INDIAN PHARMA INDUSTRY – WHAT’S NEXT?

Dear Reader,

I am honored to contribute this Editorial feature for the Indian Drugs. The timing couldn't have been better – as our industry is poised at the inflection point to take-up the next challenge.

Let me start with two exciting stories related to innovation in the pharmaceutical industry: one related to a break-through innovation and the other related to an incremental, yet very important innovation.

First, the break-through innovation. KYMRIAH™ (Tisagenlecleucel suspension for intravenous infusion; innovator – Novartis) became the first chimeric antigen receptor T cell (CAR-T) therapy to receive regulatory (US-FDA) approval in August-2017 for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse. In May-2018, it received approval for the second indication by US-FDA – the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma. KYMRIAH™ has become a landmark product in the field of personalized and transformative medicine – wherein the product is manufactured individually for each patient using the patient's own T cells.

Now, the other important innovation that is Made in India –XELPROS™ (Latanoprost ophthalmic emulsion, 0.005%; innovator – Sun Pharma). It is the first and only benzalkonium chloride-free ophthalmic drug product of Latanoprost. Its approval by the US-FDA this month marked a new milestone for Sun as well as the Indian pharma industry – as it represented a reformulated product from an Indian company to get US-FDA's nod – after going through the entire approval journey.

Both of these innovations represent a remarkable trend in our industry. I was personally very excited about XELPROS™ – not only because it was coming from our own country, but also because it was presenting itself as a validation of our capabilities as a mature R&D player in the global arena. I can certainly vouch that this is just the beginning of a host of Generic-Plus or Super-Generics or simply, reformulated drug products to make their way into the list of blockbusters.

Majority of the growth of Indian pharma was enabled by the process-patent regimen until the implementation of GATT. We saw a slow-but-definitive decline of the active pharmaceutical ingredient (API) industry over the last decade. The Chinese pharmaceutical industry was the major gainer of our decline in this business – by sheer scale, cost competitiveness and most importantly – significant improvement in quality. Today, many of the big Indian pharma companies are relying on Chinese API suppliers – either for the drug substance itself or for key starting materials.

Since the last couple of years, the finished dosage form industry in India has been on a roller-coaster ride. Indian pharma companies whose revenues were predominantly dependent of US generic business have been badly hit – majorly because of: (i) pricing pressure (ii) stiff competition (iii) compliance issues with US-FDA. As a result, we have been witnessing a phenomenon of lay-offs like never before. Post Y2K, the Indian IT companies underwent this shedding exercise and now it's the turn of those big pharma companies in India who gained “extra fat” due to the boom in the US generic business. From a regulatory compliance perspective, the agencies have been more persistent and focusing on the intent and the data integrity aspects than the GMP aspects.

We have also seen increased footprints of innovator / brand pharma companies (like BMS, GSK, J&J, Novartis, Pfizer etc.) in India – which is a big positive move. The major investments have been in R&D particularly – not with the view of seeing India as a low-cost-country but as a partner that can contribute significantly in the higher value chain through human talent and innovation spirit.

In the coming years we will see the big Indian generic pharma companies (like Dr. Reddy's, Sun, Lupin, Glenmark, Zydus, Aurobindo, Cipla etc.) undergoing a significant transformation and evolution, re-calibration and re-structuring in order to achieve operational excellence and optimized profits. We will also see a focus beyond complex generics (which has been the name of the game for the last few years) – moving towards biosimilars and macromolecules. The coming decade is going to be dominated by the emergence of small / mid-cap pharma in India – who will make an impact through their agility and innovative business / operational models. Further, we will witness a boom in pharma / biotech / clinical / technology start-ups in India. Ultimately, the innovative digital technologies and data analytical tools will be opening new frontiers for the Indian pharma industry. The major challenge for all these is going to be meeting the regulatory and quality compliance standards and avoiding short cuts to meet the ambitions of the investors. In my opinion, there will be no option but to re-define and re-position ourselves for bracing this reality.

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Dr. Shenoy has authored 30 publications in peer-reviewed journals and 7 book chapters. He has inventorship in 11 patent applications in biopharma, nanotechnology, vaccine adjuvants and vaccine stabilization.

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