



Pharma census in India

A step forward for better governance?

The first pharmaceuticals census of India aims to create a pharmaceutical map of India, which will provide details of pharma manufacturing units across the country. In an interaction with industry experts, **Saloni Vora** tries to gauge the impact of this endeavour, on planning and policy making.

In February 2008, National Pharmaceutical Pricing Authority (NPPA) initiated a campaign with regard to First Pharmaceuticals Census of India (FPCI) to develop a comprehensive database that would incorporate important information on pharma manufacturing units like investment in plant & machinery, turnover of the units by class of industry, types of units (eg; formulation or bulk drugs), number of 'own' and 'loan' licences, state-wise and district-wise employment generated by the pharma sector in India, etc. It will also include details of the distribution of number of manufacturing units that have the World Health Organization-Good Manufacturing Practice (WHO-GMP) certification, units involved in exports along with the destinations of export, pattern of research & development (R&D) expenditure, and an outline of inventory of semi-finished goods, finished products. It is expected that this broad database would be utilised by the policy makers to facilitate better governance and planning. Now, one class of industry feels that this activity should be carried out more frequently (3-5 years) considering the dynamic and ever-evolving nature of the pharmaceutical industry. However, the manufacturers doubt on the fact that providing confidential information can be beneficial, as they believe that the NPPA may use the information against companies as price control even on common generics, making their products unviable in the market.



Dr Ajit Dangi
President & CEO,
Danssen Consulting

The NPPA has taken a laudable step of conducting a pharmaceutical census and the resulting database will help policy makers to develop a long-term strategic plan for the development and sustainable growth of the Indian pharmaceutical industry. The industry has already made a global impact, and is emerging as a medicine basket for the world. As most governments in the developed world are under immense pressure to reduce healthcare costs, they are in turn looking towards countries like India and China for supplying good quality, affordable generics to their population.

The NPPA should share the census database with other policy making bodies like DCGI, ICMR, DBT, NIPER, etc, as well

as industry associations like OPPI, IDMA, Pharmexcil, etc, to identify gaps in their growth plans, and provide assistance in devising their strategies to remain competitive vis-a-vis other competing countries in this space. The database will also help MNCs and pharma SMEs to plan their investments in plant and machinery, technology, R&D as well as trained human resources. Besides generics, ancillary manufacturers of pharma machinery, packaging materials, Active Pharmaceutical Ingredients (APIs), intermediates, excipients, etc, will benefit enormously from the database to plan future expansion and investment plans.

Moreover, the census will provide raw data, but the industry and the NPPA should work in unison to convert this data into meaningful information to enable planning and devising long-term strategies. While this census aims to provide comprehensive data for the first time, its effective utilisation will depend on the way the government and industry will analyse, interpret and ultimately use it for developing policies to make India an undisputed leader in the global pharma market by 2020.



Alok Saxena

Director-International,
Elder Pharmaceuticals Ltd

India is a large country with the pharma industry spread throughout. However, there is a paucity of authentic data on the exact number of manufacturing units, their turnover, different types (formulation/bulk) as well as region-wise/state-wise break-up. Taking this scenario into account, this census will facilitate the generation of the pharma map of India, with information on various aspects such as investments, pricing & product specifications

as well as compliance to GMP by drug manufacturers in the country.

This is a progressive step to gain valuable insights into pharma manufacturing activities in the country, as it will allow the government & the industry to make plans and future policies. The census will generate extensive data on manufacturing, genderwise employment, capacity utilisations, state-wise distribution of manufacturing, consumption pattern of utilities, R&D expenditure, etc. This will help various ministries including Chemicals & Fertilisers, Health Ministry, Human Resource, Finance, etc. Further, information on the pattern of R&D expenditure will help understand the nature of research activities conducted in the country.



Dipta Chaudhury

Program Manager-Pharma
and Biotech Practice,
(South Asia and Middle East),
Frost & Sullivan

India being a highly fragmented market, with a large number of SME pharma manufacturers, this information is not readily available.

Thus, it becomes difficult to track healthcare reforms, regulatory changes, investment in the sector, and growth of the industry. The pharma census thus can address these needs by providing decision makers an insight into the manufacturing hubs, their growth, infrastructural investments and their importance in the industry on a pan-India basis. The

census will also help validate the current information on the pharma industry, and thereby confirm the growth and future prospects of this industry in India.

The industry is eagerly awaiting the first pharma census, which would help in providing a fact basis for the current opinions of the industry. This information is valuable while making policy changes, as it would enable key decision makers to study the effects of previous policies and plan the impact of any changes they may make in the future. Also, it would provide an indicator towards states and regions in the country, which are intensive towards pharma. This information will further provide a database of WHO GMP compliant companies, their turnover, reach, etc, and will provide information guidance to ministries on the state of development of the industry and help align all manufacturing facilities towards following WHO GMP guidelines.



Dr R B Smarta

Managing Director, Interlink
Marketing Consultancy
Pvt Ltd

The NPPA has taken an excellent initiative and more than 6,000 pharma units have responded to this call.

This move will definitely help in upgrading the quality of medicines, as the collected data will highlight investments in different components of pharma manufacturing.

Moreover, with the NPPA collecting information on formulation and bulk drugs as well, it will be able to justify

India's position on the global scenario. The census will further clarify the various facilities approved by the USFDA, UKMHRA, etc, which have the capacity to produce high-quality generics. Also, proper positioning of this data will help Indian pharma companies to establish their presence in the US generic market in future.

Next, state-wise classification of the data will provide direction to each state ministry and help them identify strengths of the respective states. Thus far, from other statistics, Andhra Pradesh has been noted to be leading in APIs, while Maharashtra & Gujarat are leading the formulations segment, and Karnataka on the biotechnology front. Such details can be especially tabulated from this census to strengthen each state to design specific strategies to empower its manufacturers.



Piyush Tripathi
General Manager-Sales,
Chitra Pharma Machinery

The NPPA was established on 29th August 1997 as an independent body of experts following the cabinet committee decision in September 1994 for reviewing the drug policy, monitoring the availability of drugs, identifying shortages, if any, and accordingly taking remedial steps. The NPPA is empowered to take final decisions, which are subject to review by the Central Government, as and when considered necessary. The Authority also monitors the prices of decontrolled drugs & formulations and oversees the implementation of the

provisions of the Drugs (Prices Control) Order. Keeping this mind, the census should be conducted as and when considered necessary, for that will help monitor the prices of decontrolled drugs and formulations, and oversee the implementation of the provisions of the drugs and price control order. Also, the government should establish a separate panel or committee of members having expertise in the field of pharmaceuticals, economics & cost accountancy, and the same should be entrusted with the task of price fixation revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of the established criteria/guidelines.

Proper reporting in the census shall benefit not only centralised research reach but also give requisite source to new product development and requirement records, helping maintain a broader drug control.



Rajendra Pratap Gupta
International Healthcare &
Retail Expert

The first pharma census is an interesting and important project undertaken by the Government of India. This project will provide vital insights to the policy makers and will redefine their approach towards this sector in the long term.

Moreover, data obtained from this census may be immensely useful if collected for the past three years. The census details obtained by the NPPA may help in reviewing the following parameters:

- ❖ New emerging units or old units undergoing closure or merger
- ❖ Division and marketshare between large & SMEs in the pharma industry
- ❖ Manufacturers involved in the production of life-saving and critical drugs followed by mapping the same, according to requirements in the country
- ❖ Ratio of sales in domestic trade and exports by companies to help make the trade more competitive internationally

- ❖ Percentage of the turnover spent on marketing, R&D, etc, wherein this information can be used for framing policies that can reduce cost of pharmaceutical products & boost R&D inputs from the pharmaceutical companies
- ❖ Difference in the sale, pricing and marketing of generics & branded products
- ❖ As lack of skilled manpower is a major deterrent for the growth of sector, and is a perennial problem for the Indian pharmaceutical industry, data obtained on employment & growth can be used to gauge the employment potential and capacity building for the sector

Besides, one of the major inputs is that, the government can use the data to promote the SME sector and boost regulatory compliance of SMEs in pharma. Further, the data received will enable the government to bring in some pricing and profitability norms, which will reign in irrational prices for the common man.

Hence, overall, the census is an excellent tool to increase the understanding, supervision, regulation & promotion of the sector and safeguard the interests of the industry to make it globally competitive, which will lead to logical & rational pricing for the common man. Also, this should become an annual exercise, as the pharma market is dynamic and the numbers & holding patterns change every year.



Tapan Ray

Director General, Organisation of Pharmaceutical Products of India (OPPI)

Currently, there is a pressing need for the pharmaceutical industry to generate a robust database to help formulate not only various healthcare-related policies but also to assist in measuring the level of their effective implementation. In the absence of such dependable and credible facts, most arguments taking place between the government and other stakeholders are mainly based on their individual views.

Addressing this critical need, in February 2008, the NPPA announced its intent to initiate the FPCI. This activity will capture valuable information, which could be prudently used by the government towards effective planning, policy making and good governance. NPPA is also expected to publish the census data for all stakeholders and other ministries within the government for appropriate actions.

The FPCI is expected to cover over 10,000 manufacturing units in the country in a well-structured manner so as to create an exhaustive healthcare-

related credible databank for India. Thus, this can provide credible details, among others, on the following 10 key areas of the Pharmaceutical Manufacturing Units (PMUs) to enable the policymakers to frame policies based on the ground realities and also measure the level of their effective implementations.

- ❖ Turnover by types and class (micro, small, medium and large)
- ❖ Locations with separate details of Export Oriented Units (EOUs)
- ❖ Capacity installed, capacity utilised by major products
- ❖ Number of 'own' and 'loan' licences units and by type of units, licence issued by the respective state drug controllers
- ❖ Types, class and pattern (plant & machinery, land & building) of investments
- ❖ Consumption of indigenous and imported inputs and utilities
- ❖ Adherence to Good Manufacturing Practices (GMP)
- ❖ Product types and pricing
- ❖ Pattern of expenditure on R&D, clinical trials and quality control
- ❖ Employment generated in the country by the pharma sector

This is an admirable initiative by the NPPA and data generated will be immensely useful to all stakeholders, if updated in every 3-5 years to maintain their relevance.



T S Jaishankar

Chairman, Confederation of Indian Pharmaceutical Industry and Managing Director, Quest Life Sciences

The NPPA had made efforts in the past to conduct pharmaceutical census and create a comprehensive database. However, these efforts did not yield proper results. The Authority had circulated a questionnaire among all pharmaceutical manufacturers in India, most of which did not reply. The main reason for this was said to be complications in the questionnaire.

Also, manufacturers do not think that providing confidential information can be beneficial, believing that the NPPA will use the information against companies as price control even on common generics, making their products unviable in the market.

Further, the industry does not consider the pharma census to be of much benefit. Thus, the NPPA must also clearly outline its objectives behind the FPCI with regard to the manner of utilisation of information generated and the personnel having access to these data.

In fact, the government has all relevant information like the state-wise number of licensed manufacturers, number of employees per company, etc, through the state drug licensing authorities, Employee State Insurance (ESI) and PF departments. The government can easily access these departments to obtain relevant information, which can later be periodically updated.

In order to strengthen the confidence of the industry, it is important for the government to announce the pharma policy as well as close the long pending issues of the role of NPPA and confine the price control in consultation with the industry associations.

The government should thus encourage large investment in this sector, else India may lose out to China as the largest supplier of the generic drugs in the world.