



## “India will emerge as a hub for pharma R&D and manufacturing”

... beams a confident *Padmabhushan* **Dr R A Mashelkar**, a man who needs no introduction. The latest crown in his cap is the ‘Stars of Asia’ award conferred by George Bush Sr, former US President. Dr Mashelkar features among the top 25 stars of Asia – the first time that *Business Week* has honoured any scientist from Asia in its Asian Star category. This is in recognition of his tremendous contribution as an eminent leader in the Indian science and technology (S&T) arena, his legendary role in transforming CSIR, his historic feat in safeguarding not only India’s intellectual property rights but also redirecting S&T, pertinent to the developing countries.

It is the need of the hour to have more such Dr Mashelkars for the Indian pharma industry, which is in the process of transforming itself from an era of imitation to innovation. Much as his genius in the field of S&T stands out, Dr Mashelkar is equally gifted as an able administrator. This was amply evident during his triumphant tenure as the director of the Pune-based National Chemical Laboratory (NCL), and later as the director general of the Council of Scientific and Industrial Research (CSIR) – with 40 laboratories and over 23,000 employees, the largest institution of its kind in the world – which has led innovation to increase India’s economic and social wealth.

Recipient of numerous prestigious national & international awards and chairing several key committees, nationally & globally, Dr Mashelkar has the rare distinction of being a brilliant scientist, a leading administrator and a visionary par excellence. In this exclusive e-interview with **Manas R Bastia**, he speaks his mind on the strengths & weaknesses of the Indian pharma industry, multilateral collaboration among several stakeholders and more importantly, a resurgent India as the future hub for pharma R&D and manufacturing. Excerpts...

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**It will be one year in the next month since India has embarked on the new product patent regime. How would you summarise its impact on the Indian pharma sector so far?**

The Indian pharma sector has responded very well to the challenges of the new product patent regime. Major pharma companies had already shifted their focus from imitative to innovative research, including new drug discovery. Ranbaxy, Dr Reddy's Laboratories, Wockhardt, Nicholas Piramal, Cipla, Lupin, etc, have created state-of-the-art R&D facilities so as to take on the global challenges.

**What are the strengths and opportunities for Indian pharma companies in an increasingly globalised market?**

Indian pharmaceutical companies have several advantages: abundance of trained manpower (especially in chemistry and process engineering), cost-competitive clinical research, low cost manufacturing and large markets for modern and lifestyle drugs. They also have the advantage of availing government support for niche R&D in the area of new drug development.

In Europe and the US, a number of drugs will be going off patent during 2005-2009; this offers a huge opportunity to Indian companies in the domain of generic drugs. Further, Indian companies have tremendous potential of becoming manufacturing partners globally as they provide the best cost advantage.

**It is said that contract research and contract manufacturing will be the next growth driver for Indian pharma companies. Your comments on its present state and future potential...**

The MNCs and TNCs are rethinking of ways in which new ideas could be generated and brought to the market

in product form. Also they are under immense pressure to cut costs for product-based R&D and thereafter product manufacturing. They are thus increasingly exploring India for contract research (CR) and contract manufacturing (CM). Many alliances that gained entry into India either for CR or CM are operating successfully. The focus of such alliances has not only been domestic market but international markets as well. Success of some of these alliances has led to setting up of specialised research centres by the MNCs. I see this trend to grow further. India will emerge as a hub for pharma R&D and manufacturing.

**Biotechnology (BT) is considered to be India's next bait after our accomplishments in the Information Technology (IT) sector. Where do we stand today in BT and what is the need of the hour to lead the race in a global context?**

Presently, the Indian biotech industry contributes modestly to global markets. The size of the industry is just \$ 1 billion. But the good news is that it is growing at around 35-40 per cent over the past three years. It shall become another success story for us. The National Biotechnology Development Strategy would play an enabling role. We need venture capital funding to propel entrepreneurship in this segment of industry. We need to replicate successes like that of Biocon.

**Please give us a perspective of the current trends and future challenges for the Indian bio-pharmaceutical industry. What opportunities do you foresee for value creation on the global level?**

The future belongs to bio-pharmaceuticals. On the regulatory front, the Mashelkar Committee (2005) has drawn up a new procedural framework for biopharmaceuticals, which has streamlined



the process for the first time in the country. But it needs to be implemented fast, I feel India can take global leadership in vaccines and recombinant products. We already have some success stories. We must build on these.

**Your thoughts on the next generation advances in bio-pharmaceutical industry that will bring significant benefits to the common man...**

I will like to see the next generation biopharmaceuticals with improved therapeutic characteristics on one hand and reduced costs on the other. The focus should be on debilitating and life-threatening diseases.

**Please share your experience with regard to collaboration among government organisations, private sector, laboratories and universities to synergise national R&D efforts in the pharma industry? How would you rate the progress made so far and what more needs to be done?**

Various schemes have been launched to foster collaboration among various players of National Innovation System (NIS). These include: Programme Aimed at Technological Self Reliance (PATSER - DSIR); Home Grown Technology (HGT-TIFAC); Drugs & Pharmaceuticals Research Programme (DPRP - DST); Technology Development Board (TDB - DST); New



Millennium Indian Technology Leadership Initiative (NMITLI – CSIR); and Small Business Innovation Research Initiative (SBIRI – DfT).

The DPRP is primarily focussed on synergising the strengths of publicly funded R&D institutions and the Indian pharmaceuticals industry so as to enhance the nation's self-reliance in drugs and pharmaceuticals especially in areas critical to national health requirements. The NMITLI was launched with an objective to secure a leadership position for India in niche areas, based on technology through Team India effort in PPP mode. The scheme has been operationalised – by now 41 massively networked projects – in diverse S&T areas including drugs and pharmaceuticals. NMITLI has been a tremendous success and various novel products could be launched through the well-focussed project efforts.

In the domain of drugs and pharmaceuticals, the discovery of a new drug molecule for tuberculosis for the first time in the last 40 years, and development of a unique herbal formulation for psoriasis through NMITLI could be achieved in a short period of two years. We need to put in place more schemes like NMITLI to help our industry develop world-class products.

**The R&D expenditure of Indian companies is still miniscule compared to the global average standard. What**

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**needs to be done to survive in this WTO regime?**

India's annual S&T budget is \$ 6 billion. This is less than that of Pfizer's annual R&D budget! Yet we have so many achievements to our credit. That is because a dollar goes very far in India. I am not worried by the size, but by how we lay our baits, how we leverage our strengths and how cleverly we can exploit the public-private partnerships.

**What sort of measures does India need to take to strengthen the regulatory framework with respect to drug approvals and patents?**

Government of India had constituted an Expert Committee under my chairmanship to undertake a comprehensive examination of drug regulatory issues including the problem of spurious drugs. The Committee examined in detail the existing drug regulatory scenario in the country as well as the prevailing systems in a number of other countries and performed a gap analysis vis-à-vis the envisioned situation. The Committee recommended revamping of the existing drug regulatory structure and practices to achieve a world-class system.

Restructuring of CDA and modification of the Drugs & Cosmetics Act were also suggested. To ensure safety of Indian study subjects in clinical research, sharing of responsibility by all the stakeholders, viz. investigators, sponsors, ethics committees as well as regulators was recommended. Creation of a single window clearance mechanism for approval of various applications concerning drug research and approval, including research materials, etc, within CDA was sought.

Also, rationalisation of policies and procedures presently applicable in the country for animal experiments was recommended to avoid undue delay. Effort was thus to further improve the drug

regulatory environment in the country and fully align the guidelines and setups with the global scenario. Again, this report, needs to be implemented quickly.

**How can we facilitate creation of local venture capital funds to help our pharma industry?**

We already have these funds – but the problem is that 'venture' capital has to assume the role of 'adventure' capital! We need to be more daring rather than having the mindset of a conventional banker.

**What are the key strengths that Indian pharma companies can leverage to make a mark in the international market?**

The Indian pharmaceutical industry can cash upon our rich biodiversity, large pool of S&T manpower, state-of-the-art R&D infrastructure, cost-effective clinical trials for various diseases, large drug-naïve patient population, low operational costs, US FDA standard manufacturing facilities and globally aligned IP laws.

**What is your vision for the Indian pharma industry and how can we fortify the 'Made in India' brand for long-term global success?**

I envision an Indian pharma industry, which will show three qualities: innovation, compassion and passion. It should do innovation of the highest order, not embark on beaten paths but traverse untrodden paths. I will like it to have compassion – especially compassion for the poor – by creating therapeutics for the poor that are available, affordable and accessible. I will like them to have a passion – to be the best in the world – in terms of quality of their products, the highest ethical standards and providing value for money to the Indian and global customers.