No. 66 February 2015

RIS Policy Brief

India's Growing Dependence on Imports in the area of Bulk Drugs

In the background of concerns being voiced by pharmaceutical industry and academics as well as policymakers, RIS organised a Colloquium on India's Growing Dependence on Imports in the Area of Bulk Drugs in New Delhi on 23 December 2014 to provide inputs for government policymaking. Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals inaugurated the Colloquium. Shri Ananth Kumar, Hon'ble Minister for Chemicals and Fertilizers delivered the valedictory address. Representatives of pharma industry as well as academic and other persons working in the field of public health and access to medicine participated in the colloquium.

The Colloquium observed that:

- India's growing dependence on imports in the area of bulk drugs would have impact on our pharmaceutical formulation industry, access to medicines, health security and also on manufacturing sector.
- The data available on the requirement and imports are approximations and not fully reliable. The bulk drug requirements of the country in 2010 were valued at approximately Rs. 24,000 crore of which the imports accounted for about Rs. 11,500 crore. Total import of bulk drugs from China as a percentage of the total bulk drug imports has gone up from 0.3 per cent in 1991 to 47.61 per cent in 2012. In fact, in 2011 it was 57.1 per cent.
- Figure 1 illustrates the dimension of the import dependence on China.
- As far as intermediates are concerned there is more than 65 to 70 per cent dependence on China, particularly for antibiotics, cephalosporin, vitamins, aspirin, paracetamol, metformin, renitidine, ibuprofen, amoxicillin, ciprofloxacin, cefixime, ofloxacin, ampilillin, etc.
- In the globalised market economy, no country can avoid imports and India has been importing bulk drugs from abroad for quite some time. But the more alarming fact is that this dependence is largely on one source, that is, China and this import dependence on one single country puts India in a strategically disadvantageous position. If China decides to stop its supply of intermediates and other raw materials to India, it will drastically affect India's pharma industry and bring it almost to halt. As Dr. Y. K. Hamied, Chairman of CIPLA says, "If China decided one bright day to stop export to India, we would be finished. The pharma industry is zero, both domestic and export, and we are looking at that danger objectively". Therefore, there is immediate need to address the challenges lying ahead of us in the pharma sector. Similar views have been expressed by Indian Drug Manufacturers Association (IDMA), and Indian Pharmaceutical Alliance (IPA).
- There is disconnect between the concerns expressed from various corners on the growing import dependence on China and the official statistics on trade in pharmaceuticals sector. While the pharmaceutical industry representatives raise concerns on the growing import dependence on China, the official trade statistics do not indicate the same. No government body (Department of Pharmaceuticals or Department of Commerce) provides the import data on bulk drugs on a regular basis. The annual report of the Department of Pharmaceuticals provides data only for total import, and not separately for bulk drugs and formulations. Therefore, it is quite difficult to undertake any study on

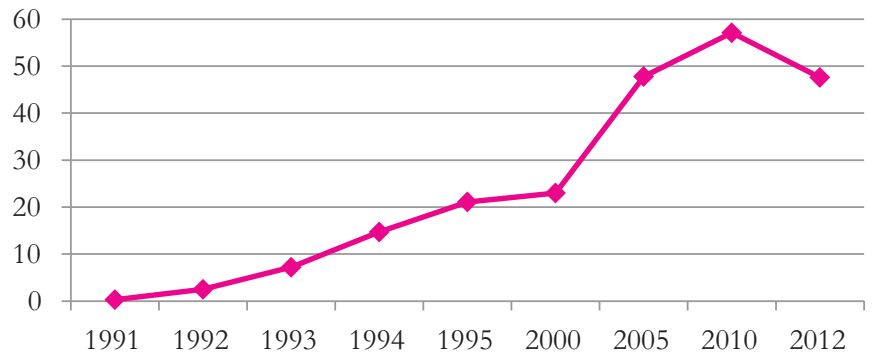
RIS *Policy Briefs* are prepared on specific policy issues for the policy makers.

This *Policy Brief* is prepared by Mr. T.C. James, Consultant, RIS based on the proceedings of the Colloquium on India's Growing Dependence on Imports in the Area of Bulk Drugs held in New Delhi on 23 December 2014.

trade in bulk drugs of Indian pharma sector. Secondly, as compared to the import data of Indian pharmaceuticals sector made available by Prowess (Centre for Monitoring Indian Economy) and International Trade Statistics of WTO, the import statistics provided in the annual reports appear to be grossly underestimated. We need proper empirical studies to get the correct picture.

- The issue is also linked with the future of India's dominance in generic medicines since the formulation industry depends on Active Pharmaceutical Ingredients (APIs). Dependence on a single country can affect the industry as that country will be deciding the quantity of supply and price. If that country opts to go for generic production, our companies will find the competition tougher; because of logistics alone they can price us out as the APIs supplied to their local companies can be cheaper and more sustainable.
- Growing import dependence for raw materials also raises concerns about the quality of finished products (formulations). Now a number of Indian firms face quality issues with formulations in the US and EU markets. When there is dependence on imports for intermediates and bulk drugs, obviously, there will be limitations in ensuring quality of the formulations. There are practical constraints in ensuring quality of imported raw materials from China. Therefore, to maintain India's position as a leading supplier of generic drugs in the world market, we need to produce the raw materials, to the extent possible, domestically.
- The future of a large number of Micro, Small and Medium Enterprises (MSMEs) in pharma sector is also likely to be affected, because of cheaper imports of bulk drugs coming from China, with whom they find it difficult to compete on prices, essentially because of the economy of scale that the Chinese firms have. Further, any strict action by the US on China firms can adversely affect India also because we are dependent on China for sourcing the products for which we seek US Drug Manufacturing File (DMF) registration.
- Another important fact is that India Pharma industry is fragmented with thousands of units, both registered and unregistered. While large number is good from a competition angle, the small size of many of them make them unviable in a global market place as larger firms can price their products out. Small units will have to work out survival strategies such as forming groups or clusters.
- The R&D investment (R&D expenditure as a percentage of sales turn over) by the domestic pharma industry as a whole has gone down in the recent years. For example, while Dr. Reddy's Labs state on their company profiles that they are maintaining an R&D expenditure of around 6 per cent, the number of scientists working in the firm has gone down from 280 in the last decade to around 30. The share in the drugs and medicines patents granted to residents during 2005-14 is only around 23 per cent as compared to 77 per cent by non-residents, reflecting the need for increased focus on innovation by the domestic firms. Two other vital concerns are that the economic system is not oriented for supporting investment in innovation for local needs and that financing systems which can provide for payments for innovation in medicine are not working for the promotion of process and product innovation in domestic

Figure 1: Share of Imports from China in Total import of Bulk Drugs (%)



Source: Computed from *COMTRADE* data based on SITC (Rev.3).

industry. We need to have financial systems that provide sufficient venture capital for domestic innovators.

- In view of the above said bleak scenario, there is a need for policy shift, regulation shift, governance shift as well as paradigm shift. In the past, when the Indian pharmaceutical industry was almost non-existent and for almost all medicines India was dependent on imports, based on the recommendations of Justice Ayyangar Committee, the government modified the patent laws in the 1970s and consequently the next 30 years saw India emerging as the dominant generic drug supplier of the world and also the major source of affordable medicines. Such shifts which encourage domestic bulk drug production are necessary. Domestic firms should find it easier to do business in the country. Pharmaceuticals require approvals from different agencies. They should be easier, transparent and faster. We also need to develop WTO compliant regulations that the domestic players should find easier to conform.
- Since the pharmaceutical industry depends on multiple set of regulations starting with land acquisition for setting up a production unit; raw materials both chemical and biological; adequate qualified human resources; availability of latest technologies; intellectual property right regime; drug marketing approvals; trade barriers, both tariff and non-tariff, in other countries, etc., it needs a coordinated approach by various departments of the government.
- We need to create an environment that is conducive to increase the production of the bulk drugs within the country. This calls for policies and regulations that domestic industry can comply with more easily compared to outside players. Updating of the domestic industry with global manufacturing standards and good manufacturing practices will enable them to maintain higher quality standards prescribed in developed countries and also exploit those markets.
- One of the problems that resulted in the decline of the fermentation industry engaged in production of the drugs was power supply. We need to ensure regular supply of electricity to ensure increased production of bulk drugs.
- We can learn lessons from China and bring changes in our policy and whole landscape of the pharma sector. As per the industry, China has several advantages such as low cost and high volume products. Most firms are state owned enterprises, whereas Indian pharma industry is entrepreneur-driven. Government provides 15 to 17 per cent draw back duty on exports to cover up the losses of Chinese manufacturers. The working shift in Chinese firms is 12 hours. The power tariff is low. The lending rate in China is 6.31 per cent whereas in India it is double. Government also provides tax incentives in more than 54 economic and technology zones, 15 free trade zones, 53 high tech parks and 56 export processing zones. As per reports, China government is drawing up a plan to invest US$ 761 million for Active Pharmaceutical Ingredient (API) with a goal of raising export value of the products by US$ 4 billion annually.
- Chinese government's three-fold thrust is: economy of scale of production, acquisition of innovation and technological superiority and export-driven growth. We also need to have focussed policy interventions.
- As regards, registration of products for import, the industry observes that:
  - China takes more than four to five years to register our product whereas we are able to do it in three to six months or maximum nine months.
  - China registration charges are more than Rs. 8 lakh per product whereas in India it is only about Rs. 1.5 lakh.
  - Anti dumping process takes almost two years in India and by that time domestic industry is at the verge of closure. It has to be fast tracked to protect the domestic industry.
  - China registers our product after inspection whereas India has inspected 10 units only so far.
  - Manpower with regulator of China is four times than what we have. Central Drug Standard Control Organisation (CDSCO) has to be strengthened.
  - More than 50 per cent units registered in India are from China, 10 per cent from Italy and the rest are from other countries.
- There is need for government to revive the public sector undertakings so that bulk drugs can be manufactured in India itself without too much dependence on market forces. Turnaround of these companies with proper management inputs is quite feasible as the

Indian Drugs and Pharmaceuticals Ltd. (IDPL) story illustrates it distinctly.

- The competitive advantages that India has are:
  - Skilled manpower
  - Infrastructure for manufacture
  - High local demand.

  We should build on these advantages.
- A major issue that affects this sector is that different ministries/departments of the government deal with different aspects with inadequate coordination; the Department of Health deals with health-related and regulatory issues, Department of Pharmaceuticals deals with drug policy, Department of Science and Technology deals with innovation, Ministry of Finance deals with taxes and Department of Commerce deals with trade-related matters. There is need for coordinated and concerted action by all of them to deal with the current problem.
- Some specific suggestions made by the industry are:
  - Cheap and stable power particularly for fermentation based products.
  - Cluster scheme: Setting up of mega parks with common effluent treatment plant, common lab, etc.
  - Special fiscal benefits for economies of scale.
  - Revival of PSUs.
  - Adequate provision of good quality Biological strains.
  - Special Purpose Vehicle funding through banks as well as longer time of moratorium.
  - Energy: Priority allocation of coal and bio fuel natural gas.
  - Rational use of anti-dumping law.
  - Single Window System: Constitution of coordination committees of various departments to help the industry through single window, like in China
  - Simpler Procedures – from doing business perspective.
- Government may look at these suggestions in a positive way since they come directly from the industry.
- India also needs to take steps to re-activate innovation by the domestic pharmaceutical industry to take sustainable leadership in the sector. Incentives, both fiscal/tax and institutional need to be provided for this. More industry-academic/research institution collaborations, encouragement of open source drug discoveries in the area of neglected diseases, setting up of incubation centres, etc., are some such steps which could be contemplated and acted upon with utmost urgency.
- It was also felt that detailed research studies should be conducted to understand emerging issues in the pharmaceutical industry that may affect health security of the country and to suggest timely policy interventions.
- The magnitude of threat from import dependence on bulk drugs appears to be grossly underestimated due to issues with estimation procedure. Therefore, a comprehensive study needs to be commissioned to gauge the actual situation of import dependence. The study team should include academics, industry representatives and government officials.
- Such studies specifically on the manufacturing side of the pharma industry are also necessary so that the goal of 'make in India' campaign becomes a reality in the sector.
- Indian pharmaceutical industry needs to have strategic focus on Asian markets for long term sustenance of exports of formulations
- Government also needs to provide more support and incentives than at present to MSMEs in pharma sector.

The Hon'ble Minister has promised to take the way forward keeping in view the policy recommendations from this RIS colloquium, but all concerned departments of the Government of India would have to move together.