



Dear Members,

This month I am on a tour of USA visiting friends and relatives before returning to India towards the end of March. I was invited to visit the College of Pharmacy, University of Findlay, Findlay, OH, USA, where I gave a talk on the topic "Drug development in India and its impact on the Global Pharmaceutical Industry. The talk was quite well received and some very interesting questions were raised, which I would share with you in the context of India's status as the pharmacy of the world. The questions pertain to the quality of pharmaceutical products manufactured in India and I told them that the 570 USFDA approved sites which manufacture generic drugs for export to the USA are subjected to elaborate scrutiny by the US drug regulator and some of the sites do receive FDA warning letters, which is a part of the process of ensuring continuing quality compliance. With so many approved sites in the country even if the US regulator audited each site once in two years, it would still be one audit per each working day and the news that some inspections have resulted in warning

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letters issued would naturally be a frequent feature. Such news can either be interpreted negatively as Indian pharmaceutical manufacturing is of questionable quality or positively as these manufacturing sites produce quality medicines only since mechanisms are in place to ensure quality all the time. My interpretation supported by the data on number of warning letters received by India as opposed to some other countries with much lower number of approved manufacturing sites was quite well appreciated.

While I answered confidently about the quality of drug products manufactured in India for export to the USA and various other countries, there existed in the back of my mind an apprehension if we can say the same about the pharmaceutical products manufactured in our country for domestic consumption. Interestingly, two news items appeared in the last week of February on this subject. The first one was a news release that the director of the USFDA India, Mr. Mathew Thomas expressed concern over the quality and efficacy of drugs sold in India that they might not be of standard quality. His concern was based on the results

of the tests that USFDA India has conducted on some drug samples that were sent to them for testing by the US Embassy Health unit. Coincidentally, the Government of India released a survey report around the same time, which is based on the results of testing of 47,000 drug samples collected from various regions of the country. According to this report only a very negligible proportion of these samples showed either a very low or no active ingredient in them, thereby indicating that lack of efficacy is not an issue with drug products intended for our patients.

Well, ascertaining quality of drug products manufactured in India for domestic consumption is not so simple as indicated by the reports of a few studies conducted. By just performing quality control tests on a few samples periodically, it is impossible to ascertain quality of drugs and their outcomes in patients. In India, we have numerous brands for each drug, manufactured by equally large number of pharma companies and to ascertain that all those companies operate under standard approved conditions by the Indian regulator is a humongous task. Further, generic versions of each drug are also being introduced into the clinical practice and whether or not all branded generics and the generic versions of a single molecule are bioequivalent is something that is not ensured. There is also no single directory that shows all formulations with different names under which any drug molecule is available in the country. Such a complex situation facilitates and encourages spurious or counterfeits to enter the market. Here again, there are different reports that show the problem of counterfeits to be either negligible or enormous. Whose report is correct and whose is wrong is not really the issue; the issue is whether or not the patients of the pharmacy of the world, can access drugs of highest quality! Once we establish that beyond doubt, we need not worry about what others say!!

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#### Our Mission

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of Pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and other on vital professional issues and support pharmaceuticals education and sciences in all aspects.

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