



## Public Health and Pharmaceutical Industry: Making the Indian Generic Pharmaceutical Industry Vibrant

Reducing the disease burden of its population has emerged as a major development challenge for several developing countries like India. In most of these countries, medicines play a significant role in the health programmes since they constitute up to two thirds of the cost of healthcare. Access to medicines at affordable prices has, therefore, become a key component of an effective healthcare system. While there are many factors influencing access to medicines, in India at least three factors are of critical importance. These are: (i) the nature of the pharmaceutical industry; (ii) the ability of the R&D system to respond to the challenge of disease burden; and (iii) the optimal pricing mechanism that can ensure medicines at affordable prices. Coupled with this is the overarching presence of a product patent regime in the pharmaceutical sector.

### The current status of Indian pharmaceutical industry

India has been the home to one of the largest generic pharmaceutical industries, which has developed over a period of four decades through conscious policy interventions by the government. In the past two decades, this industry has emerged as a global powerhouse, supplying affordable drugs not only to the large Indian market, but also to several countries in Africa and Latin America. Among its more remarkable contributions was the support it lent to the Global Fund to Fight AIDS, Tuberculosis and Malaria, which was set up in 2002 following a resolution passed by the United Nations

General Assembly. In the initial years of its functioning, the Fund procured from Indian generic firms almost 25 per cent of the anti-AIDS medicines it had supplied to the most affected countries.

What made this contribution more remarkable is that it came in the midst of growing challenges for the industry from the policy regime. On the one hand, the level of tariff protection enjoyed by the industry was rapidly coming down. Import duty of organic chemicals including bulk drugs has been reduced from 120 per cent in 1990-91 to 7.5 per cent in 2007-08 (Jha 2008). With liberalisation of tariffs, it was feared that imports would shake the foundations of Indian generic industry. On the other, the impending introduction of a product patent regime following India's acceptance of the commitments under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) had cast its long shadow on the future of the industry. The nature of the patent regime was a critical factor for the generic industry—its growth can be almost entirely ascribed to the introduction of the Patents Act 1970, a regime that did not permit patenting of pharmaceutical products but allowed only process patents.

Lately, news from the global industry, too, has been encouraging for the generic industry. Over the next few years, a number of blockbuster drugs are coming off-patent. This would have a profound impact on the global pharmaceutical industry: its major firms could suffer substantial erosion in their sales arising from the competition they would face from

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generic producers. Industry estimates indicate that in 2010, 68 per cent of the sales of market leader Pfizer included products whose patents would expire within the next three years. Similarly, for another leading firm, Eli Lilly, the risk from generic competition in the next three years would be as high as 66 per cent of total sales in 2010 (Dhar 2011).

And more importantly, the investment in research and development (R&D) has seen a phenomenal growth. The R&D intensity (R&D as percentage of sales) has increased from 1 per cent in 1990-91 to 5 per cent in 2009-10.<sup>1</sup> This forward-looking strategy helped the industry not only to produce more effective generics, which were marketed in both the US and Europe after overcoming stiff regulatory barriers, but also to embark on developing new molecules. Yet another positive aspect arising from improvements in R&D intensity of the pharmaceutical industry was the emergence of India as a major hub for contract research.

Despite these positive signals, recent developments in the Indian generic industry have been most disheartening. *First*, there is lack of interest of Indian pharmaceutical firms to engage in the production of bulk drugs, which involves the technology intensive phase in the entire process of drug production. And at the same time the focus of the business is getting centred only on formulations segment, which involve mere assembling of bulk drugs into dosage forms. Further, the liberalisation of the foreign direct investment (FDI) has resulted only in the acquisition of well performing Indian flagship generic firms, rather than new investments coming in for establishing manufacturing facilities in the country. *Second*, despite the fact that the R&D intensity has shown an increase in the post 2000 period, a closer analysis shows that the growth has stagnated after 2005-06. Most importantly, the R&D efforts on neglected diseases have been abysmally low. When the product patent regime for pharmaceuticals was introduced, it was expected that firms would invest more in R&D for diseases that are more relevant to tropical conditions. *Third*, although Indian generic firms have performed well in the face of fierce competition in the global market resulting in more affordable prices, in India, we are yet to

allow competition to play a role in determining the prices. As a result, wide variation exists in the prices of different brands of the same drug and in many therapeutic markets the market leader is also the price leader. In order to make Indian pharmaceutical industry a vibrant one catering to the needs of affordable access to medicines, the above three concerns need to be addressed. These issues and potential policy alternatives are discussed in the sections that follow.

### Growing dependence on imports

The bulk drug segment of the pharmaceutical industry has undergone some major changes in the last few years; growth in domestic production declined and the imports have gone up. The rate of growth of production of bulk drugs has declined to 9 per cent during 2005/06 to 2008/09 as compared to 16 per cent during earlier decade (Figure 1).

The change in the production pattern needs to be seen in the context of growing orientation towards exports. With the industry becoming more export oriented, the cost of production factor became very crucial, which was probably not the case when the industry was more focused on the domestic market. The cost based price control system and the practice of brand name prescription encouraged the firms to invest more on promotional activities rather than on R&D for developing cost effective production techniques.<sup>2</sup>

When the cost of production became a sensitive factor, the immediate available option was to import from cheaper sources.<sup>3</sup> This period also coincided with the liberalisation of imports in pharmaceutical sector. The “Modifications in the Drug Policy 1986” in 1994 incorporated the liberalisation measures visualised in the Industrial Policy Statement of 1991. All the restrictions on the use of imported bulk drugs were completely eliminated. The modified policy also eliminated the “ratio parameter” (between bulk drugs and formulations) which compelled the firms to produce bulk drugs locally.<sup>4</sup> Now, China has become the largest source of imports of raw materials. Fifty-two per cent of the imports is from China alone (in 2009).<sup>5</sup> In certain categories up to 70 per cent of the raw materials are imported from China (Government of India 2008). Import

<sup>1</sup> Based on Prowess data.

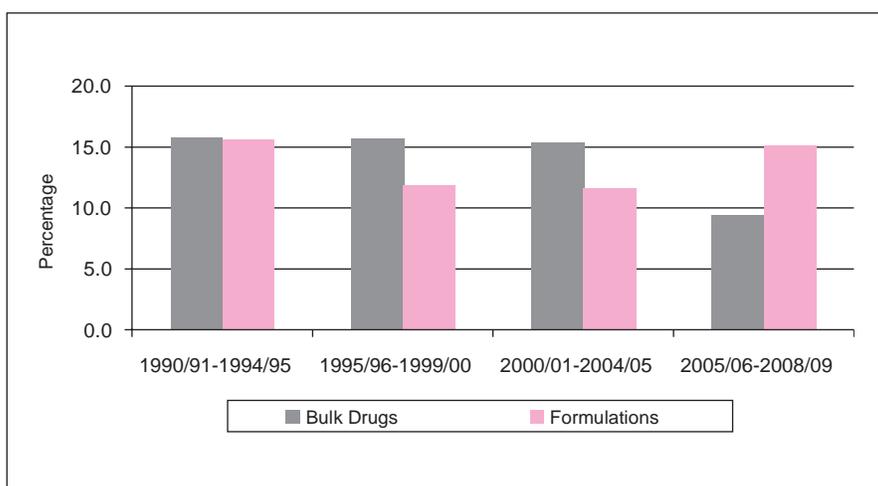
<sup>2</sup> In 1994-95 advertising and marketing expenses accounted for 5.5 per cent of sales turn over whereas the figures were 5.4 per cent and 4.8 per cent respectively in 2009-10. Based on Prowess data.

<sup>3</sup> The ratio of exports to imports of raw materials for the pharmaceutical industry has gone up from 1 per cent in 1994-95 to 3 per cent in 2008-09.

<sup>4</sup> The ratio parameter was settled at 1:4 for FERA companies. For non-FERA companies, the ratio parameter would be related to the size of a company: companies with production up to Rs. 10 crore, between Rs. 10 crore and Rs. 25 crore and in excess of Rs. 25 crore, were given 1:10, 1:7 and 1:5 ratios respectively.

<sup>5</sup> Based on UN COMTRADE Data.

**Figure 1: Growth (CAGR) in the ) Production (at current prices)**



Source: IDMA, Annual Report, various issues.

dependence on one single country puts India in a strategically disadvantageous position. In 2008 at least 50 bulk drug manufacturing units in India were shut down when import of raw materials from China was affected. The cost advantage is the factor driving Indian manufacturers to shun indigenous production and engage in imports. Theophiline from China is 10 per cent cheaper as compared to the cost of indigenous production. Chinese firms are able to sell bulk drugs at lower prices not only due to the subsidies, for example the power subsidies that they enjoy, but also due to better technologies. In fermentation (an essential process for the production of bulk drugs) Indian firms still use sugar whereas technology in China enables its firms to use cauliflower, which is much cheaper, in the process.<sup>6</sup>

The dependence on imports has increased phenomenally for some major firms. Aurobindo pharma, a major producer of bulk drugs in India, has shown its dependence on the import of raw materials going up from 31 per cent in 2000-01 to 42 per cent in 2008-09.

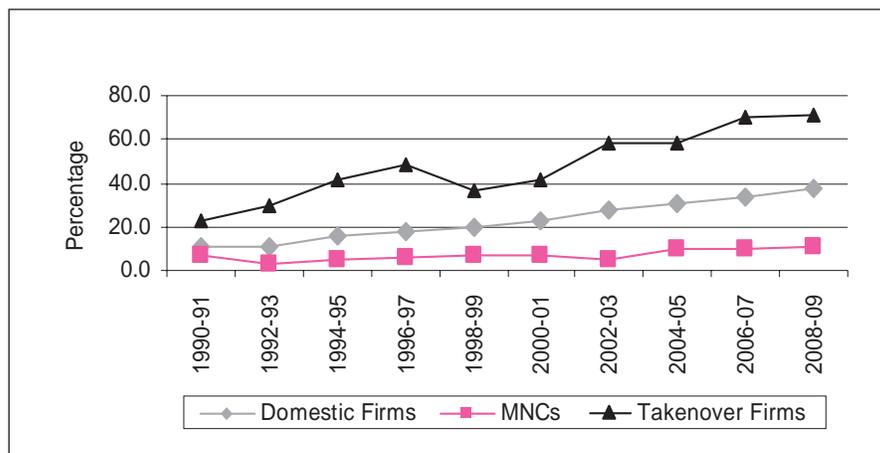
In order to revive the domestic production of bulk drugs, concerted efforts needs to be undertaken at various fronts. It has already been recommended by the Task Force of Department of Commerce on *Strategy for Increasing Exports of Pharmaceutical Products* (Government of India 2008) that a policy environment needs to be created for the small and medium chemical industry to position itself appropriately to address back-end needs of the

pharmaceutical industry. Problems faced by the bulk drug manufacturers have to be studied in detail. Revival of the bulk drug production also requires new environment friendly technologies. Basic drugs and pharmaceuticals are one among the seventeen highly polluting industries as identified by the Central Pollution Control Board. Technologies like 'biocatalysts' reduce the number of chemical processes and hence the quantum of pollution generated. Although this technology is in use in advanced countries in food production and environmental management, it hardly exists in drug production. Since the advanced countries have systematically outsourced bulk drug production to developing countries like India and China, we may not expect such technologies from advanced countries. The public sector laboratories and universities should be encouraged to take up this task. Public private partnerships or collaborative projects involving bulk drug manufacturers and public sector laboratories and universities will be forward steps in the direction of developing new technologies for the bulk drug manufacturing.

A different, but related issue, is the acquisition of leading Indian firms. The analysis shows that the firms which are most export oriented have been targets of acquisition. The four taken over firms (Matrix, Ranbaxy, Dabur and Shantha Biotech) had exports constituting 71 per cent of their combined sales turnover in 2008-09 (Figure 2).

<sup>6</sup> Came out during interaction with IDMA representatives.

**Figure 2: Exports - Sales Ratio**



Source: Prowess.

Drying up of the pipeline of new drugs and the emphasis placed on generic drugs by a number of countries have forced MNCs to get into the generic business as well. They have opted for taking over leading players in the generic segment instead of doing it the organic way. This is precisely the reason for the taken over firms in India being the most export oriented. The risk of these kinds of acquisitions of leading firms on drug prices has been pointed out during the workshop on Public Health and Pharmaceutical Industry.<sup>7</sup> It is very likely that some drugs might be withdrawn from the market if they are not priced at international levels.

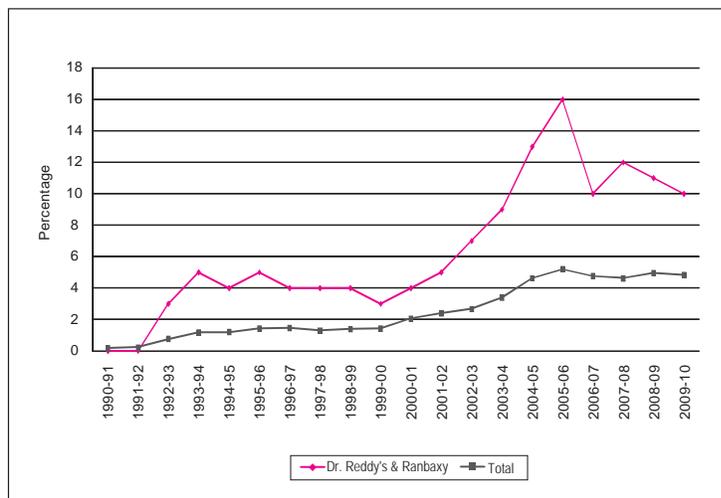
The merger and acquisition provisions in pharmaceutical sector need to be dealt with more carefully. We need to ensure that FDI route is not used just for the change in ownership and also that drug prices are not affected adversely.

### Stagnating R&D efforts

The R&D investment of Indian pharmaceutical industry grew considerably in the post 2000 period, but shows signs of stagnation after 2005. The overall trends in the R&D on the industry have been influenced by just two firms, Ranbaxy and Dr. Reddy's (Figure 3). The experience of these two firms would give us some clarity on the strength of the industry in R&D.

These two firms when succeeded in developing a few early stage drug molecules, which they subsequently out-licensed to MNCs on upfront and milestone payments for further development, the immediate response was a considerable increase in the R&D spending, reaching up to 19 per cent of sales turn over.<sup>8</sup> But when they realised that failure rate is quite high and that MNCs are not interested in developing a molecule unless it fits into their business model, the direct outcome was

**Figure 3: R&D % Sales**



Source: Prowess.

<sup>7</sup> Held at RIS on 6 February 2012. The report of the workshop and details of presentation are available at [http://ris.org.in/index.php?option=com\\_content&view=article&id=355&Itemid=48](http://ris.org.in/index.php?option=com_content&view=article&id=355&Itemid=48)

<sup>8</sup> Dr. Reddy's out-licensed its compound DRF 2593 to Novo Nordisk in 1997. With this deal, Dr. Reddy's became the first company in India to out-license an in-house molecule. Next year, the company out-licensed another anti-diabetic compound (DRF 2725), to Novo Nordisk. A third anti-diabetic compound (DRF 4148), was out-licensed to Novartis in 2001. The deal with Novartis involved milestone payments up to \$55 million depending on the progress and the company received \$5 million to start with. Similarly, Ranbaxy in 2002, out-licensed its compound (RBx 2258) for the treatment of benign prostate hyperplasia to Schwarz Pharma. Ranbaxy was expected to receive \$42 million over the next half a decade with an upfront payment of \$6.3 million to be followed by royalty payments upon commercialisation.

pruning of R&D efforts.<sup>9</sup> Dr. Reddy's removed the line "discovery led global pharmaceutical company"<sup>10</sup> from its grandiose vision statement and replaced it with "the viable vision" to transform the company into an "ever flourishing company."<sup>11</sup> In 2009, Dr. Reddy's shut down its R&D office in Atlanta, US. In the same year, the company transferred its research division based in Hyderabad to a Bangalore based subsidiary Aurigene, which offers research services to pharma firms. Dr. Reddy's has now only 30 scientists working on new drug development compared to 280 in the early years of the last decade.<sup>12</sup>

These failures are not something that is unique to India, but are pointers to the drawbacks in the drug innovation system in the country. The experience world over has been that failure rate is quite high in drug discovery and development process. The PhRMA estimates suggest that out of 10,000 molecules synthesised, only 20 reach the pre-clinical stage and 10 the clinical trials stage and ultimately only one gets the approval for marketing.<sup>13</sup> It also estimates that the whole process takes about 15 years and investment of \$1 billion.<sup>14</sup> The drug development process also requires expertise in biology and medicinal chemistry. This means that in order to successfully develop new drugs, one should have the ability to finance huge investments as well as to provide required human resources. But, unfortunately in India both are missing.

The efforts to create private venture capital for drug development have not been successful

in India. The "Perlecan" experience would best capture the situation in private venture capital. Dr. Reddy's established India's first integrated drug development firm "Perlecan" in 2005 in collaboration with Citigroup Venture and ICICI Venture, putting together \$52.2 million. Dr. Reddy's shifted four of its experimental drugs to Perlecan. Out of the four molecules, the development of three drugs had to be stopped due to the potential side effects. The remaining one did not prove to be more effective than drugs already existing in the market. In 2008, Citigroup and ICICI pulled out of Perlecan and Dr. Reddy's had to buy back their shares. The Perlecan debacle need not come as a surprise because the success of such venture would require a large number of experimental drugs. Further, the financial outlay of the company was also very small. The failure of the out-licensed molecules further inhibited private venture capital from coming forward in supporting pharma R&D initiatives. A few companies like Nicholas Piramal also established separate R&D companies, but are now in the process of remerging the R&D company with the parent firm. Ranbaxy, Torrent and Wockhardt had plans earlier for spinning off R&D units, but have not gone ahead with the implementation,<sup>15</sup> possibly owing to a late realisation which came in the wake of the Perlecan debacle.

Although FDI was expected to contribute to improvements in technology, foreign firms spend only less than 0.5 per cent of sales turnover on R&D. The study by Abrol *et al.* (2011) found

<sup>9</sup> In 2003, Novo Nordisk suspended trials on DRF 2725 after finding tumours in long-term animal studies. In the same year Novartis also decided to discontinue the development of DRF 4158. In 2004, Novo Nordisk decided to terminate further clinical development of DRF2593, as the phase II results did not suggest a sufficient competitive advantage for Balaglitazone compared to existing products. Schwarz Pharma in 2004 discontinued Ranbaxy's molecule (RBx 2258) due to disappointing results in phase II. When Merck decided to shift away its focus from anti-diabetic research, it returned to Glenmark a molecule (GRC 8200, Melogliptin) it had licensed in 2006. For a detailed discussion, please see Joseph (2011).

<sup>10</sup> Annual Report 2004-05.

<sup>11</sup> Annual Report 2008-09.

<sup>12</sup> 'Death of a Dream', *Businessworld*, January 30, 2010.

<sup>13</sup> PhRMA estimate given in Chaudhuri (2005).

<sup>14</sup> This estimate has been contested. Moreover, the R&D expenses will be lower in India primarily due to the the low salary structure of the R&D professionals (as compared to the salary in the US). McKinsey & company estimated that R&D in India would be only 40 to 60 per cent of similar costs in United States (US). CDRI estimated that it would cost only 30per cent of expenses in US (Chaudhuri 2005).

<sup>15</sup> 'Piramal may reabsorb R&D spin-off', *Live Mint*, October 4, 2010.

**Table 1: Market Leader as Price Leader – The Case of Ciprofloxacin (as hydrochloride monohydrate)**

Brand	Company	Price (Rs.) (500mgX10)	MAV in 2005 (Rs. Mn.)	Ranking in retail market share of Ciprofloxacin (as hcl monohyd) in 2005
Cifram	Ranbaxy	89.6	77	1*
Ciplox	Cipla	84.0	54	2**
Zipclin	Gufic	78.9	NA	NA
Alcipro	Alkem	66.8	15	3***
Ciprobin	Zydus Cadila	66.8	NA	NA
Abact	Nicholas Piramal	66.4	NA	NA
Cipride	Torrent	62.0	NA	NA
Zoxan	FDC	36.0	NA	NA
Perkocip	Perk Pharma	32.5	NA	NA

Source: Drug Today, October-December 2004 (for the price of brands); ORG-IMS (for MAV and ranking).

Note: \*Ranks 9 among leading 600 brands in 2005; \*\* Ranks 31; \*\*\* Ranks 245. NA-indicates that these brands do not figure in the list of leading 600 brands.

<sup>16</sup> Prices obtained from *Drug Today*, October – December 2004. These prices are for drugs containing ciprofloxacin in its normal form. Ciprofloxacin in its other forms - ‘hydrochloride’ form and ‘hydrochloride monohydrate’ form - are also used in the manufacture of drugs. In 2004, there were about 165 firms marketing the 500 mg ciprofloxacin drug (in its normal form) in India.

<sup>17</sup> The ORG-IMS data for 2011 also shows that Cifran is the market leader as well as the price leader in Ciprofloxacin therapeutic market. For details, please see Selvaraj (2012).

<sup>18</sup> In glimepride, the brand by Aventis (Amarly) is the market leader and the price leader. Price of Amaryl is Rs. 65 (1mgX10) whereas the cheapest brand marketed by Kopran is priced that Rs. 9.5 (1mgX10). For details, please see Selvaraj (2012).

<sup>19</sup> Based on data obtained from Selvaraj (2012).

<sup>20</sup> Out of pocket expenditure accounts for 67 per cent and 33 per cent in out-patient and in-patient healthcare expenses respectively (Selvaraj 2012).

<sup>21</sup> Out of pocket expenditure on drugs constitutes 75 per cent of healthcare expenditure of the poorest 20 per cent the population and 66 per cent of the richest 20 per cent of the population. For the entire population it comes to 68 per cent. These estimates are based on NSSO surveys. For details, please see Selvaraj (2012).

that the focus of R&D dedicated foreign firms in India has been primarily on the clinical trial phase, to take advantage of the availability of human subjects and their diversity in India.

Given the lack of adequate financing mechanisms for drug development and scarcity of human capital, stagnating R&D efforts in the Indian pharmaceutical industry need not come as a surprise. In order to step-up R&D in the sector at least two things are essential. *One*, a sustainable financing mechanism; and *two*, development of a pool of required human resources within the country.

Leading firms have been trying to overcome these limitations by engaging with MNCs in contract research and collaborative research. In these research partnerships, Indian firms generally had the status of the junior partner, which, in the long run, can have deleterious consequences for the country. Being partners in the global strategy of MNCs, Indian companies could lose interest in those therapeutic areas that are of importance to countries like India, for example, tropical diseases. A study found that Indian firms are spending only 10 per cent of their R&D investments for diseases more prevalent in developing countries (Lanjouw and MacLeod 2005). These allies might also withhold themselves from exercising compulsory licensing provisions, the TRIPS instruments to counter any abuse of monopoly rights of the patents.

### Uncompetitive pharma market

Though Indian pharmaceutical industry consists of a large number of firms, a few firms have been able to exercise market power in therapeutic submarkets. Exercise of market power is visible in their pricing. The example of ciprofloxacin would illustrate this well.

Ciprofloxacin is an antibiotic used in the treatment of a number of infections and is a under the purview of price control. The drug is marketed in India by more than 165 firms. The price of the drug varies between Rs. 5.50 (per 10 tablets of 500 mg) offered by Lexus India (brand-lexflox) and Saveioer Pharma (brand-save) and Rs.125 (per 10 tablets of 500 mg) by Glenmark (brand-Cipro Glen)

in 2004.<sup>16</sup> In a competitive market this huge variation in the prices is not reasonable. An analysis of the ciprofloxacin (as hydrochloride monohydrate) shows that the price leader is also the market leader (Table 1), which can never happen in a competitive market.<sup>17</sup> There are more recent evidence also suggesting that ciprofloxacin is not the only product in which price leader is also the market leader.<sup>18</sup>

In some therapeutic areas, although the market leader is not the price leader, the price of the market leader is significantly higher as compared to the cheapest brand. For example, in Atrovastatine, the market leader (Ranbaxy) has priced its brand ‘Storvas’ (10mgX10) at Rs. 93.3 whereas the lowest priced brand by Skymax is priced at Rs. 19 (10mgX10). The price of the market leading brand is 391 per cent higher as compared to the cheapest brand in this case. Similarly, the difference between the price of the market leading brand and the lowest priced brand in Atenolol and Omeprazole is 214 per cent and 233 per cent, respectively, in 2011.<sup>19</sup>

The exercise of market power in pharmaceuticals market gives an additional reason to be concerned about especially in a country where private expenditure constitutes significant share in overall health care expenditure<sup>20</sup> and expenses on drugs alone accounts for 68 per cent of health care expenditure.<sup>21</sup>

The current cost-based price control system, though successful in checking the rise in the price of selected drugs, causes considerable inefficiencies in the production system. A pre-defined rate of profit when coupled with the practice of prescription by brand name creates a perverse incentive in the industry: incentives are on the promotion of the product rather than improving the production processes. Wide variation in the prices and the price leader remaining as market leader are no surprise when such perverse incentives prevail in the market.

The proposed National Pricing Policy 2011 envisages a “market approach” by arriving at a ceiling price based on the weighted average price of the top three brands. This policy proposal implicitly assumes that market share represents efficient practicing, which is completely wrong in the Indian pharmaceutical industry. More desirable strategy could be arriving at the ceiling price based on the average price of the three or

four lowest priced brands. Consumers would be much better off. Again, the proposed strategy also will not facilitate competition in the long run as firms would have no incentive to improve production processes and to price below the ceiling price. If competition has to work in its real sense, the patients should have the choice to select cheaper drugs. The South African case is worth mentioning here. In South Africa, doctors are required to prescribe only the chemical name of the drug (since 2003) and chemists are required to inform patients about the benefits of substitution. The chemist is expected not to substitute only when “expressly forbidden by the patient to do so”.<sup>22</sup> In India various committees including the prominent Hathi Committee recommend the abolition of brand name prescription, but nothing has been done in this direction till now. Since all drug manufacturing units in India are mandatorily required to comply with good manufacturing standards (GMP), equating brands with quality parameter is no more logical. Studies conducted by the Government agencies themselves indicate that only less than 0.3 per cent of the drugs in the market are spurious/adulterated drugs.<sup>23</sup>

An area where the proposed pricing policy falls short of sight is the production of bulk drugs. The policy document states that regulation of bulk drug prices has led to decline in the production and hence bulk drug prices should be deregulated. In a market based approach, deregulation of bulk drug prices is logical. But the policy document does not substantiate the point that bulk drug production declined due to regulation of the prices. If the price regulation has caused changes in the production pattern, a similar change would have been visible in the production of formulations as well. The policy document, however, is silent on this and we do not have any evidence in the recent past to suggest that there is a shift in the production pattern of formulations. Moreover, the policy document does not clarify whether the manufacturers of scheduled bulk drugs moved into the production of non-scheduled bulk drugs. If producers have moved into the production of non-scheduled bulk drugs, there is a clear case of price regulation affecting the production. The reasons for the change in the production pattern of bulk drugs so far beyond

price regulation and we need to take into account factors such as the infrastructure and technology available in the country and the growing imports especially from China.

Another area that has implication for generic industry is the grant of patents for minor improvements or new forms of a known substance, despite section 3(d) (James 2009). Such patents limit the field of drugs that generics could embark on. The high percentage of pharmaceuticals in the overall patents granted by the India patent office may also be owing to this phenomenon.<sup>24</sup>

At the time of introduction of a TRIPS compliant patent law, India provided for enough safeguards to take care of public health needs including compulsory licence provisions. These provisions were not used until this year. The grant of the first compulsory licence in March 2012 for the cancer drug ‘Nexavir’ patented by Bayer Corporation, in favour of Natco Pharma under section 84 of the Patents Act on the grounds of non-availability at affordable price, sends a positive signal to the generic pharma companies.<sup>25</sup> However, considering the many constraints they have because of their tie-ups with the MNC firms in various areas, more confidence building measures may be required to make them effectively utilise the compulsory licence provisions. There is need for regular monitoring of the availability of medicines at affordable prices and whenever a felt need arises, *suo motu* compulsory licences be granted. The generic manufacturers should be ready and willing to exploit such licences.

### What needs to be done?

- Reenergise the bulk drug production sector. Problems faced by small and medium bulk drug manufactures need to be studied in detail. The public sector laboratories and research institutions should be encouraged to develop new technologies which are less polluting and cost effective for the bulk drug production.
- The small and medium sector needs to be effectively integrated to meet the back end needs of the pharmaceutical industry.
- A public supported venture fund is desirable to finance pharmaceutical innovations. The proposed National Innovation Fund of

<sup>22</sup> Section 22F of the Medicines and Related Substances Control Amendment Act 1965 as amended in 1997.

<sup>23</sup> In 2010-11, 49682 drug samples were tested, of which 95 were spurious/adulterated. In 2009-10, 39248 drugs were tested of which 117 were spurious/adulterated. For details, see Lok Sabha Unstarred Question No.2283, dated 12<sup>th</sup> August 2011.

<sup>24</sup> The number of patent applications for chemicals and drugs was 9084 out of 34, 287 total applications during 2009-10. Out of this 3070 was purely for drugs. See *Annual Report of the Office of the Controller General of Patents, Designs and Trade Marks 2009-10*

<sup>25</sup> Order of Controller of Patents dated 9<sup>th</sup> March 2012 in C.L.A. No. 1 of 2011 in the matter of Natco Pharma Ltd. and Bayer Corporation in respect of patent No. 215758.

Rs 1000 crore, although a good initiative, is meagre given the magnitude of investments required in new drug development. Moreover, this Fund is to be shared among different industries.

- The pharmaceutical industry and academic institutions need to work together to jointly design syllabus that would generate required human skills in the country.
- The price control system needs to be completely revamped to usher in competition in the market.
- An institutional mechanism may be conceived for challenging applications for frivolous patents as well patents that may lead to ever greening.
- This body may also keep a tab on the pharmaceutical market to monitor the availability of patented drugs at an affordable price. It can also keep a close watch over the prices of essential medicines and tropical diseases related medicines in India and other countries and advise the government on initiating compulsory licence processes wherever justified because of the price differences keeping in view the purchase power parity.

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