

Interview: Raghuveer Kini - Executive Director, Pharmexcil, India

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Raghuveer Kini, executive director of the Pharmaceuticals Export Promotion Council of India (Pharmexcil) provides insights into the key success factors that have allowed India to become the world's pharmaceutical hub and gives us his assessment of the recent plateauing of Indian exports as well as an overview of the new trends shaping the international strategies of Indian pharmaceutical companies.

Could you briefly introduce Pharmexcil to our international readers?

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) is a government agency that was set up by the Ministry of Commerce and Industry in 2004, following the recommendations of the country's four main pharmaceutical associations. Prior to the creation of Pharmexcil, pharmaceutical exports were promoted by a multiple-industry agency, and the government of India considered that it was important to create a dedicated, pharma-focus export organization to truly accelerate the international development of our country's pharmaceutical sector. It turned out that it was the right thing to do, as Indian pharmaceutical exports have skyrocketed from around USD 3.9 billion in 2004 to reach nearly USD 17 billion today.

As per Pharmexcil, we leverage our interactions with global regulatory boards and foreign delegations to guide Indian exporters through international regulations. In the meantime, we regularly invite these international partners to visit India and show them our companies'

manufacturing plants. Although India accounts for over 20 percent of the global generics market, some countries' representatives are still surprised to see India's tremendous progress and leadership with regards to manufacturing technology and quality standards.

At times, Pharmexcil also operates as an intermediary bringing together international and domestic regulators to solve any regulatory issues that might arise. Finally, Pharmexcil helps expose small and medium companies on the global stage, and the latter can leverage our market-specific analysis to tailor their export strategies.

It makes no doubt that India has managed to establish itself as the pharmacy of the world, accounting for over 25 percent of the US generics market - a performance that makes green with envy many countries around the world. What do you identify as the main success factors that have accelerated the international development of India's pharmaceutical industry over the past decades?

There have been a few learning along the way, but some strong fundamentals can be identified. First, the Government of India has been very supportive, through both the Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers. Second, Indian companies have developed a true expertise in reverse engineering - a key success factors when it comes to develop a pharmaceutical industry mainly based on generics products. Finally, I would highlight our companies' capacity to scale up manufacturing capacities while keeping a close control on thier cost-effectiveness profile, which has allowed them to bring to the global markets some of the world's most affordable products in huge quantities.

Looking at the financial year 2016-2017, we however saw that total Indian exports (including APIs, formulations, and alternative medicines) decreased by 0.47 percent, while exports of formulations - which represent two-thirds of the total exports - increased by only 0.42 percent in the meantime. Would you describe this poor performance as exceptional or shall we understand that Indian exports are facing unprecedented headwinds?

I think there were many factors involved in the plateauing of Indian exports. Globally the oil crisis has affected a large number of export destinations - including significant markets such as Venezuela. In the meantime, currency devaluation also hampered business and payments, and - again - key export markets were strongly affected, such as Russia. Increasing competition and price erosion in regulated markets has also been a key factor during this time: when refining our analysis of Indian exports, we see that exports volumes have gone up but exports values have

plateaued or decreased.

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However, we are not worried as latest results show that exports are picking up again in value; as a matter of fact, November 2017 saw a growth of 14 percent in exports value whereas in December Indian exports of pharmaceutical increased by seven percent when compared to 2016. The situation is improving, so there is no reason to be alarmed.

Since October 2015, around 35 percent of all warning letters issued by the US FDA were addressed to Indian companies. Furthermore, out of 87 warning letters issued by the US FDA to Indian companies between 2011 and July 2017, in 18 cases the US FDA has issued closeout orders. Do you think that there is a direct relationship between this increasing regulatory scrutiny and plateauing Indian exports?

Regarding the fact that Indian companies represent 35 percent of all warning letters, one should also compare this number to other countries and to the weight that Indian companies have in the US market - then you will get the real picture.

In business, one must differentiate healthy from unhealthy competition, and - in this regard - there seems to be a deliberate campaign to malign the Indian pharma industry. Let me give you two very concrete examples. A few years ago, Nigeria's regulator inspected a container and found out that the medicines it contained were placebos. These products' labels said that products were manufactured in India and exported from India; however, upon further inspection, it was found that none of these tablets were actually made in India or by an Indian company. After this worrying event occurred, the Indian Government implemented a track and trace system based on barcodes, in order to ensure that Indian medicines are always traceable.

The second example is even more illustrative: in 2005-2006, I conducted a delegation to Santiago, Chile, where around 40 Indian companies - including both Indian powerhouses and smaller companies - accompanied Pharmexcil to meet with the country's health Minister. This meeting truly emerged as a milestone in our trade relationship with Chile, and Indian exports started increasing smoothly afterwards. After a year or two, I however received a call from the Indian ambassador in Chile, who announced me that Chilean authorities had seized all Indian vaccines from the market. The reason invoked was that - apparently - children died due to consumption of certain Indian medicines. I therefore asked the ambassador to call for a press conference, during which representatives of the Indian pharmaceutical industry suggested to Chilean authorities to send seized drugs to an independent laboratory - of their choice - for testing. The next day, all

seized drugs were released, accompanied by a public statement explaining that this seizure was due to an erroneous decision.

The Indian government is very strict on quality standards and regarding the respect of domestic and international regulations. Despite all our efforts, there will always be black sheep – in India like in any other countries – but when such situations did happen, the Indian government and our country's regulators have always taken the strictest actions, including the suspension of these companies' exports licenses.

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What are the new trends shaping the export strategies of Indian pharma companies ?

US and Europe remain our major export destinations, accounting for nearly 50 percent of all Indian pharmaceutical exports. However, Indian companies are looking out to exploring new markets, notably in Africa, where we have received interesting return.

In the meantime, Indian companies have been adapting the way they bring their products to foreign market. Russia, for example, aims to have nearly 50 percent of their pharmaceuticals domestically manufactured by 2020, prompting Indian companies to set up joint ventures in the country. A similar trend is happening in the US market, where some Indian companies have recently acquired a lot of assets and/or engaged in joint ventures. Governments around the world are looking at increasing domestic production of medicines, and we have to respect and adapt to this new model.

How does Pharmexcil go about promoting India's pharmaceutical industry in new markets?

India's Ministry of Commerce and Industry as developed several targeted campaigns focus on strategic geographic areas, such as Africa or Asia.

Furthermore, Pharmexcil has been organizing the International Exhibition for Pharma and Healthcare (IPHEX) for the past six years, and the next edition will be held in Delhi in May 2018. IPHEX is a gathering of 500+ buyers and distributors from over 120 countries, and the government of India pays for all attendees' travel and accommodation expenses. In the meantime, representative of Ministries of Health from various countries are invited to voice their concerns and expectations to the global pharmaceutical industry.

Throughout the years, IPHEX has established itself as a global market place and as a major hub of interactions for the pharmaceutical industry, where all the major players in the healthcare industry converge. This truly helps generate new business in many high-potential countries for our companies.

You have been working at Pharmexcil for the past 14 years, what is the driving force that has kept you going?

I am very passionate about India's pharmaceutical industry and I believe that our country can take number one spot. Our industry and capacities are being strengthened day after day, and many exciting developments are yet to come. Just to give you an example, the Maharashtra government is about to set up a brand new pharma park close to Mumbai, which will be supported by an international airport and a cargo hub in order to establish this new park as a manufacturing and export hub of international reference.

In the meantime, we are working on reducing India's dependence on imported APIs, and Pharmexcil has recently led inter-ministerial meetings gathering together the government, academia, national laboratories and the domestic industry with the objective to shift the country's paradigm in this crucial matter.

As a final message, what would you like to tell our international executive readership about India's pharmaceutical industry?

Come to India and see our capabilities and prospects for yourself – you will be positively surprised. Without any doubt, India is able to supply all needs at the highest quality and at an unrivalled cost.

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