EXPRESS PHARMA

Indian generic pharma and global regulatory challenges

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Dr Gopakumar G Nair, *Chief Executive Officer, Gopakumar Nair Associates talks about why the regulatory scenario in the domestic markets need more support from the government for developing infrastructure, logistic and manpower as well as technical accreditation to global standards*

Indian generic pharma has come a long way since the 70's and 80's. The then Executive Director of IDMA (Indian Drug Manufacturer's Association) Dr Venkat Narayan who was earlier Joint Secretary in Ministry of Chemicals including Pharmaceuticals stated in 1987, "If we have atleast 10 to 20 Indian pharma manufactures having more than Rs 100-crore turnover, we can be confident that the Indian pharmaceutical industry has found its place in the global map."

We are proud today to have a very large number of pharma companies who have turnovers exceeding Rs 1000 crores. The recent merger of Ranbaxy with Sun Pharma has catapulted the merged entity to have a combined turnover exceeding Rs 25000 crores. Others such as Cipla, Dr Reddy's Labs, Lupin, Cadila, Glenmark, Torrent, Aurobindo, Ipca Laboratories, Strides and few others are already in the Rs 1000-crore club. The global success of these Indian pharma companies are mainly due to the entrepreneurial enthusiasm and high standards of quality and regulatory practices adopted and maintained by them. It is heartening to know that all the top Indian pharma companies have their own Active Pharmaceutical Ingredients manufacturing facilities as well as formulation facilities; inspected, audited and approved by top regulatory agencies globally.

The large turnover achieved by these companies arise from exports to highly regulated markets. However, the regulatory scenario in their domestic markets need more support from the government for developing infrastructure, logistic and manpower as well as technical accreditation to global standards.

To ICH or not to ICH

Even though India has proclaimed itself as the 'pharmacy of the world' there is international pressure on India as a whole to improve the quality and regulatory standards in the country. It is interesting to note that a working paper on “Where is the pharmacy to the world? International regulatory variation and pharmaceutical industry location' from Harvard Business School do mention India and China as having potential to offer competition in future. However, such competition is possible only with world class regulatory establishment at home. In AEI Paper on 'Pharmacy to the world: India and the global prescription drug trade,' the panelists state that the product quality largely depends on the overall maturity of a country’s pharma industry and that of the regulators.

The ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) has brought together the regulatory authorities and pharma industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation, to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. ICH is conducting many workshops and seminars in China on the various ICH Guidelines.

As per a report in ICH website, the ICH Steering Committee has agreed to open ICH technical working groups for active participation from experts from non-ICH member regions and countries of the ICH GCG (Global Cooperation Group). Experts from countries include Australia, Brazil, China, Chinese Taipei, India, Russia, South Korea and Singapore, and other harmonisation initiatives, such as Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Countries (GCC), Pan American Network on Drug Regulatory Harmonization (PANDRH) and Southern African Development Community (SADC), will now have the opportunity to have technical experts participating in many ICH technical working groups thereby actively contributing to ICH Guideline development.

The Deputy Director General and Head of Regulatory Affairs at the European Generic Medicines Association pointed out that, the vast majority of ICH guidelines become regulatory requirements and guidance that are directly applicable to generic and bio similar pharmaceuticals manufacturers.

It is imperative that Indian regulatory authorities have to take note of the increasing clout and importance of ICH and join the initiative atleast as an observer as early as possible. To become an ICH member, the country's regulator has to join as an observer and eventually upgrade the domestic regulatory framework to meet ICH standards and offer for inspection and approval.

ICH AND IGDRP

The availability of quality generic drugs, also known as multi-source medicines or pharmaceuticals, play an increasingly important role in helping to address rising healthcare costs and in promoting access to essential medicines worldwide. This, however, has led to significant pressures on medicines regulatory authorities (RAs) charged with the review and approval of these products. In addition to an increased workload associated with the growing number of generic drug applications, RAs must now also contend with more sophisticated generic drug products and complex global production and distribution chains.

Given these challenges, the need for regulatory cooperation and convergence has long been recognised. This has led a group of regulators to launch the International Generic Drug Regulators Pilot (IGDRP). The three-year pilot entails a series of concrete measures to facilitate the timely authorisation and availability of safe, effective and quality generic medicines.

But it is also being warned that a scheme's success will stand or fall on the support of pharma and other interested parties-although the incentive is that generics should be authorised in different territories in a co-ordinated way at around the same time. Further, sharing assessment reports in real time with participating agencies outside the EU will accelerate the process and make the science of the process more robust. Since the start of the IGDRP, when the first meeting was held on Ottawa in October

2011, considerable progress has been made along with, heavyweight support of the European Directorate for the Quality of Medicines & Healthcare (EDQM) and the World Health Organisation (WHO) overseeing it as observers.

As the initiative enters its third and final year as a pilot, the RAs are also examining the possibilities of work sharing in active substance master file, inspection of sites conducting bioequivalence and bio-analytical studies, and on pharma quality issues. It is expected that work underway should lead to advancing regulatory convergence and the piloting of new models of cooperation prior to the end of 2014. It is, however, unfortunate that the leading high quality generic pharma manufacturing and exporting country, India, is neither a member of IGDRP nor the member of qualifying organisation, ICH. In the light of India's leadership as global generic source and supplier, India need to become at least an observer in ICH as well as IGDRP at the earliest.