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Pharma cos should improve brand building exercise

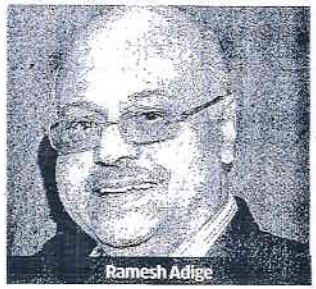
Ramesh Adige

In terms of revenue, the pharmaceutical industry in India is approximately Rs 2,27,500 crore ($35 billion), out of which exports account for 55 per cent, i.e Rs 1,25,000 crore ($19 billion). The growth rate has consistently been in double-digits usually in the low-teens. On the other hand, US is the world's biggest pharma market, valued at $360 billion, which is nearly a third of the global market of approximately $1.1 trillion.

Indian generics companies view the US as a key overseas market and export over Rs 26,000 crore ($4 billion) to the US. To keep the increasing cost of healthcare and insurance premia in check, the US will continue to give opportunities to the Indian generics companies to export quality affordable medicines to that country subject to getting regulatory approval from the USFDA on cGxP viz current Good Clinical Practice, Good Laboratory Practice, and Good Manufacturing Practice. 'First to File' opportunities in the US give the legally successful generics company a six-month marketing exclusivity, leading to a big spike in revenue and margins. This is an added allure to be present in the US market. Of late, we find that many more of the large Indian pharma companies are under the intense gaze of the USFDA and have been issued Form 483s (though this is not an uncommon observation negative list based on site inspection). In most cases documentation for many of the previous years are to be examined minutely. To get over the distrust is not an easy task.

Like everywhere else in the world, whistle-blowers are informing the regulatory agencies, leading to more scrutiny from the USFDA (a red flag is issued almost every fortnight). Needless to say, when the USFDA issues an Import Alert, it damages the brand image of the company. Its stock price and revenues take a beating and the company's efforts get concentrated on fire-fighting in the regulatory sphere. The price of non-compliance is crippling, crisis management is debilitating and reputational loss can sometimes be irretrievable along with loss of market share. Companies are realising that it is better to spend millions on CGMP (Current Good Manufacturing Practice) rather than billions on serious compliance issues.

Some believe that the extreme focus is an arm-twisting measure adopted by the US to pressurise India to amend its IPR policies etc. Some say it is a tactic encouraged by big pharma companies. Others feel that Indian generics companies are not compliant and the USFDA is justified in their actions. All these make for a heady cocktail. What stands out from all of this, is that no company in any area of economic activity, can afford to take on the regulator.


Ramesh Adige

USFDA has raised the bar. Our generics companies can meet the challenge and will come out stronger.

Quality of Indian generics

I do not think it will be fair to use a broad brush regarding the quality of Indian generics. There is no instance of sub-standard drugs being marketed by Indian generics companies, anywhere in the world. Yes, there are examples of product recalls, voluntary or otherwise, but no serious cases. What is being questioned is data integrity, and manufacturing processes, which may lead to the final product being of sub-standard quality. Whereas, earlier 483s or Warning Letter roadblocks could be overcome within months, of late, it is taking longer and longer to get an all-clear signal from USFDA. Other regulatory agencies of the developed markets such as Japan, Australia and Europe, by and large have no major issues with the Indian generics companies.

I feel Government of India should hold stakeholder consultations and see if a pathway can be identified to join the Pharmaceutical Inspection Co-operation Scheme (PICS), which is an agreement between 46 participating national regulatory agencies on CGM. Once India joins PICS, the cost and time for regulatory inspection/procedures will come down drastically. To do this, not only do the Indian Pharma companies require to adopt international best practices, but our national regulatory agency called the Central Drugs Standards Control Organisation (CDSCO) and the State FDAs have to be manned by well trained persons with domain expertise. This may take time but will be hugely beneficial. Once you get a PICS country's regulatory approval, it will be valid for export to other member countries as well. Industry should also support our CDSCO as it plans to increase fees for plant inspection and drug approvals. This fee will help in capacity building in CDSCO and State FDAs.

Adoption of cGxP norms will require both capex and increased revenue expenditure. Quality by Design (QbD) processes must be introduced eliminating human intervention. Small companies will face the heat and may have to wind-up. Medium and large companies will be able to invest to meet the strict regulatory guidelines of the developed world. This is where the GoI should step in by giving grants or low-cost funds to meet the modernisation and capital expenditure of Indian generics industry to meet USFDA standards. Immediately, there would not be any increase in domestic prices of drugs as most of the essential medicines in India are under price control. Prices may rise in the future but hopefully, due to the intense competition, it will be in moderation. Indian generics companies also need to fix responsibility for regulatory lapses. If heads have to roll, so be it. The signal should be loud and strong. When the manufacturing, quality assurance (QA), quality control (QC) and regulatory teams find something is not right, the batch has to be destroyed. Quality and compliance, these two terms should be ingrained in the culture and DNA of companies.

One of the problems is the pressure on CEOs worldwide to deliver growth both in the top-line and bottom-line. This is the quarter-to-quarter syndrome. This pushes managements to cut corners. The outcome can be catastrophic and Q-Q can as well become *'Qayamat se Qayamat tak'* (from one disaster to another). The Boards of companies and other stakeholders should take a medium to long-term perspective for fixing performance parameters for management.

India is in the centrestage because it supplies affordable and quality generic medicines to the world for important therapeutic segments like cancer, diabetes, neuro, cardiovascular, pain, antibiotics, AIDS, dermatology etc. We must do everything possible to keep the pre-eminent position of the Indian generics industry safe and protected. GoI and Indian pharma companies should work together and take planned and calibrated steps to improve the brand building exercise. We should constantly strive to make high quality products with the 3As viz availability, affordability and accessibility. The 200 per cent weighted deduction available to Pharma R&D presently, should be continued by GoI.

One thing is certain, if we don't pull up our socks now, China may over take us to become the pharmacy of the World. China is a clear and present danger in the field of APIs, and poses an increasingly strong threat in the formulations space, including in the area of anti-retrovirals (ARVs). While dealing with the USFDA, generics companies will do well to remember the latin dictum *'abundans cautela nonnocet'* (one can never be too careful).

(The author is a former executive director at Ranbaxy)

Industry