

Address by Chief Guest Shri Ashok Kumar, Secretary, Department of Pharmaceuticals, Government of India for the 42nd Annual General Meeting of OPPI on 20th September, 2008 at Hotel Taj Mahal Palace & Tower, Mumbai

Shri Ranga Iyer, President OPPI, Members of OPPI, ladies and gentlemen

At the outset, I would like to thank OPPI for inviting me to this meeting and giving me an opportunity to meet and address their members. I do realize that OPPI is a unique organization with several of the members from multi-national companies operating in India. Some of these companies have a presence in India for a long time and have been playing an important role in the healthcare needs of the country. They have brought new drugs and new technologies into the country.

It is heartening to know that the pharmaceutical industry in India has been growing at almost one and half times the rate of growth of the Indian economy for the last few years. India today occupies a place among the top three countries, so far as the exports of generic drugs as well as APIs is concerned. The real growth of the Indian Pharma Industry has taken place after independence of the country and more particularly after 1972 when the Patent Act, 1970 law was passed. Government played an important role by setting up some major public sector companies like IDPL and Hindustan Antibiotics Ltd in the 1950s and 1960s for making bulk drugs. This helped in establishing a base for the industry with easy availability of some of the bulk drugs in the country. Today Indian industry has established a strong presence at the global level. I am very hopeful that the robust growth will continue in the years to come. OPPI as one of the premier organizations of pharma industry has an important role to play in the growth of the sector.

A new Department of Pharmaceuticals has been created recently by Government with a view to put greater focus on this important sector. The Department has been assigned several new functions including promotion of research, education and training, public-private partnership, international cooperation, intersectoral cooperation etc. We are keen to come out with new schemes in some of these areas which would help industry in innovation and their growth. After taking over as Secretary in the Department I have held several meetings with other associate Departments like DST, DBT, DSIR and ICMR. Some new ideas have emerged based on which new schemes could be drawn up. However we would like to know the industry's views also for proper framing of these schemes. One of the key suggestions given to us is that the Department should come out with several extra-mural schemes which would help catalyse research and innovation in the sector. Also, as you are aware, Government has sanctioned six new NIPERS in the country. These NIPERs are to be set up in the public-private partnership model. We would like industry to play an active role in the setting up and running of these NIPERs. This would help in better utilization of the capacities and infrastructure of these Institutes. Another important scheme which is being discussed is the sale of unbranded generic drugs through dedicated outlets in districts, may be initially one in each district. A concept note has been prepared and circulated to all the Associations for their views. We have discussed the proposal in a meeting held on 12th September, 2008 in Delhi in which Mr. Zarir Charna from OPPI also participated. You may recollect that this issue was discussed in the last meeting of the Pharma Advisory Forum chaired by Hon'ble Minister for Chemicals, Fertilizers and Steel in April, 2008.

I am happy to know that there is a growing partnership between the MNCs and the domestic companies in the areas of R&D and contract manufacturing. Several of your members and MNCs from overseas are conducting clinical trials in India for new drugs. This has been possible due to the conducive policies

adopted by Government. Schedule 'Y' of the Drugs and Cosmetics Rules was amended in 2005 to allow for multi-centric concurrent clinical trials in India. The latest international norms have been adopted in this regard. This has enabled MNCs to concurrently start clinical trials in India along with trials in other countries. You know better that the cost of these trials is very low as compared to the cost in developed countries. Similarly the revised Schedule 'M' of the Drugs and Cosmetics Rules has been made mandatory for all pharma plants in India. This lays down the standards and quality of manufacturing operations.

With the presence of a large number of pharma companies India has almost become self sufficient in the production of most of the medicines. However, we are often told that many drugs launched in developed countries have not been launched in India even after several years. I would urge you to identify such drugs and based on their requirement in the country help in the early launch of these in India. I am addressing this to you and MNC companies operating here. You will have to play the role of a bridge between your Principals aboard and India.

A major factor which is critical for future growth is the focus on R&D. I am happy to know that over the last few years, industry has been increasing its investment in R&D and particularly drug discovery. Some of the bigger companies are investing as much as 5% to 10% of their turnover in this area. One of the most significant developments in the recent past has been the introduction of new product patent regime. I am happy to note that more than 90% of the product patents granted by the Indian Patent Office pertain to the Pharmaceutical products. This shows the innovative potential as well as interest of Pharmaceutical producers in Indian market. I understand that many of these product patents pertain to the members of OPPI. As you are aware that a Committee in our Department is looking into various aspects of this issue and would be finalizing its report soon. The issue of pricing of patented

medicines is a complex one and balancing the conflicting objectives of the Pharma companies and patients is a difficult task. I am sure that Committee would come out with a workable model base on which the Department will be able to take an appropriate decision.

As you are aware Government is providing several fiscal incentives for R&D. These are by way of weighted deduction upto 150% in income tax which has been extended upto 31st March, 2012, several concessions in customs duty on the import of R&D equipment etc. Government has also substantially increased the budget under its Drug and Pharmaceutical Research Programme handled by DST. Government fully realizes the need to support such efforts by industry, looking to the future health challenges faced by the country. We would like the members of OPPI to further step up their investment on R&D in India and take advantage of these incentives. We would like to have suggestions in this regard also.

Healthcare is one of the priority areas of the Government it finds a place of prominence in the National Common Minimum Programme of the Government. One of the major objectives is to raise the public spending on healthcare from nearly 1% of GDP as at present to atleast 2-3% over the next few years. Action has already been initiated in this direction by spending up public health spending through health programme like the National Rural Health Mission.

Government has recently approved a major health insurance scheme for the workers of the unorganized sector this also includes BPL families. Through this scheme, the entire BPL population is proposed to be covered within a period of five years. This scheme is proposed to be implemented in partnership with the States. This is a major step forward and reflects Government's commitment towards these vulnerable sections of the population. However, several more incentives are required to effectively take care of the gaps in healthcare in the country and for improving access of essential medicines to the poor people.

Industry should come forward in this regard in the spirit of public-private partnership.

One of the problems with which industry is deeply concerned pertains to the menace of counterfeit and fake drugs in the country. This issue was also highlighted by industry before the Group of Ministers. Government is fully alive to the problem and is determined to check this menace in the country several steps have already been taken by the Health Ministry and the States also. Legal provisions are being tightened to provide stiffer punishment to the offenders, and as I mentioned earlier quality parameters through Schedule 'M' of Drugs and Cosmetics Rules have been made mandatory. Now no manufacturing activity can take place without the adoption of these norms, which help keeping a check on the quality of medicines. Government has also initiated steps to set up an autonomous Central Drug Authority in the country which will help in effective implementation of the provisions of the Drugs and Cosmetics Act. Suitable improvement in the functioning of State Drug Regulatory Authorities is also contemplated and underway. Many of the States have made significant improvements in their monitoring and implementation mechanisms.

I would like to thank you all for your contribution in the growth of the Indian Pharma Industry and your role in meeting the healthcare needs of the people of this country. I am sure you will continue your efforts to meet future challenges also and your social responsibilities and work with Government to address the problems of the people with focus on the poor. These problems are complex and daunting and would need support of all the stakeholders to come and work together. I have no doubt in my mind that together we can face the challenge and make drugs affordable and accessible to all sections of the population.

As many of you may be aware there is an important international event being held by FICCI with the support of both the Departments of Chemicals and

Petrochemicals and Pharmaceuticals in Mumbai from 20th to 22nd October, 2008. It is called 'India-Chem, 2008' We would like the members of OPPI to participate in it and take advantage of the business opportunities which will be made available there.

In the end, I would like to express my best wishes to OPPI and all its members for their future endeavors.

Thank You