

Department of Commerce, Ministry of Commerce & Industry of India - Sudhanshu Pandey, Joint Secretary



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Tags: [regulation](#), [vaccines](#), [FDA](#), [compliance](#), [quality](#), [process](#)

The Indian joint secretary for commerce and industry, interviewed at CPhI Worldwide 2014 in Paris, discusses India's place in the global pharmaceutical landscape, and emphasizes the country's contribution to the world's health.

India has gone to great lengths at this CPhI conference to brand itself and show the world about its achievements in the world of pharma. Why did you decide to make such a large effort in this regard?

Our branding statements, which can be seen on various placards, banners and display boards at CPhI this year make statements about true facts: the number of US FDA approved plants India has, the percentage of its vaccine supply to the world, how many antiretroviral products India supplies. Most of this is happening silently—it is time for the world to understand and acknowledge the contribution India is making to the global healthcare sector. India makes this contribution for the benefit of the global citizen; it is not as great a benefit for India or Indian companies as it is for them. We are sharing the fruits of our knowledge and development in the pharmaceutical sector with the rest of the world.

How did India as a nation come to the realization that it needed to send a coordinated message about India's contribution to the pharmaceutical industry?

It happened over a period of time. India itself is faced with the huge challenge of catering to the health requirement of almost 1.3 billion people. Unfortunately, when we achieved independence, the traditional healthcare infrastructure, which had its roots in thousands of years of our civilization, was adversely shaken. Switching over to the modern system of medicine took a long time. Over the past 60 years the longevity of the Indian population has nearly doubled. Despite the fact that we did not have a very strong foundation in Western medicine, India had one inherent advantage: its scientific bent of mind: added to this, India's education system produces top-notch chemists, scientists, and biologists. Since the pharma sector is basically a combination of the knowledge of these three fields, India is in a strong position to share this knowledge with the world. This is where our roots lie.

Recently, last year in particular, India made the headlines for some frictions with the US FDA, which has come down very strongly on many Indian manufacturers. What is your response?

We take this as one of the phases of understanding in the evolution of the Indian pharma industry; however, we don't entirely agree with what was reported in the media. The US FDA is well within its rights to ensure compliance with their laws, but what was reported in the media was completely incorrect information, the reason being that not many journalists understand the nuances of the pharma industry, or how it has to be reported.

There are two philosophies that drive regulatory regimes around the world. The first is driven by risk-based analysis, which is followed by Europe. The underlying principle of this is that at the end of the production process, you analyze whether the product that you are producing is risk-free for the patient or not. This is how you judge the quality of the product. The second approach is the investigative approach. It is more of a process-driven approach, where the rules are laid down during the production process, and then, you investigate whether or not the process has been followed. In this approach you are putting more emphasis on the integrity of the process rather than on the final product. And yes, there may have been some errors in reporting and in the process employed, but the integrity of the final product was never the issue at stake,

For a long time, India was considered the pharmacy of the emerging world, whereas today it is considered the pharmacy of the entire world. Do you think this would explain the sudden attention?

There is a combination of many factors in this concern. First of all, we have to candidly acknowledge that this is also part of the evolution of Indian companies' learning processes. They

are learning that whatever process they are following, and whatever findings exist, they have to accurately document and report them. Furthermore, the point that you are making is definitely valid, not only in the pharma sector, but in any sector. As an Indian sector reaches higher levels, it's bound to attract attention, which is what is happening currently.

Our message from the Indian pharma industry is very simple. We do not see pharma merely as an industry; it is much more than that. It deals with the sensitive issue of human diseases and human life. We would like pharma companies to be not only responsible, but for media to be responsible as well.

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