



# ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA

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## **Address by Mr. Ranga Iyer, President At OPPI AGM on Saturday, August 8, 2009**

Two years ago, I was given the honour to head OPPI. It has been a high point in my career. I have, with the advice and support of my colleagues in the industry, tried my best to advance the interests of the pharmaceutical industry. As I hand over charge to my able successor --, let me share my thoughts on the key aspects of the Indian pharma industry, OPPI's achievements and the unfinished agenda.

The Indian pharmaceutical industry has come a long way and is widely regarded as a global success story on par with the software industry.

We not only manufacture in the country most of the medicines required, we are a major exporter of generic medicines to the developing as well as developed world. The Indian pharma industry is increasing its investment in research.

The industry's growth projections have been reaffirmed by Deloitte which has forecast that the industry will touch \$16 billion by 2015.

Our medicines are among the most affordable in the world. Essential medicines cost less in India compared to neighbouring Pakistan and Sri Lanka and this is largely due to the competition in the market place for all essential drugs.

The financial downturn has had minimal effect on the industry and the global pharmaceutical companies are showing interest in generic business in BRIC countries.

As OPPI President, I have been interacting with various industry associations, overseas visitors, government officials and academic institutions. They are all fascinated by the progress made by the Indian pharmaceutical industry, the fact that India has more than 100 US FDA approved plants – the largest number in any country outside North America. They are also struck by the fact that this industry has been registering double-digit growth in India unlike several other industries that were impacted by the financial crisis.

Indian companies have made a mark in the US, the world's leading pharmaceutical market, as reliable supplier of generic medicines. India is a topper in ANDA and DMF approvals given by the US FDA. No wonder the US FDA has established its office in India.

Indian companies have now begun to forge new alliances with big global companies. These collaborations are helping to shepherd Indian drug companies into a new era of innovative drug discovery. However, Indian regulations governing patents, drug approvals, and clinical trials are still required to be updated. As the global companies are forging alliances with Indian companies, we need to make the environment friendly and attractive compared to competitors like China.

In addition to a significant pool of trained biomedical and chemistry professionals and a strong bioinformatics tradition, India has a large genetically diverse population to recruit patients for clinical trials. Clinical trials constitute almost 70% of the cost of bringing a new drug to the market.

The share of the top three markets – the US, Europe and Japan — slipped back to 46% last year from 74% in 2001, while the emerging markets moved several notches up to 25% from 8%. By 2020, emerging markets could well reach \$400 billion—equivalent to current combined sales of US and key EU markets. Let us not forget that India has competition from China and other emerging markets. While we have competitive advantages, we also have the disadvantage of an intellectual property regime that is not yet robust.

Firstly, we need to adopt the global definition of patentability. Patentability of incremental innovation remains a contentious issue in India. Allowing patents for incremental innovation will be beneficial to our patients and the domestic industry. The Indian industry, with its ingenuity and process expertise can come up with incremental innovations that add value for the patient by improving efficacy, safety and compliance. It will be a win-win situation for the patient, the industry and the government which is facing a huge public health problem.

By not encouraging incremental innovation, we are in effect saying that any effort to make a drug more effective and safer is not innovation.

Incremental innovation is **not** ever-greening. First of all, incremental innovation will not get a full patent of 20 years. It gets a much shorter patent, sometimes as short as 7 years in some countries. And, don't forget, the patent for the original drug and the patent granted for incremental innovation are independent of each other.

Incremental innovation on existing drugs is very important for countries like India faced with tropical diseases such as malaria, dengue and TB. They are steps on the ladder of innovation. The biggest beneficiaries of incremental innovations would be the Indian patients.

Data generated from clinical trials make up almost 70% of the cost of bringing a new drug into the market. The companies that oppose regulatory data protection today will be the most vociferous in demanding it when they succeed in bringing a new drug into the market on the basis of data that they have generated through costly trials.

I am glad the Government has now accepted in principle the need for data protection. I hope the new government will introduce data protection to reassure all innovators – Indian as well as foreign -- that their costly investment in research will be protected.

Until recently, all the discussions on patents and data protection involved only the Government, the industry and NGOs. A very important stakeholder – the doctor – was not involved. After all, it is the doctor who needs newer medicines that are better, safer and convenient for the patient. OPPI took the initiative to conduct

workshops with doctors on all aspects of IPR. Their feedback has been positive. I am glad that they are now joining the debate.

The other major issue facing India is the urgent need to expand access to healthcare. Let me recall the OPPI mission statement: “To make continuous contribution towards **achieving healthcare objectives of the nation** while professionally addressing the collective interests of its members and **encouraging innovation for inclusive growth.**”

The pharmaceutical industry's growth and achievements have not contributed to a proportionate impact on the healthcare scene because of wide gaps in India's healthcare infrastructure.

This is a matter of deep regret to all professionals in the industry.

We were fortunate to listen to our former President Dr Abdul Kalam today. He toured all over India during his tenure as President, meeting people from all walks of life, especially children for whom he had a special affection.

One of the components of his vision for India by the year 2020 is to make it “a nation where the best healthcare is available to all.”

This vision can become a reality only if India thinks big and invests heavily in healthcare infrastructure. Currently India’s investment at 1.2% of GDP is the lowest in the region.

We are nation of a billion-plus people but only 35% of our population have access to modern medicines.

OPPI’s mission to make a significant contribution to healthcare objectives of the nation can be fulfilled only if there is an accelerated investment in healthcare infrastructure.

In a written reply in the Lok Sabha, the Government said India spends Rs.37 per head per month to provide healthcare facilities for its one billion-plus people.

The Commission of Microeconomics and Health set up by the World Health Organisation estimated that the minimum expenditure for essential health intervention for one person should be at least \$ 34, that is, Rs.1, 600 per year.

Though India’s health budget for 2009-10 has increased by Rs.3,107 crore to Rs.22,641 crore, the allocation constitutes a little over one percent of the GDP.

We are proud of being part of BRIC countries, but our healthcare infrastructure does not stand comparison to China, Russia and Brazil. To cite only one example, India has 0.6 doctors per 1,000 people compared to 1.06 in China and 1.15 in Brazil.

The spate of news reports in the media on Government’s move to control pharmaceutical prices contribute to the myth that prices are standing in the way of access to medicines. This is not true at all.

Nearly 200 million Indian women and more than 80% of children in India have iron deficiency anemia. The cost of iron supplement is only one rupee. Yet the low price has not helped rural health because of lack of rural availability. It shows a delivery failure.

According to a study published by the Ministry of Health, a villager has to travel an average 2.2 km to reach the first health post for getting a paracetamol tablet, over 6 km for a blood test, and nearly 20 km for hospital care.

The pharmaceutical industry caters to 350 million population consisting of 150 million in the formal sector and 200 million who are above the poverty line.

The 650 million who have no access to medicines today – consisting of 300 million above the poverty line and 350 million below the poverty line – largely need essential medicines. To dispense these essential medicines which is the need today, we need doctors, clinics and chemists. Sanitation and hygiene are the major health hazards in most parts of the country.

I am glad the Government is trying to reach essential medicines to those without access through the Jan Aushadhi program. It was inspired and implemented by Shri Ashok Kumar, who is with us today. Sir, I complement you on your efforts. The initial feedback on Jan Aushadhi scheme is favourable. OPPI applauds this laudable venture which aims to establish retail outlets in every district of the country. This will be a major step in improving infrastructure.

Talking of improving access to healthcare, I would urge the Government to go one step further. Why should not a Government, which intervenes in ensuring the availability of agricultural products, agricultural inputs, fuel and kerosene to the underprivileged, consider similar intervention in providing medicines to those below the poverty line? We at OPPI will be happy to work with the Government in any program that improves access of medicines to the poor.

The other major issue that impacts the health of the people and reputation of the country is the menace of spurious drugs. I am happy that the Health Ministry is seized of the issue. The Drugs & Cosmetics Act was recently amended to provide stricter penalties. The Government has launched a countrywide survey on 61 brands to assess the size of the spurious drug industry. The Health Ministry has proposed a whistle blower policy to reward people who inform and help seize spurious, adulterated and misbranded drugs.

Let me now dwell briefly on other major OPPI initiatives during the last two years. For the first time, OPPI has collaborated with NIPER and CSIR, two prestigious R&D organizations run by the Government. It is part of OPPI's public-private partnership initiative to encourage innovation in pharmaceutical R&D. OPPI instituted the "Scientists & Young Scientists Award" to encourage original research in pharmaceutical sciences.

I am glad to report that OPPI's interface with the Government has reached a new high. We played a proactive role in drafting of CDSO guidelines on biologicals. We also worked closely with Government departments in streamlining cold chain management in Mumbai and Delhi international airports.

In the field of academics, OPPI worked with international institutions like Wharton and Boston, and with Indian institutions like the Indian School of Business, Indian Institute of Management, Pharmacy and other colleges to develop tomorrow's leaders.

Clinical trials are the cornerstones of research and innovation in our industry. Global clinical trials are relatively new to India. No wonder there are several misconceptions on the subject. OPPI has put together a Code for Conduct of Clinical Trials. It will help reassure the public about the high ethical standards that OPPI member companies profess and practice while conducting trials.

OPPI has formulated and published guidelines and code for cold chain management. We are now working on a uniform code of marketing practices for the industry. We also worked with Ernst & Young for a research report on Indian Contract Research and Manufacturing Services and with YES Bank on Indian Pharmaceutical Industry – Vision 2015.

We still have an unfinished agenda to pursue especially in the areas of Pharmaceutical Pricing Policy and Indian Patents Act.

As I lay down my office as President, I would like to thank all the people with whom I have interacted over the last two years. Professionally, I have learnt more about the industry from each and everyone I have interacted with and personally, I have made a lot of friends, both of which I treasure very much.

I thank all Govt. officials for granting time and giving us an opportunity to present our point of view.

I thank my colleagues in the Executive Committee, the Presidents and office bearers of other associations and the staff of OPPI who have supported me in the last two years.