Interview: Dilip G Shah – Secretary General, Indian Pharmaceutical Alliance (IPA)

"Policymakers need to look at the industry's issues today, and provide the clear guidance on how the government could help resolve them."

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Dilip G Shah, secretary-general of the Indian Pharmaceutical Alliance (IPA) and member of the Expert Review Committee on Access to Medicine (ATM), discusses the association's commitment to

assisting the Indian government with policies that ensure access to affordable medicines for all as well as the requirements that every candidate needs to meet to become a full member of IPA; a substantial R&D focus being one of the highest priorities.

Can you give our international readers an introduction to yourself and your background?

I graduated from the premier business school in India, the Indian Institute of Management (IIM) in Ahmedabad and have 50 years of varied experience in the pharmaceutical industry. I have addressed several WTO workshops on TRIPS, WIPO seminars on IPRs and Public Health, WHO meetings on Access to Medicines and several other international meetings and conferences. I am a Member of the official Indian Delegation to WTO Ministerial Conference in Cancun. Furthermore, I appeared before the U.S. International Trade Commission (USITC) and testified in Investigation No.332-543 Hearing in Washington DC in 2014.

Currently, I am the Secretary-General of the Indian Pharmaceutical Alliance (www.ipa-india.org), Member of the Expert Review Committee on Access to Medicine (ATM) Index (www.atmindex.org); Member of the CPhI International Advisory Board; Member of the Board of Advisors of

Pharmabiz.com (Weekly); and Member of Task Forces and Expert Groups constituted by the Government of India for accelerating growth of the Indian pharmaceutical industry. I was Chair of the International Generic Pharmaceutical Alliance (IGPA) for two terms (2005-07) and (2010-11).

In addition to this, I am an independent director on the boards of Fresenius Kabi Oncology Ltd and Anuh Pharma Ltd and CEO of Vision Consulting Group (www.vision-india.com), a firm specialized in strategic planning. Before starting Vision in 1997, I was a Member of the Board of Directors of Pfizer India for whom I worked for 30 years.

Can you introduce the IPA to our international readers and explain the criteria required to become a member of your association?

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The Indian Pharmaceutical Alliance (IPA) was established in 2000 and represents research-based national pharmaceutical companies. The Association represents overall USD 25 billion, 46 percent of the domestic market which amounts to USD 7.5 billion – and USD 18 billion as two thirds of exports. Invitation is required if one wants to join the association as the main essential criteria. Firstly, the candidate must have a measurable respect for IP rights, as we support a strictly TRIP compliant IP rights regime.

Secondly, in terms of market share prospective members must have at least one percent of the market, although under special circumstances we allow members with half percent share of the market. Sun Pharmaceuticals has the biggest market share with 8.7 percent, followed by Cipla. What is worth noting is that the top four Indian companies alone have around 20 percent market share.

Thirdly, we want our members to showcase strong commitment to R&D. When we started the operations, we were unsure of what the R&D spending should be, but we all agreed that it needed to be substantial. Back then, companies had 1-2 percent of R&D spending, whereas now our member’s research related spending ranges between 2-13 percent, with an average of eight percent. Lastly, all members must have at least one manufacturing facility approved by the US FDA, UK’s MHRA or EMA. They must be conscious of quality, GMP, and compliance.

How hard is it to manage companies that are constantly in cutthroat competition?

Unlike other associations, only company CEOs can participate in our meetings, out of respect for the other heads present. The IPA is a secretariat-driven association; we hold only four CEO meetings a year, broad directions are agreed on one occasion, and the rest of the time it is driven

by a secretariat. Our 20 members have been competing intensely in the market in a cutthroat competition. However, they have seen tremendous value. Making those entrepreneurs sit at one table and focus on the common issues was quite a challenge. They simply needed a forum to make them realize they face similar issues, and now the level of mutual confidence is there.

What is your direction and positioning today?

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We are always considering ways to assist the Indian government especially with policies that ensure access to affordable medicines for the poor, without compromising the growth and development of the pharmaceutical industry. We also actively contribute in the discussion with policymakers with regards to the impact that the proposed policies will have on the industry. Looking from an international perspective, we think about how to project the Indian industry as a global benchmark of quality and affordability, which is the ultimate goal.

What is the IPA's take on the current draft Pharmaceutical Draft Policy 2017?

Policymakers need to look at the industry's issues today, and provide the clear guidance on how the government could help resolve them. The new Draft Pharmaceutical Policy 2017 addresses a range of issues including indigenous production of active pharmaceutical ingredient (API), quality control and regulatory approval, manufacturing arrangements, foreign direct investment, innovation and R&D and intellectual property. A major portion of the draft is devoted to pricing and makes various recommendations for the re-structuring of the National Pharmaceuticals Pricing Authority (NPPA) and changes to the Drug Price Control Orders (DPCO).

What is absent from the draft is a plan with concrete goals and measurable actions that the government and industry need to take. Brand-building is the first step forward towards innovation. In order to have a sustainable and recognizable portfolio, the brand has to stay. Thus, if we want to foster innovation and inspire the industry to innovate, they will have to be able to innovate in order to enrich their branded portfolio.

There are several other items in the Pharmaceutical Draft Policy towards which the industry is very hesitant. Government needs to be able to make distinctions between the rich and the poor. For the poor we are ready to advocate for the supply of free medicine and industry is ready to partner in and help with reaching that goal, but the pricing cannot be the same for everyone. Industry needs to be able to invest in research if it is meant to grow, develop and meet the future requirements of the country, because, as of today, half the population of the country does not have access to

modern medicine. They are still on traditional medicine or no medicine at all. This is to do with many issues, among others a lack of infrastructure. There are people, even in the rural areas, who are willing to spend anything out of pocket for medicines. What the Government has focused on in terms of infrastructure is roads and telecommunications, but they also need to consider health infrastructure so that the poorest sections of the population have access to medical facilities.

Following infrastructure investment, accessibility will be the factor that will make doctors go to those areas. This is the future of the industry, and if you help 500 million people in the country who have not been exposed to current treatments, this is the chance to make them your customer. I firmly believe if we work on those issues together we will deliver both the growth of the industry and the access to medicine for India.

How would you characterize your relationship with the FDA and the rest of the US administration? Does India have the potential to be the export leader to the US?

The global pharmaceutical industry faces the challenge of upgrading quality systems and delivering life-saving medicines at affordable prices simultaneously. India is no exception. In India, pharmaceutical companies have had mixed success in upgrading their quality systems.
The number of warning letters from US FDA to Indian manufacturing sites has increased in the last five years. While the proportion of OAI and VAI decisions in US FDA inspections has remained the same (around 65 percent), the number of inspections increased by 30 percent in 2015. In 2015, when some of our members received warning letters from the US FDA, it came as quite a surprise. We did not, however, take the view that India and Indian companies were being targeted as we had a fairly positive relationship with the US FDA.

We entered into a biannual direct dialogue with the FDA that will benefit both sides. Approximately 1,400 manufacturing units in India are WHO GMP (Good Manufacturing Practices) certified, 573 facilities are FDA approved and over 800 are UK MHRA approved. India continues to have the highest number of US FDA-registered manufacturing facilities outside the US, and we will work toward becoming a quality benchmark globally. As the industry continues to grow and expand in scale and complexity, it is crucial to pursue quality excellence relentlessly.

What role can Indian companies play in bringing medicine prices down internationally?

We have already brought them down by increased competition. India offers a low-cost innovation and manufacturing. Also, India-made generics sometimes cost almost one-tenth of branded drugs sold in the US for example. The relative affordability of these generic drugs compared to their patented counterparts has not only enabled India to provide quality drugs at low cost for its own

people, but has also made India the de facto pharmacy for the world. However, access to affordable medicines cannot be limited to India only. In all countries, including the US, there is a large section of society which cannot afford drugs. The Indian industry is providing affordable medicines to the world. Its model is serving social cause through financially viable enterprise.

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