EXPRESS PHARMA
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'Indian regulatory scenario is far from rosy at these times'

I have been a firm believer and a positive thinker on Indian pharma industry and its capabilities and strengths to scale the global technological and turnover tables and stables since the 1970s. In tandem with the strategies of the Indian government in the 70's and 80's, the Indian pharma industry picked up the gauntlet, stood up to the challenges and proved their might beyond doubt with the excellent growth, both in quality standards and in global generic pharma dominance, which commenced in early 1970s' and is continuing in the post-2005 product-patent era.

During the 1970's, the deliberations leading to the then famous “Hathi Committee Report”, which laid the foundation for the growth of the pharma industry, was held by the government intently and intensely with the representatives of the Indian pharma industry. It was conducted with mutual trust and sense of partnership for growth. This trusted partnership continued upto the finalisation of the 1978 Drug Policy. Then active members of Parliament along with even the Minister for Chemicals (in-charge of pharma) used to join brainstorming sessions to finalise the Drug Policy of 1978 which laid the road map for growth of India’s basic drugs and formulation industry. The 1986 Drug Policy was substantially guided by the Indian pharma industry with full co-operation, participation and stewardship from the Chemical and Fertiliser Ministry as well as the Indian parliament. After the liberalisation in the 1995 Drug Policy, the National Pharmaceutical Pricing Authority (NPPA), the defunct proposal of National Drug Authority (NDA) became mired due to the extremely gross (mis)interpretations of Drug Price Equalisation Account (DPEA) and demands thereof, on the Indian pharma industry. Some of these doubtful and quaintly calculated demands led to sickness among smaller companies and a general mutual mistrust between government and the industry.

The national pharma industry, led by Indian Drug Manufacturers' Association (IDMA) under a united umbrella until then, started splintering, working at cross purposes and started voicing confusingly differing opinions and views. The government who was looking forward to dominate the industry, took this opportunity to divide the industry and the Associations to their advantage. This turn of events, along with strong emergence of the pharma NGO lobby, has started weakening the post-2000 Indian pharma industry. Pharmaceuticals Export Promotion Council (Pharmexcil), born in mid-2000 as a result of persistent efforts of IDMA, has attained an eminent stature in shortest time. The services rendered by IDMA in last fifty years and Pharmexcil in last few years have really helped Indian pharma industry to become the 'Pharmacy of the World'.

Some noteworthy changes in the pharma sector are:

Patents: The Indian Patent and Trademarks Office, which was down in the dumps till mid-2000, got a boost with the appointment of an upright Controller General. The IP Regulatory atmosphere in the country made notable strides thereafter. The provisions of the Patents Act, 1970 as amended up to 2005 and the procedures under the Patent Rules 2003, as amended up to 2006, started getting implemented in letter and spirit. There is an increasing trend for transparency with occasional ground for despondency. The various office actions are becoming extremely delayed and non-uniform on the patent regulatory front.

Trademarks: On the trademark side, there have been considerable clearing of backlog and cleaning up of the system. There is a need to keep the momentum going forward. The Central Drugs Standard Control Organization (CDSCO, office of the DCGI), in the meantime, discontinued granting new product approvals with brand names. This controversy has been settled favourably by clarifying that approved generic drugs can be branded thereafter.

The ISA, IPEA and Madrid Protocol: India has become International Search Authority (ISA) and International Preliminary Examining Authority (IPEA) on the patent front. However, much need to be done to create the infrastructure and logistics required to put this in place. Even though the notifications announcing ISA and IPEA are already announced, there is an urgent need to recruit, train and empower the needful manpower. All this and streamlining the patent office, requires funds and logistic support. If government will use the funds rightly and in a result-oriented manner, the proposed increase in patent fees is justified. India has joined the Madrid Treaty and Protocol, opening up filing of a single Trade Mark

Application to all specifically elected countries of the world with an effective date of July 8, 2013. While there are few hundred applications filed from overseas designating India, only a couple of applications have been filed from India designating overseas contracting parties. This move will substantially help Indian generic pharma to build its pharma brands globally through the "Brand India Pharma Campaign" programme, sponsored by Pharmexcil.

The Pharma policy 2013 epilogue: An eagerness to depart from the past, not only in the pharma policy (which is monitored and pushed by the Supreme Court of India). by enlarging the basket, but also in the procedures, such as the new 45 days limit for price-cuts, have put the success of the much awaited New Pharma Policy on the wire and in the air. The lack of unity in the pharma industry has also negatively impacted the hitherto strong voice of the national pharma industry. The going looks tough for Indian pharma both on the domestic front as well as in the international arena.

Even though, there are provisions and opportunities in the new Pharma Policy 2013 to encourage innovation, the current stalemate in "new drug" approvals and the deadlock on clinical trials, clearly close this gate even before opining it. Delays in patenting, as stated elsewhere, add to the misery.

The clinical trial quagmire: The pharma regulatory scenario in India has never been so dismal, it is reported that National Institutes of Health (NIH) of US recently scrapped nearly 40 chemical trials in India. Clinical trials of drugs have plummeted steeply in 2013. From nearly 500, the figures have slipped to nearly 200 in 2013. Simple approvals for novel drug delivery systems of widely used active pharma ingredients are also held up in this quagmire. India is in the forefront of rational combination therapy in the world. This strength must be taken forward. The new drug delivery systems must be given clearance through fast track, while the debate on advanced CTs for new chemical entities and the dosage forms thereof goes on. The new stringent norms on CTs appears to be driving the Indian pharma industry's growth going down south. A strong leadership from a united Indian pharma industry and a joint national approach by the Ministries and departments of health, pharma, commerce and others (such as Environment, Industry etc.) alone can salvage the loss of "place of pride" of Indian pharma industry in the global community.

- **Dr Gopakumar G Nair,** Founder, Gopakumar Nair Associates