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Venkat Jasti asks Govt. & Industry to play pro-active role to tap the potential

post-2005

The pharmaceutical industry is regarded as one of the most highly regulated industries in the world. To meet the demands of a multi-national global economy, pharmaceutical companies must comply with high regulatory standards of numerous countries. According to Venkat Jasti, President, BDMA (Bulk Drug Manufacturers Association), the Indian pharmaceutical industry, and the bulk drug industry in particular, has a tremendous potential in the ensuing IPR regime starting January 2005, provided the industry and the government play a pro-active role. Though large Pharma companies have realized the big opportunities and challenges before them and are preparing to upgrade their capacities and facilities to meet international standards, the Government of India is yet to move on fast track. The government has not yet finalized the long-awaited Patents Act and it is already too late to take advantage of the opportunities that are coming in the near term. VENKAT JASTI spoke to PNV NAIR of Pharmabiz.com on the problems and rospects of the Bulk Drug Industry and its preparations to meet international challenges. Excerpts of the interview:

Q: Do you think that the Indian pharma industry is well-equipped for the post-2005 regulatory regime?

A: Yes and No. Though the large players are preparing themselves for the regime, small and medium companies are lagging behind. The Government of India has signed the WTO Document in 1995 and the country is bound by the regulatory regime from 2005. But we have wasted so much time and nothing concrete has been done so far. The government has not yet finalized the Patents Act which would have given some guidelines to the small and medium companies to prepare themselves. Even if the government finalizes the Act now, it will be too late for these units to comply with the regulations. At the same time, large units are preparing themselves extremely well without depending on the government.

Q: There are more than 600 bulk drug manufacturers in the country, of which 50 % may be able to survive the regulatory regime. What will happen to the rest?

A: Naturally, it may be 50% in the initial stages. Slowly their number may be reduced to 25 % over a five-year period with mergers and acquisitions. Those who are not able to improve within this period may become supporting/complementary manufacturing units supplying their products/services to intermediaries. But the value addition will be very less in that case.

Q: Is there any concrete plan towards mergers and acquisitions. What should be the model for such mergers?

A: There cannot be any model for mergers/acquisitions in the private sector. If the units have some value and potential, they will be taken over by some big companies. Otherwise, they will be destined to close down. Mergers and acquisitions have already started in the country with companies like Dr. Reddy's, Ranbaxy, Aurobindo Pharma, and Matrix Labs etc. taking the lead.

Q: Are you satisfied with the present investment in drug discovery and R&D in the pharma industry?

A: Yes, it is a tough situation. On one side we are asking them to upgrade their facilities and concentrate on international standards and on the other we are expecting big investments on R&D. In the absence of sufficient venture capital and support from financial institutions, many small and medium level companies would not be able to spend on drug discovery. Even the Pharmaceutical Research Fund promised by the government has not been set up. Again, big companies are doing admirable work in this direction and are even competing with multinational companies by discovering new molecules and new chemical entities. Of course, it needs heavy investment with long gestation periods. Only with proper mindset one can enter into this high-risk venture. However, there is a very good start.

Q: Is there any scope for new entrepreneurs in the industry?

A: There is always scope for new entrepreneurs, but the size does matter at this stage. Small players have no place as they will not be competitive in global business. The cost of setting up a pharma unit with R&D has gone up substantially. Unless one has the funds to set up a state-of-the-art facility meeting international regulatory requirements, it is difficult to survive. Technocrat entrepreneurs who have the mindset can set up boutique operations in R&D and succeed. However, for such entrepreneurs the opportunities will be greater in the IPR regime and there will be minimum risk.

Q: Do you think India is taking the right steps in Intellectual Property Rights? What are your suggestions to speed up the matter?

A: No doubt, India has taken the right direction, but it is too late. The industry has a tremendous stake and potential in the IPR regime, but the government is dragging its feet. As I said earlier, the government has not yet finalized the Patents Act. If it is done at the last moment it will be of no use as we will lose the first mover advantage.

Q: What is the role of BDMA in the improvement of the bulk drug industry at this crucial moment when the IPR regime is only one-and-a-half years away?

A: BDMA is trying to bring in awareness among the members about all aspects of the regulatory regime, including international guidelines, Intellectual Property Rights and marketing, and is trying to bring out the best that is possible. It is holding seminars and symposia, and is arranging business tours to and from various countries. Of late, BDMA has planned a series of seminars on IPR related issues and the first such seminar was held in Hyderabad on June 10. The

Association is working towards common test criteria which will be acceptable to the mature markets in the US, Europe and Japan which account for more than 80% of the drugs market in the world.

BDMA, in close association with the Government of Andhra Pradesh, is trying to promote the industry in an organized manner. The government has constituted a Task Force on Pharmaceutical Industry with the Chief Minister himself as Chairman and the Major Industries Minister as Vice-Chairman. After the successful initiative in AP, other states have also launched similar activities with the help of BDMA.

Unfortunately, the government of India is not doing anything right for the industry. Even the government policies are mired in litigation. In the absence of a national initiative, individual units are looking after themselves in most cases. A lot more need to be done for which everybody is looking towards the Government of India.

Q: Do you think dumping is a serious issue for the industry? What are the problem areas?

A: Dumping is a serious matter with China as the major culprit as of now. This is because import regulations are not strictly implemented in the country. However, India has a good procedural system which is good for the industry.

Q: Bulk drugs imports under Advanced License Scheme (ALS) has been Exempted from registration, though BDMA had represented to the Centre against this move. What is your reaction?

A: We are worried that the government of India is not doing the right thing and helping the Indian manufacturers, which is unfortunate. Since the government has given the exemption already, it should be for a short period. The government should actually inspect the premises before giving the exemption. As we said in our representation to the government, the exemption would not give a level-playing field to the domestic industry. Indian exporters are required to register their products in the respective countries. Then, this rule should apply to imports of drugs into the country as well.

Q: What is the fate of the proposed Pharmexcil, now that it has been decided to be set up in Mumbai?

A: Pharmexcil will be set up with Mumbai as its headquarters and Hyderabad the Registered office. Again, there is delay in the concerned ministry in clearing the files. "We are waiting for the go ahead from the Government of India to start the activities."

Q: What is the scope for international tie-ups and joint ventures, especially in the African and Latin American countries? What are your experiences after a series of interactive meetings of delegates from these regions with Indian entrepreneurs?

A: The possibilities and advantages are more in the US and in Europe than elsewhere. It will be in the form of contract research, manufacture, marketing and services. Though various countries in Latin America and Africa have their own rules and regulations, some Indian companies have already penetrated these markets. These countries are also looking towards India because of cost factor and quality.

Q: The pharma industry is projected to grow from the present $ 5.5 billion to $ 25 billion by the year 2010 and to $75 billion by 2020. Do you think these targets are attainable?

A: The projections are too far-fetched. $ 25 billion is attainable in another 10 years for which we have to do a lot of pro-active action and thinking. The industry has to upgrade itself to meet the challenges and grab the opportunities. It must also forge ahead with innovation instead of imitation utilizing the technical man-power which is available in plenty. And any initiative must have the full backing and support from the government.

(Pharmabiz)