Global Challenges for Indian Pharmaceutical Industry

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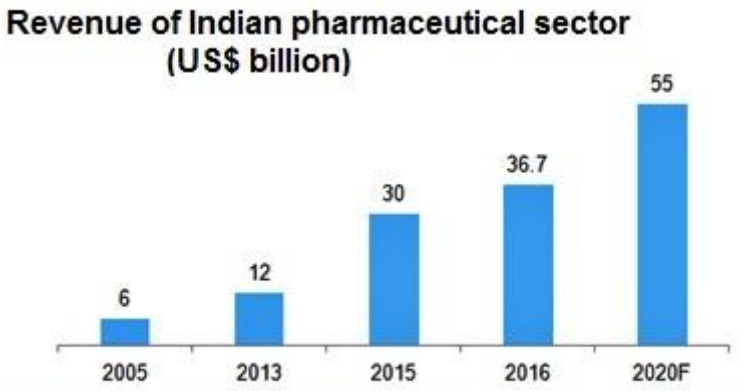
[3]The Indian pharma industry is on a good growth path and is likely to be in the top 10 global markets by value by 2020. High burden of disease, good economic growth leading to higher disposable incomes, improvements in healthcare infrastructure and improved healthcare financing are driving growth in the domestic market.

Pharma companies are growing both organically and inorganically. Inorganic growth is happening through licensing and partnerships as high valuation of assets is making acquisitions difficult. Further, companies are organically improving their operations and productivity by increasing field force sizes, penetrating in Tier II and III cities and by expanding their product portfolios.

But now a day's pharmaceutical companies are facing trouble during audit. If we look into the growth rate of Indian pharmaceutical industries, it will fabulous.

[2]The Indian pharmaceuticals market increased at a Compound annual growth rate (CAGR) of 17.46 per cent during 2005-16 with the market increasing from US$ 6 billion in 2005 to US$ 36.7 billion in 2016 and is expected to expand at a CAGR of 15.92 per cent to US$ 55 billion by 2020.



Source: Department of Pharmaceuticals, PwC, McKinsey, TechSci Research
Notes: F - Forecast, CAGR - Compound Annual Growth Rate

By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size.

[1]The Indian pharmaceutical industry is going through a period of significant volatility and uncertainty, requiring companies to re-visit their traditional growth strategies to succeed

Some of the key findings observed from the current audit faced by the major pharmaceuticals are summarized below,

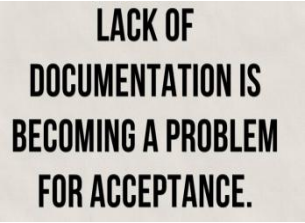
Subject knowledge:

As we all knows now a day's regulator are usually willing to discussed with the down the line team member. People like operator or line supervisor are not adequately trained. They are sufficiently knowledgeable sometime but they fear to open up their mouth in front of the auditor. Some time it was evident also the process what operator are following that was correct but it was not in line with the approve document or instruction. So, there is GAP in actual process and available document.

Assumptions: People are highly knowledgeable.

Reality: Doer is seeking for the support from their senior. But they don't have sufficient time because they engaged in meetings. Addition to this lack of problem solving skills and decision making capability.

Improper documentation/ instructions:



Available documents/records are not meeting with the principles of ALCOA+. In my views no one has come to job for doing wrong thing. Leaders providing less time to prepare good document and they are crazy about the output by executing the document. So, before proper review people are initiating the executions. Finally auditor are getting disputed document during review.

Assumptions: We should know our procedure and documentation are done as per ALCOA+ expectation.

Reality: Operating procedure are not adequate. Sometimes SOP's are read first time by the operator or supervisor in front of auditor. So, during explanation people are literally struggling to find the exact paragraph what asked by the auditor.

Insufficient manpower:

Always we are ready to go with the less man power. Poor operators are unwillingly extending their working hour. We should not consider human as a machine, human are drive through emotions. They need mental and physical peace. Regular over-time can be caused non compliance to GMP.

Assumptions: We have sufficient manpower.

Reality: Always lack of man power was observed.

Work plan:

Poor work plan always hampered our work & life balance. Anyhow end of the day we need to deliver as per our commitment. But commitment is always coming with narrow timelines. Hence the timelines are not provided based on the proper work assessment. It was fixed by the higher management and further reduced by the team leader to make happy the management. So, closer of any work done in hurry and lots of deviation we left behind.

Assumptions: Things will move automatically move without plan.

Reality: Confusion what is the priority and what need to be close first?

Implementation of new Technology/Project:

Whenever we are going for new technology proper risk based assessment not considered. Our expectations are compromised based on the budget allocated for particular project by management. So, what we procured that in not meet our expectations. Teams allocated for the project are worked based on the targeted timelines not for the quality of technology. Sometime machines are procured for the audit commitment and after that people sent the machine in the scrap. Because that was not meeting the expectations of the user.

> Assumptions: Implementation was perfect within the timeline that is the assumption.
>
> Reality: Only the success mail floats over within the management group and people are appreciate for success. But reality was somewhat different.

Existing system up gradation:

As we already discussed implementation project completed with some gaps. For that we find lots of compliance issue during routine usages. So after several discussions managements allocate additional funds to fulfill those compliance gaps. But present as improvement or new requirement or continuous improvements. Based on that people are nominated to excellence award for the achievement during company annual meet.

Assumptions: Team was efficient for gap assessment

Reality: People in the shop floor dealing with number of complication for the up gradation

Over commitment to regulatory agency:

Regulators are god for us. After getting approval from regulatory, we can able to see growth in our business. So, during the regulatory inspections management members are giving lots of commitment to regulators. Once the audits end it result with lots of CA-PA (Corrective and preventive action). But further no evaluation for CA-PA allocation, timelines, closer and appropriateness.

Assumptions: All proposed action plans are closed. Compliance activity done as proposed to regulators.

Reality: Number of gaps will found if you review them carefully and improper evaluation & closer.

Selection of new assignments/project:

Usually selection of new project is done with lots of expectations. Initiation of new project gives impact to stock market. But numbers of project ware get aborted due to different reason. That will cause huge financial loss to organization.

Assumptions: Will give positive impact to the stock market.

Reality: But it caused financial loss.

Conclusion:

[3]The Indian market provides significant growth opportunities for the pharma industry. However, for the industry to sustain a robust growth rate of 15–20% till 2020, companies will have to rethink the way they have been doing business.

Pharma companies will continue to grow inorganically through alliances and partnerships. They will continue to focus on improving operational efficiency and productivity. However, to meet the requirements of changing business environment, they will have to adopt new business models and think of innovative ideas to service their evolving customers faster and better.

Developments in the health insurance sector, medical technology sector and mobile telephony can help the growth of the pharma industry by removing financial and physical barriers to healthcare access in India.

Overall, the various regulatory interventions require careful consideration by the pharma industry. How companies adjust to the regulatory environment as they seek to capitalise on the opportunities provided by the Indian market will be an interesting space to watch in the coming months.

As emerging markets become increasingly important and as India's role among these markets becomes progressively significant, both domestic and pharma MNCs will need to adapt their business models, organisations and processes and create customised strategies.

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