PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Deccan Herald, Bangalore
Sunday 10th January 2016, Page: 11
Width: 10.67 cms, Height: 36.03 cms, a3, Ref: pmin.2016-01-12.20.14

Miscellaneous

'Pharmaceutical lobby in India is weak'

SK Vyas is an independent pharmaceutical professional with over 45 years of experience in the industry. In an interview with *Deccan Herald*'s **Sunil Raghu**, he says Indians generally like to work and not maintain records.

How do you see the recent spate of warnings issued to Indian pharma companies by the US regulator USFDA? Is there any reason to doubt the quality of Indian generics and its manufacturing?

This is nothing new. Initially, we started small but today we have become the largest suppliers of generic drugs to the US. In volume terms, we must be 35 per cent to 40 per cent, and may be around 10 per cent to 15 per cent in value terms. We also have the highest number of USFDA approved plants outside the US. There must be more than 150 USFDA approved manufacturers in India.


SK Vyas

Indians have been getting huge value by selling generics and so everybody wants to get in to the US market. Initially, people set up a new dedicated plant in consonance with all the guidelines. When the US regulator comes in to check the facilities, the manufacturers get clearances and they begin to manufacture and supply to the US market. Once they get the approval, they begin to get into multiple generics. Over time, their plants become older and when inspection comes, the trouble begins.

But what is the real problem?

Basically, the problem is with our work culture. We generally cannot do the things right the first time. We always repair. The Americans do not accept that. What happens is that the 90 per cent problems where USFDA has issues with Indian manufacturer is data entry and maintenance and its integrity. You take a drug and analyse it, you find that it is not passing. Then you do it thinking that you have not done the process properly. What you do is that you delete the entry of failed analysis from the computer and begin with the new analysis. The USFDA comes with computer experts and they retrieve the deleted entry and take a serious note of this. This is not proper according to them and they feel that our systems of testing are not proper. This happens in almost all the companies. If your trial run fails, many a times their records are deleted. However, USFDA checks for the minutest data scrupulously. Thus data integrity becomes a huge problem.

As a practice, we also do not protect our data with a password. Each legal user interface has a unique ID and is to be used by only one person. This costs money. Sometimes, to cut costs, people allow more than one user to access in to the system using the same login ID and password. The USFDA is now going to the extent of checking whether only a particular authorised person has logged in every time or has it been used by more than one person. This they do to verify the integrity. At times, the person is not in the laboratory but is shown as logged in. The computer record keeping is also poor. When the USFDA tries to verify the hard copies of the records, they find issues of over writing or double writing. At times some of the papers are even destroyed.

Do you mean to say that the problem is intentional?

Not everyone is doing these mistakes intentionally. No promoter of the company will do these kinds of mischief as they are earning money. At times this is done by the people at the shop floor. Many a times it does not come to notice of even the supervisors. So there is a systemic problem of verifying and validating the data that is submitted before the USFDA. It is a cultural problem. It is noticed only during inspection, because the amount of records that come are humongous, and you have to maintain all the records. You have to work for four hours and record it for six hours. In India, we generally like to work and not maintain records. It is not our culture and this is what hits us.

Are Indian firms not geared up despite many years of experience?

The problem is that we have expanded exponentially. Suppose a particular pharmaceutical company had 10 approvals three years ago. Today, they may have 200 ANDAs. So suddenly in two years you have submitted data for 200 products. To maintain data integrity for 200 products is not easy. And if you have not maintained data for each ANDA submission, you are bound to land up in trouble with the regulator during inspection.

But I believe that in case of Sun Pharma, the question is not about data integrity but issues with its manufacturing plant?

That is the problem. People began expanding even through acquisition route. So they may not know problems with the facility. Moreover, most of these manufacturing facilities are in remote areas and away from big cities where you can perhaps get right human resources. Some of the plants are in Baddi or Sikkim or remote locations like Yanam or Vizag in Andhra Pradesh, so what kind of control would people have. You need perfect people to be in place to do the job right. You generally expand facility and bring in more manpower. But to train them properly and get them into the right frame of mind or culture is very difficult thing to do and maintain. So you end up losing control over the people.

How big is this problem for Indian players?

According to some estimates doing rounds, the market cap of big five came down by up to Rs 95,000 crore. They may have lost business worth Rs 10,000 crore but the loss of market cap was massive. This is the kind of problem that it creates. The second problem is that though you have 30 per cent of market share of the US generics and fighting the pharmaceutical lobby there, the pharmaceutical lobby in India is particularly very weak. The American pharma lobby is the major funding contributors to Congress and Presidential campaign. They have been in the past believed to have put pressure on Congress and law makers to see that the USFDA acts tough against their competition.

Many people say that lobbying by MNCs is responsible for action against Indian pharmaceutical industry?

The question is not about lobbying. Yes, lobbying may be there for the USFDA to become stricter. What the USFDA has found may not be completely wrong. Let us take an example, recently they visited a unit of a big pharma company, they found the presence of disease causing pathogens in the water being used for manufacturing of generic drugs. What the engineers of the unit had done was that they tore the records and threw them in the dustbin just before the inspectors reached. During inspection, regulators chanced upon the torn papers and they got to know of the discrepancy in data. How can you justify such an act? In 45 years of my experience, I have found that generally USFDA is one of the most honest and strict organisations.

(For full interview, please visit www.deccanherald.com)