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Editorial Open Access

Role of Generic Pharmaceutical Industry in Healthcare

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Editorial

Generic pharmaceutical industry plays critical role in producing affordable medicines. More importantly, this industry sector helps in management of the health of majority of people living under the poverty across the world. Innovator companies invest heavily in bringing the medicines to the market. It becomes their fundamental right to get the return on investment. Obviously, medicines will extremely be costly at the first place. There will be close to 20 years of window for innovators to sell their products in the market. Thereafter, medicines are bound to get genericised and there is a surge of competition among generic players including innovator companies to sustain in the market due to tremendous cost pressure. Regulatory bodies across the world also encourage to the accessibility of quality driven generic medicines for the masses.

Many players from all over the world try to put their products in the market but only few of them emerge as the leaders mainly due to quality of the medicines that they produce from all the aspects. In order to provide quality medicines to the patients at par with the innovator's product, generic pharmaceutical industry has to play very critical role. The challenges pan out from design of cost effective synthetic route with least PMI (Process Mass Intensity) and high atom efficiency to the innovative packaging. The fiercest competition being encountered is in the design of the shortest innovative non-infringing synthetic route with extremely high efficiency. This involves high degree of intellectual control over chemistry knowledge and integrative capabilities of the scientists to implement recent advances in this field to the synthesis of APIs (Active Pharmaceutical Ingredients). In this scenario innovative research and development becomes extremely important and industry academia collaboration can't be avoided. Moreover, there are number of other disciplines e.g. analytical research and development, crystal engineering, process engineering and formulation sciences face similar challenges. Therefore, it is recommended that improving R&D efficiency is mandatory to sustain in the pharmaceutical industry business. Indian companies need to build R&D capabilities which are modern, integrated, and efficient capable of mitigating risks associated with product development and manufacturing. Effective best practices for sharing and continuous information exchange through knowledge management would help in maximising R&D throughput. In order to maximize R&D productivity in a bigger sense one needs to encourage innovation, use of technologies with an aid of unrestricted funds for R&D and incentivization.

Indian generic pharmaceutical industries represent third largest market in the world by volume with roughly 15% growth in last five years contributing over $10 billion to the global pharmaceutical market since 2010. India has done well in recent past but generic opportunities started retreating which is quite evident in business declining trend, due to para IV filing misses from $24 (2007) to $3 billion (2012). This is directly connected to the complexity of the molecules and exhaustive patenting by the innovators. This warrants redesigning of the strategies to help grow and catch up with the same pace that we had in 5 to 7 years back. Indian generic industries must think of focussing on value added generics, semi-synthetics, new drug delivery systems, niche products and biosimilars. Intelligent outsourcing may also be considered as complementary activity to support business. US, Europe and Japan enforce very stringent quality and regulatory requirements. With these regulated market quality standards one should think of capturing other markets as these would offer distinctive advantage over other competitor. Indian pharmaceutical industries need to watch out pricing regulation, new trade barriers from US and Europe, GDUFA, QbD and compulsory licensing.

In essence, generic industry plays very important role in healthcare as it helps to provide affordable medicines leading to healthier life style and increase in life expectancy. Sustainable strategies amalgamated with green chemistry and engineering would help in safe guarding the environment and bringing business. Most of the challenges associated with supplying quality medicines through generic industries are daunting yet surmountable as they can be met through right strategies in place, people's management, right product selection at right time and letting the technical leadership to lead by being at the front.