of the pharma industry. The reintroduction of product patent would mean that companies would not be able to copy drugs patented after 1995. In other words, most Indian companies may face an acute decline in market opportunities after 2005. It is also pointed out that a shift-over to a product patent regime would demand that basic capabilities of indigenous research be developed. While the large players have already begun thinking in the direction of upgrading their R and D capabilities, or tying up with leaders in the field, the small units are caught in an awkward position because of their lack of financial resources, trained manpower, lack of affordable and accessible testing facilities, etc.

It has also been argued that in the changed patent scenario, the compulsory licensing provisions are diluted considerably to ensure 'working' of patents. As importation is considered as working of a patent, the failure to meet the obligation of import alone would be seen as the legitimate condition to issue a compulsory license. This means that the government will not be able to use the compulsory

licensing provision to facilitate technology transfer. These have grave implications for the reform measures underway in the country, the success of which depends on increased and undeterred flow of foreign technology (DRPSCC, 1993).

It needs to be recognised that India does not have an effective import regulation system. Import regulation is limited to specific categories of biological drugs and most of the drugs are imported into the country by providing a warranty and paying a paltry import license fee. There are no statutory provisions to check the manufacturing and quality standards. On the contrary, exporters from India are subjected to strict registration modalities by almost all countries (*Express Pharma Pulse*, March, 2000).

3.2 Good Manufacturing Practices

The concept of Good Manufacturing Practices (GMP) is an integral part of quality assurance – the assurance that medical products are consistently produced and controlled in accordance with quality standards appropriate to their intended use (Ganu *et a*l., 2000). Mandatory GMP were introduced in India after the mid-1980s by introducing schedule M to the Drugs and Cosmetics Act of 1945. Schedule M specifies quality standards under different categories like: (a) general requirements including location, water system and waste disposal; (b) buildings and premises; (c) personal sanitation, hygiene and training; (d) production and operation controls; (e) quality assurance and quality controls, and stability and validation studies; (f) documentation; (g) complaints and self inspection; and (h) special requirements for special individual category of formulations.

In the post GATT scenario, the expression 'quality standards' is expected to mean much more than a simple analysis of the final product for compliance to their labeled claims. It means total control over procedural parameters. In order to build up quality in the end product, adequate precautions are to be taken to prevent contamination in mix-up. In addition to chemical purity, bioavailability and microbiological purity of drugs are to be ensured. The WHO guidelines on GMP for pharma products, the main purpose of which are to prevent contamination and ensure the reproducible quality of drugs by controlling all variables, urge that:

- all manufacturing processes are clearly defined, systematically reviewed, and shown to be capable of consistently manufacturing pharma products of the required quality that comply with their specifications;

- all necessary facilities are provided including qualified trained personnel, adequate premises and space, suitable equipment and services, correct materials, containers and labels, approved procedures and instructions, suitable storage and transport and adequate personnel, laboratories and equipment for in-process controls;

- instructions and procedures are written in clear and unambiguous language;

- operators are trained to carry out procedures correctly;

- records are made (manually and /or by recording instruments) during manufacture to show that all the steps required by the defined procedures and instructions have actually been taken and that the quantity and quality of the product are as expected and any significant deviation fully recorded and investigated;

- records covering manufacture and distribution are retained in a comprehensive and accessible form;

- a system is available to recall any batch of product from sale or supply; and

- complaints about marketed products are examined, the causes of quality defect investigated, and appropriate measures taken (Ganu *et a*l., 2000).

Thus, the GMP guidelines cover comprehensively the entire process right from manufacturing till the product reaches the final consumer.

In the light of the above, the Drug Control subcommittee has proposed revamping of the Schedule M. *Inter alia*, the amendment of Schedule M would make it mandatory for firms to observe the following:

- maintain a ratio of 1:2 between the constructed area and surrounding premises to prevent environmental pollution;

- install of a validated water system to aid monitoring and control of bio-burden levels, a good disposal system (in the absence of which arrangements to recycle rejects), proper systems of environmental control, with emphasis on buildings, till the primary packaging is complete;

- supply filtered air in all production areas to prevent environmental pollution;

- establish specifically designed areas for production, quality control and storage and ancillary activities;

- provide adequate precautions to segregate the manufacture of highly potent drugs to avoid cross contamination;

- allow for adequate operational and process controls to ensure reproducible quality of drugs;

- ensure total quality control from raw materials procurement till the retail counter;

- conduct detailed stability studies to establish the quality of drugs in different climatic and storing conditions; and

- devise clear and realistic documentation procedures (Venktaeswarlu, 2000; Nair, 2000).

Further, tighter regulations by the Food and Drugs Administration (FDA) and the move to global standardisation have created a need to prove compliance with environmental standards for each production batch. This would require reference standards (RS) to ensure chemical/ biological purity as also to check for known impurity profiles. The Indian pharmacopoeia specifies 400 to 500 such RS. But there exists a wide disparity between the demand for and supply of RS. The Central Drug Laboratory located in Calcutta is able to meet only 30 per cent of the overall requirement.

In short, the pharma firms are required to upgrade their investments substantially to be able to compete effectively in the domestic as well as global markets. It is evident that most of the smaller players will find the game too tough to engage in.

In Section 4, we will try to identify some opportunities that are unfolding before the Indian firms, which have the potential to make the industry strong enough to withstand domestic and global competitive pressures.

4. OPPORTUNITIES FOR INDIAN SMALL ENTERPRISES

As mentioned earlier, to operate within the framework of the new and impending patent regime and to adhere to the inevitable WHO-GMP, have been posing both threats and opportunities to the small firms. The amended patent laws will have far-reaching implications for the Indian pharma industry in areas like new product introduction, R and D, pricing policies, exports, competition and investment

decisions. Simply put, at the firm level, the main threat relates to the pressure of heightened competitiveness and the major opportunity remains that of expanding markets beyond boundaries. However, overpowering the constraints and exploiting the opportunities to the firm's advantage are easier said than done. Limited field enquiries revealed interesting plans and strategies the entrepreneurs of small firms were envisaging. Whereas some hoped to diversify to such products as cosmetics and herbal products, the items which do not come under the purview of the new patent regime, others wanted to quit the pharma sector in toto; instead they would try out totally different lines of manufacturing or processing or services, e.g., converting the entire unit to provide for a bottling plant for beverages.

However, for many small firms competing in the global market seems eventual and they appreciate the need for preparedness for it. Further, the nature of the sector is such that most entrepreneurs are sufficiently educated, often with relevant technical qualities, and alert to foresee the exacting demands the new market would place on them. Maintaining technological dynamism, obviously, holds the key for success in the market. But the real constraints are finance, up-to-date information (both on technology and on markets) and resilience. More often than not, the individual small firms, by virtue of being *small-sized* only, shall find it extremely difficult or even fail to proceed without dependence upon and/ or alliance with other R and D or manufacturing firms, irrespective of their size and location. Yet some firms would prefer catering to specific product segments, as some others would place confidence in promoting business or excelling in technology through fostering networks of a wider connotation. We shall briefly discuss the variety of responses/ strategies that small firms can actually proffer/ adopt while faced with the challenges of globalisation.

4.1 Alliance with Global Majors in R and D

The cost of bringing a new drug into the market is large and growing, along with increasing complexities in developing a new drug and high degree of uncertainty involved in drug development (SPJIMR, 1998). The demand for bringing IPRs into trade negotiations from the industrialised countries has definitely a reflection of this rather uncomfortable situation, which the large global players find themselves in. At the same time, with the increasing accent on profits, the pharma companies are increasingly reorienting strategies to focus on cost-cutting, downsizing, mergers and acquisitions. Given that their comparative strengths lie mainly in distribution, marketing and handling of regulatory and development procedures, these companies have to seek partnerships or contract out research. In fact, there has been significant growth in contract research – spanning the entire development of a

pharma drug right from concept to marketing - over the past 20 years. Presently, there are about 800 contract research organisations (CROs) and the global market for contract research is close to US $ 4 billion or 12 per cent of the R and D budget (Agarwala, nd).

As the small pharma firms are no longer in a position to manage the lengthy and expensive process of drug development on their own, many of them could convert themselves into CROs. Indian small firms stand a good chance in the contract research market as allies of either multinational pharma companies or global CROs. Indian companies can profitably play an important role in carrying out clinical trials, and collating and analysing data from other sources (Exim Bank, 1998). It needs to be noted that more than two thirds of the R and D investment by pharma companies in the developed world would be deployed outside the companies in partnership with institutions and research companies.

It is estimated that in the area of total drug discovery and development, the existing Indian capabilities are adequate for almost 60 to 70 per cent of activities involved. The industry is well equipped to carry out drug development (which accounts for about two-thirds of the R and D costs), including pilot production of new drugs for clinical trials, in a cost-effective manner involving only a fraction of the cost incurred in the US. Many international pharma firms as well as CROs would be willing to work with partners across the R and D value chain so that they can focus on distinct segments and minimise the risk involved. If small firms do not want to be forced out of the scene for want of investments and sales force, they have to tend towards such alliances. The Indian small firms could benefit from this trend, cashing in on its large manufacturing base for active ingredients and other intermediaries, the large pool of talented and inexpensive technical manpower and low cost of research. It may be worthwhile recollecting the findings of a study done in the mid-1990s to examine how the small and medium enterprises perceived the post GATT 94 scenario to be affecting them. The respondents from the pharma production sector (with average size of plant and machinery worth about Rs. 30 lakh) did not think it possible for them to opt for technical collaborations given their size and scale and resource position (Keshari *et al*., 1994).

4.2 Going the Generics Way

Patent expired drugs and patent expired therapeutic equivalents of patented products represent a sound business opportunity for Indian manufacturers as, in any given year, their number is more than that of the new molecules that reach the market. It is pointed out that by 2003, the generics market in the US alone would

worth about $18 billion, accounting for more than 40 per cent of the world generics market (Surender, 2000). The number of drugs going off patent between 2000 and 2005 is given in Table 6. It is true that when drugs go generic, their prices fall from the level of patented prices. But still, the size of generic market would be large enough to make the business profitable for firms. However, the Indian experience, so far, shows that it is the large firms who have responded to this "drug rush". It is not a coincidence that the first to have sprung into the generic bandwagon are seven Indian pharma majors – Lupin, Morepen, Ranbaxy, Wockhardt, Cipla, Cheminor and Sun Pharma – with a combined turnover of about Rs. 4500 crore. Obtaining approval of drug control authorities in the developed countries is highly expensive and time consuming. It is shown that the above seven companies will have to pay over the next five years at least 10 per cent of their combined turnover in order to procure the necessary clearances from the US Food and Drug Administration (*ibid*).

Another profitable business opportunity for Indian small pharma firms could be manufacturing of niche products (like advanced drug delivery systems, biotechnology, complex bulk chemistry and manufacturing of difficult formulations like sterile antibiotics and anti cancer drugs). These face less competition, while they realise high margins. Moreover, they have longer product life cycles (Exim Bank, 1998). Another area where Indian companies could focus is the traditional medicine production segment known as the Indian System of Medicine (ISM). Using simple and non-polluting technology, the ISM has an active market for both extracts and purified compounds.

4.3 Networking

An effective mechanism in the hands of small firms to participate in the global market with confidence and ability is to act together. Small firms, when alone, would not be able tackle the pressure of competition individually; the economies of scale and scope both would eventually go counter to their interest. Instances galore whereby collective business promotion has worked effectively even when the constituent firms are small in size. A pertinent example is the case of WHO-GMP compliance by small and medium scale surgical instrument manufacturers in Sialkot, Pakistan that enlists the initial flaying but subsequent acceptance resulting in their enhanced business in the global market (Nadvi, 1999). Identification of the markets, accepting large orders as a group, preparation of collective dossiers, sharing cost for technical and business consulting, group exports, etc., are some of the ways by which small firms can not only minimise their production cost, but also the transaction cost. Use of internet as a major medium of information search and

sharing, the essence of collective business efforts, is seen as enhancing gains from networking. Particularly, so far as small pharma units are concerned networking between and across other agencies involved in the business would hold the key for successful performance in the ever-changing global market.

5. CONCLUDING OBSERVATIONS

Consequent upon globalisation, in most technology-intensive, knowledge-based industries heightened competition has been the most prominent phenomenon. For firms in such industries, to be a player in the global market, adherence to high quality standards is the *sine qua non* of survival and growth. The growing emphasis, especially by those operating at the frontiers of technological advancement, on intellectual property protection and also setting strict quality norms in production for participating firms, have been interpreted both as a threat as also an opportunity for the firms from the developing nations; for the small firms, specifically.

Considering the case of the Indian pharmaceutical industries, in this paper, we have enquired into the likely implications of the global regulatory norms for small enterprises, and their potential response. At a basic level, participation in the global market entails upgrading technological capabilities, through either in-house R & D or collaborative research. In either case, undertaking relatively huge investments at the firm level is inevitable, along with restructuring of the organisation of production and management. Whereas the large and established firms have shown their preparedness, for the small firms restructuring remains a tough decision to take. Those who would not consider confirming to the regulatory framework worthwhile, may diversify or exit business. But those who would, the options are several; the most important being collective action, especially if the aspiring firms are part of an industrial cluster. Joint business promotion through networking holds much hope for enterprises, even though small in size, to be active players in the global market within the framework of regulations. Whether such participation in the global market, where large domestic firms and MNCs dominate, is ultimately beneficial to the small units remains much within the realm of speculation, at least for the time being.

Table 1

Production of Bulk Drugs and Formulations in India

Year	Value (Rs. Million)			Indices		
	Bulk Drugs	Formulations	Total	Bulk Drugs	Formulations	Total
1980-81	2400	12000	14400	100	100	100
1984-85	3770	18270	22040	157	152	153
1989-90	6400	34200	40600	267	285	282
1990-91	7300	38400	45700	304	320	317
1991-92	9000	48000	57000	375	400	396
1992-93	11500	60000	71500	479	500	497
1993-94	13200	69000	82200	550	575	571
1994-95	15180	79350	94530	633	661	656
1995-96	18220	91250	109470	759	760	760
1996-97	21860	104940	126800	911	875	881
1997-98	26230	120680	146910	1093	1006	1020
1998-99	31480	138780	17026	1312	1157	1182

Source: *Indian Pharmaceutical Guide, 1998*; Annual *Report (1999-2000)*, Department of Chemicals and Fertilizers.

Table 2

Estimated Employment in the Pharmaceutical Industry

Sector	Employment (in lakhs)
Direct	
Organised sector	2.90 (10.1)
Small scale units	1.70 (5.9)
Total	4.60 (16.1)
Indirect	
Distribution trade	16.50 (57.7)
Ancillary industry	7.50 (26.2)
Total	24.00 (83.9)
Direct plus Indirect	28.60 (100)

Source: OPPI, *33rd Annual Report 1998-99*.

Table 3

Export of Bulk Drugs and Formulations

Year	Value of Exports (Rs. Millions)			Indices		
	Bulk Drugs	Formulations	Total	Bulk Drugs	Formulations	Total
1980-81	113	351	464	100	100	100
1984-85	293	995	1288	259	283	278
1989-90	3505	3142	6647	3102	895	1433
1990-91	4134	3714	7848	3658	1058	1691
1991-92	7226	5586	12812	6395	1591	2761
1992-93	4095	9655	13750	3624	2751	2963
1993-94	5308	13108	18416	4697	3734	3969
1994-95	7601	15055	22656	6727	4289	4883
1995-96	11329	20448	31777	10026	5826	6848
1996-97	15811	25092	40903	13992	7149	8815
1997-98	17379	33432	50811	15380	9525	10951
1998-99	23277	30385	53662	20599	8657	11565

Source: Same as in Table 1.

Table 4

Import of Bulk Drugs and Formulations

Year	Value of Imports (Rs. Million)			Indices		
	Bulk Drugs	Formulations	Total	Bulk Drugs	Formulations	Total
1980-81	872	96	968	100	100	100
1984-85	1784	102	1886	205	106	195
1989-90	4256	551	4807	488	574	497
1990-91	3226	849	4075	370	884	421
1991-92	4585	961	5546	526	1001	573
1992-93	5084	1195	6279	583	1245	649
1993-94	6127	1383	7510	703	1441	776
1994-95	8114	1730	9844	931	1802	1017
1995-96	16300	2700	19000	1869	2813	1963
1996-97	17050	3450	20500	1955	3594	2118
1997-98	18270	4300	22570	2095	4479	2332
1998-99	19180	5400	24580	2200	5625	2539

Source: Same as in Table 1.

Table 5

Ratio of Exports to Production and Imports

Year	Exports/ Production			Exports/ Imports		
	Bulk Drugs	Formulations	Total	Bulk Drugs	Formulations	Total
1980-81	0.05	0.03	0.03	0.13	3.66	0.48
1984-85	0.08	0.05	0.06	0.16	9.75	0.68
1989-90	0.55	0.09	0.16	0.82	5.70	1.38
1990-91	0.57	0.10	0.17	1.28	4.37	1.93
1991-92	0.80	0.12	0.22	1.58	5.81	2.31
1992-93	0.36	0.16	0.19	0.81	8.08	2.19
1993-94	0.40	0.19	0.22	0.87	9.48	2.45
1994-95	0.50	0.19	0.24	0.94	8.70	2.30
1995-96	0.62	0.22	0.29	0.70	7.57	1.67
1996-97	0.72	0.24	0.32	0.93	7.27	2.00
1997-98	0.66	0.28	0.35	0.95	7.77	2.25
1998-99	0.74	0.22	0.32	1.21	5.63	2.18

Source: Same as in Table 1.

Table 6

Number of Drugs Going Off-Patent

Year	Number of Drugs
2000	7
2001	7
2002	4
2003	4
2004	5
2005	8

Source: Surendar (2000)

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