

## **“The new-found confidence with which Indian entrepreneurs are investing in pharma support services is laudable”**

... says Dr Gopakumar G Nair, IPR consultant and advisor

**T**he transitional phase of the Indian pharma industry is expected to continue till 2010. The visionary strategy that the Indian pharma will adopt, at least now, will decide its status and success in the future. Dr Reddy's Laboratories (Dr Reddy's) chose the 'innovative' route to 'drug discovery road' as early as 1992. The Para IV challenge route is slowly yielding new strategies of negotiated deals for sharing the benefits. The protagonists of benefit-sharing in traditional knowledge and biodiversity have new company from challenger-turned benefit-sharing strategists. This emerging scenario is bound to invite fresh challenges.

The 'knowledge-driven' innovative drug discovery (at least in part) enterprises emerging from the group have been actively pursuing research-driven development and growth agenda.

In spite of the inherent risks, this group is expected to perform extremely well in the coming years. Overseas corporations, who are in this field or those who aspire to join the 'drug discovery' bandwagon, will increasingly need Indian alliances.

Those companies, which are engaged in the production of high quantum, moderately priced generic will continue to be successful in the coming years. Albeit the pricing pressures on this generic segment, the growth and success is guaranteed resulting from a near \$ 200 billion patented drug expiries in the coming years. Further, compared to the risk-taking Para-IV challenges and NCE/NME chasers, this segment opting for a near zero risk element, could well be the slow and steady winners in the coming decades. The API/drug intermediates 'chieftains' are expected to strengthen their operations. China is, of course, a serious competitor in large commodity APIs. India has its position cut-out in

speciality intermediates, tailor-made chemicals and pharmaceutical building blocks needing high quality criteria, impurity profile and ppm/ppb limitations. It will be a natural fit for overseas clients to enter into long-term relationships with Indian counterparts for product and process development as well as contract manufacturing services. It will be characterised by uniformity, reliability and dependable documentary support with high comfort levels.

The outsourcing bandwagon from India is expected to be overcrowded in spite of the re-emergence of Italy, the free-to-operate status of East Europe and the new-found confidence of a few other developing countries in Asia and Latin America.

The recent enthusiasm for Indian formulation (dosage form) industry to upgrade themselves to 'global plus' standards not only in investments, facilities and quality standards, but also in mastering the 'CTD' (Dossier) art to perfection (and to routine), will immensely benefit Indian pharma company to become a global organisation, marketing its own branded generics in relatively advanced developing countries and even developed countries (increasingly). Emerging trends of domestic manufacturing by other developing and even under-developed (LDC) countries like Bangladesh and increasing 'friendly' grants of medicines from developed countries, coupled with low price-realizations and financial risks, make market-re-engineering from LDCs to developed markets, at least for those who can meet regulatory challenges.

With more and more Indian pharma companies opting for overseas inspections and approvals of their manufacturing sites, coupled with spate of regulatory approvals in almost all developed countries, the number of USFDA (and others similar) approved manufacturing, CRO, CRAM sites and regulatory filings like DMFs and ANDAs are expected to double every few years. The day is not far when India will have more FDA approved manufacturing units and more ANDAs filed than others, more than even the US manufacturing units and US ANDA filings themselves.

The new-found confidence with which Indian entrepreneurs are investing in pharma support services, such as analytical services, diagnostic services, data management services and clinical research operations is laudable. These will prove worthwhile in the long run and will help India to move to the forefront of the global pharmaceutical industry.

