***Sustainability in pharma supply chain***

*In a special report for* ***Express Pharma****,* ***Kshama V Kaushik*** *and* ***Rosanna M Vetticad*** *of Thought Arbitrage Research Institute review the regulatory mechanisms in Maharashtra and Gujarat, together accounting for 45 per cent of all pharmaceutical manufacturing units, to understand what these states do to help small and medium pharma companies improve their commitment towards long-term and sustainable development*

Small and medium enterprises are the backbone of any developing economy, contributing to its social and economic development. They contribute a large proportion of the industrial base and significantly to exports as well. In India, according to the 2012-13 annual report of the Ministry of Micro Small and Medium Enterprises (MSME) there were a total of 361.76 lakh MSME units (registered and unregistered) in the country employing 805.24 lakh people as of 2006-07. MSMEs contribute eight per cent of the country’s GDP, 45 per cent of the manufactured output and 40 per cent of our total exports. The mission of the Ministry is to achieve a cumulative growth of 40 per cent in the number of registered enterprises and to enhance this sector’s contribution to GDP from the present eight per cent to 10 per cent by the end of 12th Plan.

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| **Fig. 1: Turnover wise Distribution of Units** |
| http://pharma.financialexpress.com/images/2013/20130615/20130615ep14.jpg |

**Structure of Indian pharmaceutical companies**

The Indian pharmaceutical industry consists of approximately 10,500 units, most of which are in the small sector. 300-400 of these fall in the medium to large organised sector. It is estimated that 36.5 per cent of the total market share is contributed by the top 10 manufacturers. The medium and large domestic companies in fact have been the drivers of growth, contributing 75 per cent of domestic sales and over 90 per cent of exports. Table 1 presents a clearer picture of the fragmentation in the industry.

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| **Table 1: Turnover-wise distribution of Units1** |
| **Turnover (Rs Crores)** | **% Distribution** |
| 0-10 Cr. | 70% |
| 10-50 Cr. | 20% |
| 50-100 Cr. | 5% |
| 100-500 Cr. | 3% |
| 500 + Cr. | 2% |

While 70 per cent of the units earn revenues of only up to Rs 10 crores, only two per cent of the total number of units generates revenue of more than Rs 500 crores.

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| **Fig. 2: State wise distribution of pharma manufacturing units** |
| http://pharma.financialexpress.com/images/2013/20130615/20130615ep15.jpg |

In terms of geographical distribution, almost 45 per cent of the total pharma manufacturing units are located in two states alone – i.e. Maharashtra and Gujarat. Refer to Table 2:

Considering the fragmented nature of the industry we can safely conclude that a large number of the pharma manufacturing units in the states of Gujarat and Maharashtra are likely to be medium or small in nature, which primarily supply to the larger units. While sharing sustainable practices is crucial to the relationship between a company and its stakeholders (including suppliers), the government should also take steps to help and encourage the smaller units in their endeavour towards sustainable development. Considering that contract manufacturing is a growing element in the pharma industry, none of the top 10 pharma companies (barring one), studied in a report prepared by TARI2 had detailed discussions on their suppliers and how they ensure sustainable practices at the supplier end. With India emerging as a global player in the pharma industry, it will have to comply with globally accepted standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practices (cGMP) and Good Clinical Practices (GCP).

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| **Table 2: State-wise distribution of pharma manufacturing units** |
| **S.No.** | **State** | **Number of Manufacturing Units** | **Total** | **%age to total** |
|  |  | **Formulation** | **Bulk Drugs** |  |  |
| 1 | Maharashtra | 1,928 | 1,211 | 3,139 | 30% |
| 2 | Gujarat | 1,129 | 397 | 1,526 | 14% |
| 3 | West Bengal | 694 | 62 | 756 | 7% |
| 4 | Andhra Pradesh | 528 | 199 | 727 | 7% |
| 5 | Tamil Nadu | 472 | 98 | 570 | 5% |
| 6 | Others | 3,423 | 422 | 3,845 | 36% |
|   | Total | 8,174 | 2,389 | 10,563 |   |

For the purpose of this report, we look specifically at the states of Maharashtra and Gujarat (since they have the largest number of manufacturing units) to understand, what (if any) regulatory mechanisms exist in these states to help small and medium pharma companies in improving their commitment to their stakeholders towards long-term and sustainable development.

**Regulatory environment in the pharmaceutical industry - Maharashtra and Gujarat**

The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics through licensing in India. Among other things it stipulates that the manufacture and sale of drugs and cosmetics shall be undertaken only by qualified persons. It also contains stringent provisions to keep a check on the manufacture of spurious and sub-standard drugs.

Under the act, the regulation of manufacture, sale and distribution of drugs is primarily the concern of the state authorities while the Central Authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view to bringing about the uniformity in the enforcement of the Drugs and Cosmetics Act. The Drug Controller General of India is responsible for approval of licenses of specified categories of drugs such as blood and blood products, I. V. fluids, vaccine and sera.

**Maharashtra3**

The Food and Drug Administration (FDA) of Maharashtra is the focal point for consumer protection (with respect to drugs, cosmetics and food) in the state of Maharashtra. It is designated as the licensing authority for the grant of the drug manufacturing licenses under the Drugs and Cosmetics Act, 1940 for the entire state. The FDA, as a part of its mandate, is also required to analyse drug samples at its Drug Control Laboratories at Mumbai and Aurangabad. Maharashtra is the first state to set up an independent Intelligence Branch with a separate police wing to assist in investigations under Acts enforced by FDA. Apart from granting or renewing licenses for drug manufacturing units, it issues various certificates, including WHO GMP (good manufacturing practices) certificates.

The role of the FDA is to ensure safety, efficacy, purity and quality of drugs and to ensure availability of drugs at reasonable prices. Its objects include:

* To ensure safety, efficacy, purity and quality of drugs;
* To ensure availability of drugs at authorised prices;
* To create an awareness about the importance of proper storage of drugs;
* To eliminate irrational combinations /banned drugs;
* To study the problems and suggestions made by the stakeholder;
* To collect the information in general about the drug trade and take necessary steps; and
* To prepare policy regarding drug matter.

The Drug Control Laboratory which operates under the administrative control of the Commissioner, FDA employs qualified, experienced and trained staff for the analysis of, among other things, bulk drugs, drug formulations (like tablets and capsules), antibiotic formulation, and vitamins, in its laboratories at Mumbai and Aurangabad, equipped with modern, sophisticated, computerised and analytical instruments. All activities from the receipt of samples to final dispatch of reports are computerised using software developed by HCL in accordance with FDA & Drugs Control Laboratory requirements.

**FDA Maharashtra has:**

* USFDA approved units (60 units as per the list provided, having US FDA, MHRA, Health Canada, TGA & other certifications).
* List of WHO GMP certificates issued as of February 2010 (168 units).
* Details of items ‘not of standard quality’ (NSQ) with reasons, found by the FDA from samples of drugs and cosmetics drawn for testing and analysis by the Drug Controls Laboratory. There are around 150 items declared NSQ between July 2012 to January 2013.

**Gujarat4**

The Food and Drugs Control Administration (FDCA), Gujarat has been in existence for the past 53 years. As in Maharashtra, it is primarily entrusted with the implementation of the Drugs & Cosmetics Act – 1940 & Rules 1945 and is the licensing and controlling authority for drug manufacture and sales. According to the FDCA website, Gujarat is the first state to initiate online software for sales and manufacturing licenses in January 2007.

The Food & Drug Laboratory (FDL) set up at Vadodara is the first NABL accredited government laboratory in the country. In addition the FDCA has two other regional food laboratories for testing of food samples, one at Rajkot and one at Bhuj. It is setting up one more state-of-the-art Food & Drug Laboratory at Dethali, in Patan district of North Gujarat. This new FDL lab is designed according to the latest GLP norms, with the latest equipment and instruments. Constant upgradation of facilities and equipment in laboratories have always been a priority of the FDCA. The FDCA lays great emphasis on training its officers new and in service with the objective of sharpening their knowledge, not only to maintain the performance of the FDCA but also to achieve newer landmarks.

Drugs inspectors regularly draw samples of allopathic drugs and raw materials used to manufacture them from dealers, manufacturing units, doctors, hospitals, CHC, PHC etc. and send them to FDL, Vadodara for testing and analysis. If the sample is declared as ‘Not of Standard Quality’, action is initiated as per policy and report to head office.

As in the case of the Maharashtra FDA, the FDCA also grants certificates including WHO GMP and State GMP. The Intelligence Branch (IB) takes prompt action on any information related to manufacturing / selling of spurious, misbranded or drug / cosmetics manufactured without licenses.

* There are 3,164 drug (allopathic, homoeopathic, ayurvedic) and cosmetic manufacturing units in Gujarat as of June 16, 2012.
* In the year 2012, 5,333 samples were drawn by the FDCA for testing of which 463 or 7.99 per cent were found to be Not of Standard Quality.
* The details of sample declared as ‘Not of Standard Quality’ (NSQ) is sent through SMS to all retailers, wholesalers, District Health Officers (DHO), PHC / CHC, CMSO and State Drugs Controllers of India. This is the first ever initiative taken by any Drugs Controller to ensure effective recall of NSQ medicines.
* There are 460 units who are WHO GMP holders and 191 units that are State GMP holders.

The FDCA periodically undertakes informative programmes, interviews / demonstration of testing kits on Doordarshan, other television channels and All India Radio.

**Programmes and policies towards sustainable development of the SMEs-initiatives undertaken including 12th Plan strategy**

While the drug control authorities at the state level have a strictly laid out mandate, there are no programmes and policies in place to assist the SMEs in the pharma industry to grow into sustainable business units that are able to meet the competitive standards set by domestic and global players. However, there are various measures undertaken or planned to be undertaken at the central level. These are too recent to assess whether they have been/will be implemented and the actual impact they will have on the small and medium companies.

**Department of Pharmaceuticals**

National Institute of Pharmaceutical Education & Research (NIPER) set up in 1984, has among its primary objectives the nurturing and promotion of quality and excellence in pharma education and research, toning up the level of pharma education and research by training future teachers, research scientists and managers for the industry and profession, collaborating with Indian industry to help it meet global challenges and study the sociological aspects of drug use and abuse and rural pharmacy etc.

According to the 2011-12 Annual report of the DoP, NIPER started conducting training programmes at the newly established Small and Medium Pharmaceuticals Industry Centre (SMPIC) for the small and medium pharma industry on the aspects of GMP and GLP, instrumental analysis and manufacturing of APIs and formulations. However, no information is available on the number of such programmes actually conducted. The centre also plans to provide a focal point for industry academia interaction.

Apart from the above, the DoP as part of its capacity building measures towards providing support to the SME pharma industry for quality manufacturing, has, with the help of Ministry of MSME, expanded the Credit Linked Subsidy Scheme (CLCSS) being operated by the Ministry of MSME for providing financial assistance for technical upgradation of Schedule-M standards. More than 140 items of plant and machinery have been added to the eligible list of equipment for which assistance can be provided. The department has also proposed a scheme of financial assistance to MSMEs for WHO-GMP, US FDA and other international standard manufacturing compliances. The vision of the DoP is to make India the largest global provider of quality medicines at reasonable prices. It has set the upgradation of SMEs to WHO-GMP and training of professionals therein, as one of its goals for the 12th Plan.

**12th Plan initiatives**

The Working Group set up for the 12th Five Year Plan has recommended several schemes and initiatives targeted towards the SME sector of the pharma industry. India being a signatory to the WHO certification protocol on the quality of pharma has accepted the WHO-GMP standards as an integral part of the standards for exports of pharma products. Since export of generics to the high growth emerging markets is to be a key strategy for growth of the pharma industry in India, the up-gradation of SMEs to WHO-GMP standards would enable them to export their products and thereby increase profitability. The 12th Plan target is to have at least 2000 WHO-GMP standard units by the end of 2017 so as to enable the SME sector to increase and sustain its participation in the pharma industry growth process According to the report of the Working Group, there are currently about 800 units that are certified by the Central Drugs Standard Control Organization for WHO-GMP production. Given the ambitious target of achieving $ 100 billion production by 2020, 1000 - 1200 units will have to be assisted in raising their manufacturing standards to WHO-GMP levels. It also envisages a need to upgrade at least 250 units to US FDA/EDQM/TGA and other International Standards by 2017 and training of 5,000 working professionals in WHO-GMP and other International Standards GMP requirements. As stated above, the ministry has devised schemes for the up-gradation of SMEs to WHO-GMP, USFDA/EDQM/TGA and other international standards which include:

* Interest-based subsidy scheme at the rate of about ` 1 crore per unit of assistance to be implemented in partnership with IDBI/SIDBI for upgrading SMEs to WHO-GMP manufacturing standards to capitalise on the generics opportunity - about 1,200 units out of 10,563 SMEs in the country
* Specific assistance for standards higher than WHO-GMP to selected SMEs – 250 units, to build competitiveness of very high standards and second line of internationally capable industry for high value pharma products for strong regulated but high value markets
* Infrastructure building for pharma industry particularly for SMEs – building on the strength of existing clusters so as to provide infrastructure gaps for higher production including taking care of environmental concerns, power and labs testing, etc. Providing financial and technical assistance to improve financial sustainability of SMEs on one hand and also safeguard the environment from the hazards associated with the unplanned growth of the industry.
* Among the industry development schemes, the working group has suggested:
* Opening a National Formulation Development Centre (NFDC) to assist the SMEs for the development of new formulations which are the source of increasing production in the domestic and export market. This is primarily due to the fact that development of generic formulations from patent products for small and big molecules (biosimilars) is a challenge for the SMEs.
* Develop software, under the technical guidance of Drug Controller General (India), for helping the SMEs in achieving various regulatory compliances which would be distributed by the department to the industry free of cost.

**Conclusion**

The Indian pharma industry has grown from an almost non-existent entity to a force to be reckoned with in the production of high quality generic drugs in India due to the low cost of production and high quality facilities. It is one of the fastest growing sectors in the Indian economy and grew at 14 per cent5 in revenue terms in 2011-12 vis-à-vis 2010-11. The growth can be attributed to legislative reforms, growth in contract manufacturing and outsourcing, foreign and domestic acquisitions and joint ventures and India’s efforts to comply with the World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPs) obligations.

A significant feature of the Indian pharma industry is that the current fragmented structure is changing as a result of consolidation through mergers, acquisitions, brand takeovers etc. The main drivers of this trend have been:

* to widen therapeutic coverage thereby diversifying and reducing the risk of being active in limited segments;
* increasing the sales base, as increase in sales can support larger R&D budgets which are essential to remain competitive;
* strengthening the marketing and distribution reach and network; and
* realising savings in costs.

However, the focus of such transactions now is likely to move to the actual quality of operations in the manufacture of these generic drugs, particularly in light of the recent cases eg: US-FDA and Ranbaxy, Sun Pharma, Dr Reddy’s Laboratories etc. The bans on these firms have been lifted over the last year as the companies have taken corrective actions and are improving manufacturing processes. While it is pertinent to note here that India is the only country with the largest number of US-FDA compliant plants (more than 100) outside the US, 793 WHO-GMP approved plants, and 153 European Directorate of Quality Medicines (EDQM) approved plants with modern state-of-the-art technology6, the need for large and small players to continue to improve and maintain good manufacturing processes is more important now than ever before.

While the drug control administrations of Gujarat and Maharashtra are required to perform all the functions mentioned earlier, they do not appear to specifically target the small and medium units that operate within the pharma industry. Particularly in the case of compliance with GMPs, there is no specific effort/guideline provided to the SMEs in complying with these strict regulations put in place by WHO and the US FDA. According to WHO, its GMP are that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy; for this reason, risk assessment has come to play an important role in WHO quality assurance guidelines.

Furthermore, no specific direction is given towards helping these units in meeting environmental standards including conservation of water and energy, waste management and managing effluents and greenhouse gas emissions, or adoption of norms for the overall health and safety of employees in the manufacturing process, sustaining and retaining talent, etc. While the contribution of the SME sector in the pharma industry in terms of its economic and social impact is phenomenal, the sector still does not receive due credit in some areas, particularly in terms of financial assistance. For innovation, technical upgradation, growth and sustainable development, the SME sector would need adequate funding to maintain its competitive advantage at the domestic and international levels.

The pharma industry is set to grow at a phenomenal rate; stringent demands from the international community and multi-national companies on the impact the sector has on environment, economy and human resources will inevitably be focused on SMEs that operate on a large scale in the industry. In such a scenario, the government has to take some proactive steps and ensure implementation of the schemes it proposes. Unless actionable suggestions are implemented under the aegis of the various regulatory authorities in existence at the state and central levels, the sustainable growth of the SME sector may be affected, thereby impacting the overall growth the sector as well.

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