

Pharmaceutical Industry in India: Challenges to Combat

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Abstract – The pharmaceutical industry in India is having high potential to grow. The way of industry is full of challenges and hurdles. The steps to be taken are very simple and easy. It seems that the major issue is with patent a related aspect which needs to be addressed. However the article discusses the other challenges faced by the pharmaceutical company. It also suggests how to combine the technology, science, education and innovation to achieve the desired growth of pharmaceutical industry.

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INTRODUCTION

The Indian drug industry has contributed altogether to worldwide medical services by guaranteeing high calibre, reasonable and available medications around the globe. The business has become quickly throughout the most recent decade and has been instrumental in driving generics infiltration around the world. In the course of the most recent 15 years, Indian organizations have done well in the nonexclusive business and have manufactured billion dollar associations on the rear of generics R&D.

India stays an appealing objective for nonexclusive R&D and assembling of drugs attributable to its solid abilities over the worth chain. While India is the third biggest drug market on the planet by volume, however, the business has been affected by a few difficulties like the patent bluff, critical cost disintegration, union at the merchants' level, expanding rivalry and expanded administrative examination in worldwide business sectors. In any case, we accept that Indian pharma industry attributable to its solid essentials, can grasp these difficulties and conquer this transient condition to revitalize the direction of solid development. The initial step is to recognize the powers impacting everything and rethink the procedure and working model to address them.

The most debatable aspect of pharmaceutical industry is the law relating to Patent. The Indian law of patent has seen a roller coaster in terms of pharmaceutical patents.

Advantages of Patents in Pharmaceutical Industry

- In the drug business, patent add to generally 80% of the complete income produced and is a key component characterizing the accomplishment of a medication producer.
- Obtaining patent security is essential to shield the creative methodologies utilized in the drug business.
- Patents deals with the issues of encroachment by not letting the contenders effectively copy the productions of any medicine or treatment.
- As creating and producing new medication include extraordinarily significant expenses, patent licenses in the pharma business help in recapturing the speculations that are brought about during the phase of innovative work.

In March 2005, India's Parliament endorsed patent guidelines to prevent domestic drug creators from duplicating new medications created by other. The new law, correcting India's 1970 Patent Act, influences everything like electronics, software and drugs, and has been required for quite a long time as a condition for India to join the World Trade Organization. Beforehand, organizations could duplicate medications found or concocted by different organizations by tweaking the procedure used to make them.

The new patent framework perceives enlisted unique medications as items regardless of how they are created, along these lines making it unlawful to duplicate medications still under patent. Likewise, apparently the 2005 corrections have discarded the act of "evergreening" of drug licenses, where patent proprietors supposedly attempt to expand patent life through award of new licenses by minor "developments" or enhancements for definitions, measurement structures or minor compound varieties of a previous protected item. However, the new law[1] likewise clarifies that any innovation that upgrades the known adequacy of the substance or results in another item or utilizes at any rate one new reactant is patentable and that solitary the simple disclosure of another structure or of any new property or new utilization of a known substance or cycle is avoided. It may not be too hard to even think about proving that the improved dose structure is more useful or that one new reactant is associated with the realized cycle to make the item.[2]

Problems in patent laws generally raised

1. Under the new law, a maker of generics can apply to copy a patented drug, but only after it has been marketed for three years. The generic's maker however must pay a "reasonable" royalty. The new law does not define what can be considered to be "reasonable". Though it is also contended that reasonability should be based on facts and circumstances of each case.
2. Restriction on patent rights are so stringent that it may result into less patent done in domestic market. This was a very important issue raised by pharma companies but after analysing the data revealed by various agencies it can be concluded that the Indian market is so attractive that companies really wants to register the patent in India.
3. The Indian government has said it would step in if price rises were excessive but has not said how that would be determined.[3] Some analysts have stated that

Public health opens up new opportunities

In recent times it has been observed that the public health aspect is focused more by the governments. In this process at one place where the compulsory licensing is supported by the human rights defenders, the new opportunities are also opened up in which conducive environment have been created. Research is developing and policy of government is also twisted in a manner which can support the development of new drugs.

Vaccine market boom

Another aspect of health-related aspect focuses on preventive medication which includes vaccine market. Various government policies are also made to arrange the vaccines for all specially the children. This aspect also supports the vaccine market as well as new products.

Lifestyle drugs: a demand based industry

The third category of drug fall under this segment. Various lifestyle drugs are demanded by the young generation like cosmetics drugs, body building drugs, hair therapy related drugs, skin therapy related etc. this has created a market of lifestyle drugs in the Indian market. Some companies are only focusing on this particular type of drug products.

Consumer self-medication tendency

In India self-medication is a practice adopted by the consumers. This result into a demand generated market. One more thing is very peculiar about this is these product does not allow the other products of same nature to be made popular in the market. The fine examples are Eno, Dygine, Crocin, Disprine etc. this creates a new type of competition in the market.

Alternate methods of treatment is underpenetrated

The next important aspect about the pharmaceutical industry is that allopathy has captured the market very well. The other methods of treating the ailment are also very effective but not penetrated well. These alternative drug market is still untapped. The growth can be visible once big players will start producing the drugs used in the existing market.

Capability to create market is crucial factor

The pharmaceutical market is having capacity to create the market. As it is also discussed above that Indian market is demand based. The pharmaceutical industry is having capability to create market. India is having the highest number of ANDA approved centres outside America.

CONCLUSION

While numerous patterns expect a country to improve our practices, others expect us to expand on their qualities. It will be basic for the Indian generic industry to progress itself to a advancement player or a solid biosimilar association to drive esteem development and address a few development challenges. Indian pharma organizations likewise need to drive full consistence with the developing administrative rules by sending worldwide best-practices in an

India shop floor setting. There should be recharge centre around tasks greatness particularly determined by new age innovation and abilities. Basic changes like accomplishing self-reliance on API are likewise more significant. India is a dominant player in the global generics market, with the largest number of USFDA-approved labs outside the USA, and holding a 30% share (by volume) of the US generics market. However, India has been witnessing increasing competition from other nations such as South Korea and China, who are also trying to establish themselves in the global generics market. Indeed, competition is always better for the patients seeking cheaper medicines and better access to healthcare.[4]

The pharmaceutical companies need to focus on product specialization which will result into more efficient product. technology, science, innovation and education can be combined as four pillars to build the strong foundation for pharmaceutical industry to grow.

REFERENCE

1. Section 3(d)
2. A Confusing Patent Law for India, Economic and Political Weekly, April 16, 2005
3. The New York Times, March 24, 2005, Section C, Page 6, Column 5
4. <https://www.sathguru.com/news/2017/05/03/innovation-in-indian-pharma-empowering-stronger-global-presence-but-fraught-with-challenges-for-serving-indian-market/>

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