Brief Note
Survey of Indian Pharmaceutical Enterprises for Meeting National and Global Health Needs

Background

The pharmaceutical sector is one of the key 25 sectors identified by the Government of India under the ambitious 'Make in India' initiative, which is likely to provide the necessary impetus to the sector in order to achieve its true potential. At present, the Indian pharmaceuticals industry is third largest in volume and the tenth largest in value, globally. The country's domestic pharmaceutical market is estimated at INR 2,428 billion and is expected to grow at approximately 12 per cent Compound Annual Growth Rate (CAGR) over the next three years.

Indian pharmaceutical enterprises are performing a significant role in providing affordable medical products worldwide. However, despite an attractive value proposition, the Indian pharmaceuticals industry is facing multiple challenges in terms of growing concerns over the quality of drugs, price control measures, international standards, over- dependence on China for bulk drugs and lack of clarity and predictability in regulations and the Intellectual Property Rights (IPR) regime. Complex approval procedures and stringent regulations too have led to a considerable slowdown in the clinical trials industry, impacting the innovation and drug discovery environment in the country. In order to promote new thinking on innovation, transfer of technology and access to medicines and to engage with the Indian Pharmaceutical enterprises, it was decided to collect information from such units.

Consultation Objectives

This survey was according to the World Health Assembly resolution (WHA61.21) which had identified a number of deliverables under Global Strategy and Plan of Action on public health, innovation and intellectual property (GSPA).

The objective of the survey was to enable Pharmaceutical enterprises to:

1. Identify measures needed to promote production and technology adoption/transfer
2. Develop networks for promoting access to medical products at national and global levels
3. Identify areas/ mechanisms for WHO and Indian Government to perform a supporting role

The results of the survey are proposed to be discussed at a national level meeting that includes relevant authorities and selected participating enterprises.

Methodology

A sample survey of pharmaceutical industries registered under section 2m(i) and 2m(ii) of the Factory Act, 1948 and/or with the District Industry Centre of the State/UT decided to be undertaken by World Health Organization Regional Office for South-East Asia (WHO-SEARO) and WHO India Country Office for the following two categories, namely;

- Pharmaceutical & Medical products i.e. **Group I**
- Machinery, Equipment & Parts i.e. **Group IV**

List of pharmaceutical Industries in India

According to the data available with Central Statistics Office of the Ministry of Statistics & Programme Implementation, there were 6902 pharmaceutical units registered up to 31.03.2014. Out of 6902 units, 5311 pharmaceutical units were relevant for the survey. Out of 5311 pharmaceutical units, 4956 were engaged in the manufacture of drugs and medicines i.e. Group I and 355 in the medical device/equipment i.e. Group IV. These 5311

units were spread over in 292 districts and 27 States/UTs of India. Representation from Maharashtra was the highest with 893 pharma units followed by Andhra Pradesh, Gujarat, Himachal Pradesh and Uttarakhand with 783, 781, 458 and 359 pharma Units respectively.

Sample selection

The data from the 5311 pharmaceutical units, identified as above, were further analysed for the selection of sample and two-stage stratified sampling method was applied. In the first stage, the cities having at least 50 pharmaceutical uints were selected. As a result 56.54% i.e. 3003 pharma units were found to be concentrated in the 35 cities of 13 States/UTs. In the second stage, all the 3003 units were segregated according to size class of employment as per the table given below. All the units with size of employment more than 200 were selected whereas for stratum of size of employment less than 200 a few units were selected so as to get a sample of 28%. Therefore, a sample of 860 pharmaceutical units was selected to undertake the survey of the Pharmaceutical sector. The sample size was kept to higher side so as to adjust to the closure, non-response and non-pharma enterprises.

Questionnaire and Instruction manual

The draft questionnaire was finalized and accordingly an instruction manual was prepared to explain the concept and definition of each and every question of the questionnaire, based on the recommendations from WHO officials, industry experts, officials from several ministries of Government of India and other stakeholders. The questionnaire comprises of six blocks. The first block was designed to harness the information on 'Profile and Financial particulars' of the pharma enterprise, which inter-alia includes, Employment, Investment in Plant & Machinery, Gross Output, Total Input, product category, imports of raw materials, gross sale value and value of exports for the last three year along with destination, problem faced in the export, foreign collaboration, etc. Block 2 deals with Technical know-how, Technology transfer and R&D and Innovations for Product/Process development. In Block 3 & 4, information was sought on Licensing/Legal issues and contract manufacturing. In block 5 & 6 was designed to gather information on Storage, Transportation, Distribution of drugs & medicines to the distributer, wholesaler/retailers and Tax burden.

Method of data collection

In order to collect and complete data from the enterprises, following strategy was adopted:

- **a)** It was clarified that the investigators to be deployed for the survey are those that have experience in conducting similar surveys for the sector /surveys organized by NSSO, government of India.
- **b)** These investigators would personally visit each pharmaceutical enterprise selected for the survey to help fill in the questionnaire.
- **c)** Several meetings were organized with the data collection agencies for the purpose of training the trainers at New Delhi, Mumbai, Kolkata, Hyderabad and Ahmedabad. These training sessions included class-room training as well as mock interviews. In a later stage of training some trial calls were made by trainers in the presence of field investigators.
- **d)** In order to assist the data collection agencies, top officials from regulatory Government organizations in the Centre and States, were approached. Several meetings with pharmaceutical enterprise associations were organized so as to harness their support in the data collection. In this regard, Letters from WHO Representative were addressed to the pharmaceutical enterprises seeking their cooperation in data collection. Similar appeals of cooperation from covered units were also sought from Dr G.N. Singh, Drug Controller GOI, IDBA, CIPI and other Associations.
- **e)** In order to obtain quality data from the selected pharmaceutical industries, several meetings with pharmaceutical industries associations were organized prior to commencing the data collection.

Findings

Based on data collected through the survey and the opinion of the respondents in the pharmaceutical industry, the following conclusions emerge from the analysis:

1. There is remarkable difference over majority of the parameters among the two distinguishable categories of the units covered.
2. Units with smaller investment in Plant & machinery (P&M), lesser number of employees, with lesser capital deployed are having lower scale of operations as compared to the opposite category of units. There are about 20 percent units in this category.
3. Units in these categories are mostly proprietorship firms or partnership firms.
4. Units in this category are not high-growth units, rather content with the relatively slower growth and do not have very ambitious plan.
5. These units normally do not have any R&D facilities, not innovative, do not have foreign collaboration and have very low level (or nil) exports.
6. Clearly this segment of pharmaceutical industry has to be given a different level of treatment.
7. The information obtained and analyzed from remaining units also suggests there could be more categories based on size of operations (on parameters mentioned earlier like: investment in P&M, R&D, exports, foreign collaboration, innovation, adoption of technology.
8. Units having more than Rs.50 crores investment in P&M are at other extreme of operating parameters.
9. Based on this analysis, it could easily be concluded the “size” is the biggest discriminatory factor. Type of ownership (proprietorship, partnership, Private limited or public limited company) and Investment in P&M are two major factor representing “size”.
10. With the increase in ‘size’, the problems faced by pharmaceutical units tend to reduce.
11. The above conclusion easily applies to availability & deployment of skilled manpower, retaining the skilled manpower, return on investment, business-growth (here it was based on three-year trend).
12. With the increase in ‘size’ construct, the growth parameters are increasingly favorable.
13. ‘Larger’ units show more exports, higher (per-unit) output, better adoption of technology, more investments in R&D, and foreign collaboration.
14. These ‘larger’ units have wider (geographical) area of marketing, have relatively better transportation facilities, lesser dependence on outsourcing facilities, and also lesser areas of complaints.
15. However, there are issues of disagreement with the system.
16. The level of disagreement or expectations from the system is more for the smaller units. With increase in ‘size’, this tends to decline.
17. Key parameters of growth of pharmaceutical industry such as –exports, foreign collaboration, innovation, R&D activities, availability and affordability, have shown strong relationship with ‘size’ indicators. The statistical measure of this relationship –correlation & associations are strong.
18. Majority of the units have many expectations from regulatory authorities, state government s, departments of central government and also ‘international bodies’ like WHO.
19. Most of these are related to a favorable and unambiguous policy regime, smooth implementation without hassles (e-governance, faster operations of regulations/compliance, less barriers, smoother documentation procedures).
20. Help is expected in assessing the market, exports, financial support, easy terms, encouraging policy steps, supportive role of administration.
21. For ‘smaller’ units all-round support is required. Training for unskilled manpower, common pool of facilities like R&D clusters, documentation assistance for exports, and assistance in foreign collaboration, storage and transportation.

Recommendations
Overall the recommendations are in four categories.

(A): MSME sector in pharmaceutical products manufacturing

1. A stimulus package for micro, small and medium enterprises in pharmaceutical sector should be provided.
2. Pharmaceutical companies with less than 100 employees or with investment of less than Rs.1 crore in Plant & Machinery should be identified and brought into a special plan to upgrade these units.
3. An effort should be made to overcome the problems faced by MSME units. This could be done by setting-up of an organization (with focus on development & finance) to revitalize and upgrade the small units.
4. This segment of pharmaceutical industry needs stimulation, support and technological upgradation.
5. Financing on liberal terms, tax incentives, training and technological assistance should be provided to this sector.
6. Facilities for R&D through clusters developed in geographic areas with high concentration of such units should be identified.
7. Training centers should be set up to train unskilled persons specifically for pharmaceutical operations.
8. Setting up of a centralized marketing agency to domestically market pharmaceutical products.

(B): Medium to large units in Pharmaceutical sector

1. Setting up of a products-monitoring and regulation organization to identify the need gaps.
2. Promotion of R&D activities through tax-incentives, sharing of joint R&D efforts by involving industry associations.
3. Provision of centralized warehouses with modern storage facilities such as cold-chain and atmospheric –controls.
4. Facilities of e-governance in licensing and regulations.
5. Introduction of time-bound processes to facilitate faster compliance and smoother administration
6. Export promotion through incentives. Financing facility at liberal terms for units engaged in exports and international trade.
7. Port-facilities with specialized storage at ports to minimize damage due to delays.
8. Technology transfer through setting up of mega R&D laboratories exclusively devoted to pharmaceutical sector.

(C): Manufacturing of medical devices

1. Introduction of policies to sustain the growth observed.
2. Technological tie-ups and collaborations to product-upgrade through technology transfer.
3. Promotion of in-house R&D facilities.
4. Avoidance of delays in regulation through e-governance.

(D): Pharmaceutical sector

1. Opening an International trade training body, in collaboration with industry associations in Pharmaceutical sector to train personnel for exports. Documentation support and training in DGFT/FDA/GMP/effective international marketing.
2. Time–bound approval mechanism to increase transparency and cut avoidable delays in licensing etc.
3. Close cooperation between regulatory bodies of the governments (state and central) and pharmaceutical-industry for information dissemination, creating data bases.
4. Strengthening existing foreign collaborations with liberal policies and introduce possible tie-ups and collaborations for small and medium units.

5. Encourage deployment of more investments in the sector from foreign investors as well as domestic investors.
6. Reduction of taxes on products to enable manufacturers to have lower mark-ups for wholesale and retail trade. This will ensure availability of medicines and devices at lower prices to the end consumer.
7. Providing help and training to obtain international licenses to manufactures and marketing agencies.
8. Revision of DPCO in discussion with industry.

In addition to the above, the various departments and organizations of State governments and central government also have a specific role. These are summarized in the following table:

Issues	Agency	Action Required
Export	DGFT	Documentation, e-governance
	MEA	High Commissions and embassies in different countries should help in Identifying potential for exports in their countries for medicines and devices.
	Min.of Commerce & Industries (MOCI)	Setting up of export processing zones, 100% EOUs in special zone
FDA permission, Poor Infrastructure at ports, Too much paper work, Regulatory, Marketing and IPR	MOCI, MOHFW	To address the impediments faced by the pharma industries in the exports. The impediments in the exports inter-alia include, FDA permission, Poor Infrastructure at ports, Too much paper work, Regulatory, Marketing and IPR.
	Min.of shipping	Arrange appropriate storage facilities at ports. Faster disposal /clearance of material to be shipped
Technology Upgradation	MSME, MOCI	The micro and small enterprises were found to legging behind in the areas of technology upgradation and investment. Therefore, MSME ministry should take targeted initiatives to boost micro and small enterprises relating to pharmaceutical sector through various schemes and programmes to strengthen infrastructure, technology upgradation and exports from micro and small enterprises and for promotion and development of these enterprises.
R &D	Department of Pharmaceuticals	
	CSIR	Help in organizing research and development of new medicine etc. making labs available for scientists and researchers for industry R & D personnel.
	CDRI	(same)
	Min.of Finance	Liberal taxation policy to encourage investment in R&D activities. This may include provision of tax concessions, exemptions in setting up the R &D

		laboratories.(Many such schemes are already in practice)
Pricing	DPCO	A realistic view of cost of production and also include hidden costs.
Foreign Collaborations	MEA	Identifying importers in different countries where the presence of Indian pharmaceutical industry is negligible. Help in identifying technology available , technological tie-ups possible
Overall assistance in growth	MSME	Encouragement to the smaller units by liberal financial assistance in the form of loans, grants-in-aid, exemptions. Special facility to organize R &D laboratories and facilitate smaller units to hire these facilities. Organize special facilities for transportation. Address the pharmaceutical industry differently
Skilled manpower	Min. of Skill development	Identify trades and skills in short supply, existing gaps in manpower supply and demand for pharmaceutical industry. Provide trained manpower to the units suffering from high .attrition rate
Information, Data base	Ministry of Electronics and IT	Creating international database on demand & supply of various formulations. Information dissemination for the benefit of pharmaceutical industry.
API Promotion	Department of Pharmaceuticals	Development of industrial park for API
Quality Standards	Bureau of Indian Standards, National Sanitation foundation	Quality standards for production, raw-material processing, marketing conditions, packaging, Storage , Sanitation related standards