'Pharmaceutical lobby in India is weak'

S K Vyas is an independent pharmaceutical professional with over 45 years of experience in the industry. In an interview with Deccan Herald's Anil Nagda, he says Indians generally lack the working and technical knowledge.

How do you see the recent spate of warnings issued to Indian pharmaceutical 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 30 per cent to 35 per cent in value terms. We also have the highest number of USFDA approved plants outside the US. These must be more than 165 USFDA approved manufacturers in India.

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Are Indian firms not geared up despite many years of experience? Is there any reason to doubt the quality of Indian generics and its manufacturing?

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But I believe that in case of San Pharma, the question is not about data integrity but issues with its manufacturing plant. That is the problem. People believe expanding even through acquisition route. 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 (remote) places or remote locations.

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 thousands of products. To maintain data integrity for 200 products is not easy. And if you do not maintain data for each ANDA submission, you are bound to land up in trouble with the regulator during inspection.

How big is this problem for Indian pharma?

According to some estimates, doing round the market cap of big five companies is close to Rs 50,000 crore. If you lose business worth Rs 10,000 crore but the loss of market cap is massive. Thus, the problem that it creates. The second problem is that though you have 50 per cent of market share of the US generic and biologics market, the pharmaceutical lobby is a huge industry as you know. The American Medical Association is the lobby that is more or less dominating Congress and Presidential campaigns. They have been in the past believed to have put pressure on Congress and lawmakers to ensure that the USFDA is successful against their competitors.

Many people say that lobbying by USFDA is responsible for action against Indian pharmaceutical industry? Is there any action that you think needs to be taken?

The USFDA is a big company and it can do whatever it wants. It has been a policy of the USFDA to publish the data only in the US and not in India. They have only published the data in the US. They have not published the data here.

Do you mean to say that the problem is international?

Not everybody is doing this. There are a few companies who are doing this, but not everybody. It is not a big problem.

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