EXPRESS PHARMA

'Not having data exclusivity is a boon for biosimilar or biobetter prospecting in India'-

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Dr Gopakumar G Nair, Founder, *Gopakumar Nair Associates speaks with Usha Sharma and predicts that data exclusivity and other hurdles related to technology transfer will sum up the whole debate and will nail the 'biosimilar/biobetter dreams, at least in the short span of two to five years*

Comparing the evolution of the global biotech/ biopharma industry and in India, what are the steps for India to reach to the next level of maturity?

Identifying, evaluating and mapping Indian biotech proficiency, both within the country as well as overseas (NRIs), is the most urgent priority for moving towards the next level of maturity. India needs to attract biotech talents and nurture them. In the fields of biotech education and training research, regulatory bodies and industry, India needs practically qualified human resources. China succeeded in attracting overseas Chinese to participate in its renowned biotech revolution which involved and integrated Taiwanese and Hong Kong-based professionals. India needs to look at human resources in biotech/ biopharma field, as a priority. Additionally and equally importantly, India needs to put in order and strengthen its biotech/biopharma regulatory agencies, systems and mechanisms. India is threatening itself with failure, with its regulatory mechanism falling far short of the growth potential. Growing at an average of 20 per cent year-on-year may turn out to be a pipe dream (leave alone maintaining the momentum), if prompt attention is not taken to resolve and remove these bottlenecks.

The global market has evolved from biosimilars to 'biobetters'. Do you think India is likely to be a hub for biobetters or a preferred destination in the near future?

Biosimilars are facing stiff challenges from regulatory hurdles. Biobetters are the better bets but with better regulatory bottlenecks. India can become a hub for biobetters for this very reason provided we address the roadblocks speedily and efficiently. India has few biotech/biopharma industry leaders with proven enigmatic excellence. India also has many emerging young entrepreneurs and vibrantly innovative corporates most of whom are languishing for want of clear pathways to progress. With some hand holding from DBT and other expert bodies, India could move on with their biobetters and build confidence to extend their operations globally. However, the biobetters need to go through the entire marathon race as a new chemical entities (NCE) or new molecular entities (NME), which could be a herculean task, beyond the reach of Indian biotech companies and beyond the capacity of Indian regulatory bodies. Further the enormous investments in taking a molecule to market through the clinical and regulatory approvals will undoubtedly be beyond the reach of existing players, without active involvement from the government.

What are the other opportunity areas in the biotech sector in India?

India is a leader in generic pharma, both active pharmaceutical ingredients (APIs) and formulations. India is emerging as a leader in vaccines (at least few of them) thanks to the innovative enthusiasm of a couple of enterprising corporates. However, India has failed to integrate biology or biotechnology with chemistry in a big way. Indian API leaders need to adopt biotransformation approaches increasingly. Except one or two corporates who took early risks and entered the field of stem-cell research, India has not given encouragement at national level to integrate stem cell research and commercialisation into chronic therapies and treatments. Labelled as the 'Diabetics capital of the world', India can transform itself to be the 'Diabetic treatment and cure' capital of the world with focus on stem cell therapy research and treatment centres. These are a few opportunity areas. I would not suggest any biotech research related Indian flora and fauna, especially herbs, plants and micro-organisms of Indian origin, for fear of the aggressive postures and threats of the biodiversity authority of India.

Could you give examples of key biotech companies to watch for in India and mention what sets them apart?

Biocon, Biocon and Biocon is what comes to one's mind when asked to identify key biotech companies in India. Serum Institute, Panacea, Intas Biopharmaceuticals, Reddy Biologics are a few to look forward to. Others are NCBS-TIFR, National Centre for Biological Sciences (NCBS) though non-commercial, Heterobio, Virchow biotech, Cipla, Zydus Cadila, GVK Biosciences and others. At least, based on private communication, one could expect Strides to invest their cash (through Agila deal) in biotech ventures.

From the regulatory point of view, are India's laws for the biotech sector up to the mark? Are they being implemented as required?

India needs to put its house in order with additional qualified manpower and convincingly adequate regulatory provisions and mechanisms, sooner the better for the biotech dreams. Implementation is the bane of India's regulatory laws. Currently, Indian regulators are jittery and worried about the onslaught from the NGOs and the courts.

From an IP point of view, what are the hurdles for biopharma players in India?

Even though the transnationals demand data exclusivity and cite this as a major hurdle for technology transfer and early entry of biologics into India, one must take note that not having data exclusivity is a boon for biosimilar or biobetter prospecting in India. Let us take the recent example of Trastuzumab (Herceptin). The innovator, Roche, had recently opted not to renew its patent for Trastuzumab in India. In spite of the Health and other Ministries publicly declaring their intention to grant approval for a biosimilar to Herceptin, no Indian biotech enterprise has at least, till now, known to have come forward to 'pick up the gauntlet'. This will sum up the whole debate and will nail the 'biosimilar /biobetter' dreams, at least in the short span of two to five years.