

CHEMTECH + PHARMA 2009 – INAUGURAL FUNCTION
12th February, 2009, Mumbai
10.00 a.m. to 12 noon

**LEVERAGING OPPORTUNITIES IN THE
PHARMACEUTICAL INDUSTRY**

Tapan Ray, Director General
Organisation of Pharmaceutical Producers of India

As we know, Indian Pharmaceutical Industry may broadly be divided into three sectors:

- Domestic formulations,
- Export of APIs and formulations and
- Contract Research and Manufacturing Services (CRAMS)

The shadow of recession may be looming large on the Indian stock market; Indian pharmaceutical companies seem to have pulled up their socks to effectively convert this problem into opportunity and wither away the effect of global meltdown on the Indian Pharmaceutical Industry.

This global economic slowdown intertwined with credit crunch are not expected to significantly retard the progress of the industry. There are 2 main reasons for this:

1. The domestic pharmaceutical market continues to experience healthy growth.
2. The demand for generic medicines in the international markets will continue to gain greater momentum.

It is estimated that U.S.\$ 109 Bn. worth of patented drugs will go off patent by 2015. Indian pharmaceutical companies are diversifying in many global generics markets to leverage this opportunity. Currently India accounts for one fourth of the generic drug applications made to the U.S. FDA. Out of 187 DMFs filed with the U.S. FDA during October-December 2007, Indian companies filed 89 DMFs. Ranbaxy topped the list with 13 DMFs, Dr. Reddy's and Aurbindo Pharma followed next with 10 DMFs each. This trend continues.

Prices of medicines is one of the lowest in India and quite low compared to other developed nations where Governments are trying hard to bring down healthcare costs by encouraging the use of quality and affordable generic medicines. The need for medication is also growing with the ageing world population and changing disease patterns, keeping the window of opportunities for India open even during this trying period.

The world's largest pharmaceutical market – the U.S. is a market of immense potential for Indian pharmaceutical companies with a generic penetration of over 60% by volume. It should continue to grow under the new government of President Barack Obama who is expected to have a pro-generic healthcare agenda.

All these positive trends signal a significant market opportunity for Indian pharmaceutical companies who have over the past so many years carved a niche for themselves in the global markets.

Currently, India exports over U.S.\$ 4.2 Bn. of bulk drugs and U.S.\$ 4 Bn. of formulations. Indian pharmaceutical companies are gradually increasing its market share in the generic space to register their global presence. Companies like Piramal, Cadila, Glenmark, Lupin are acquiring companies both in the U.S. and Europe. This trend continues even during the current phase of financial meltdown. In addition, India can emerge as a centre for development of low cost bulk drugs and formulations, since cost of R&D and clinical trials are much cheaper in our country. Indian pharmaceutical companies can emerge as rich R&D outsourcing hubs for the MNCs in not too distant future. Thus major emerging growth areas for Indian Pharmaceutical Industry even during the phase of global financial crisis are:

- Contract research which includes both drug discovery and clinical research.
- Contract manufacturing services.

Amidst all these, clinical research is one of the most promising growth areas for the Indian Pharmaceutical Industry.

As a result of steady increase in outsourcing requirements by MNCs, the number of Indian companies in clinical research has already exceeded 100 from around 10, just a few years ago. Many biotech and pharmaceutical companies in our country are now preparing themselves to become clinical research units of global standards. The international market for CRAMS, which is currently estimated over U.S.\$ 35 Bn., is gradually showing more

interest in India as an outsourcing hub. At present, India has a share of less than 2% in global outsourcing and considering the world class skills in pharmaceutical science and chemistry, India should be able to capitalize on this big opportunity and continue to show a healthy growth. A recent study by OPPI-Yes Bank indicates that India has a potential to become the third largest market for pharmaceutical products and services in terms of incremental growth just after U.S. and China. By the year 2015, total pharmaceutical related market in India, OPPI-Yes Bank forecasts, is expected to be U.S.\$ 49.7 Bn.

Moreover, as we see today, the healthcare services are expanding fairly rapidly. Thus the demand for newer and innovative pharmaceutical products is expected to go up significantly. In the post-patent regime, as the Indian Pharmaceutical Industry stepped into a new paradigm, by making a transition from reverse engineering to discovery and development of new molecules, some of the Indian companies, very likely, will launch their own new chemicals entities (NCEs) by the year 2011.

Simultaneously, India will continue to emerge as a preferred global supplier of affordable drugs of international quality standards. All these will not happen without India marshalling all its strengths to encash these opportunities during this trying period. So far, Indian pharmaceutical Industry, by and large, has been able to absorb the impact of the global financial meltdown effectively. There is no doubt, that we need to overcome many challenges to leverage these opportunities. There is a

crying need not only to focus more on R&D but also to make the R&D initiatives more productive. There is also a need to make Indian Patents (Amendment) Act 2005 more robust and innovator friendly. It is quite essential to manage costs effectively together with effective management of various resources that the industry has at its disposal. During this period, the Pharmaceutical Industry is also facing challenges of unprecedented fluctuations in foreign exchange which need to be addressed with innovative strategies.

The basic fundamentals of India are expected to remain strong even when other countries are experiencing the heat of global meltdown. During this period, the Industry expects that the Government will continue to play its role to help, not only to tide over this crisis, but also to maintain a healthy growth for the Industry. The Industry also expects that the Government will provide adequate measures with a clear focus on structural and economic reforms to give a newer thrust to ensure that the Pharmaceutical Industry remains able to effectively fund its growth plans.

Thank you.
