

Everything Cannot Be Locally Produced,' Says IGBA Chair

Sudarshan Jain Also Warns Against Reliance On Single-Source APIs

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- INTERVIEWS

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Executive Summary

In an exclusive interview with *Generics Bulletin*, IGBA chair Sudarshan Jain said that a resilient and diversified supply chain is critical, but localized production may not be the answer to everything. IGBA secretary general Suzette Kox and Jain discussed key lessons to be learned from COVID-19, the IGBA's focus on regulatory harmonization, and challenges in driving the adoption of generics, biosimilars and value-added medicines.

IGBA CHAIR CALLS FOR CO-ORDINATION BETWEEN EUROPE, INDIA AND THE US FOR A RESILIENT SUPPLY CHAIN

“The International Generic and Biosimilar medicines Association supports a diversified supply chain but the answer for everything is not localized production,” said Sudarshan Jain, chairman of the IGBA and secretary general of the Indian Pharmaceutical Alliance, in an exclusive interview with *Generics Bulletin*.

Jain insisted on a resilient and diversified supply chain, but pointed out that “if we have localized production for everything in all markets in the world, it will lead to an increase in cost.” He added, “If the product is available for a country from two to three suppliers then there is no necessity of policing everything.” Moreover, Jain insisted that “we have to be very cautious in our approach, as a diversified supply chain is important. But a diversified supply chain is different from localized production.”

Weaknesses in the global pharmaceutical supply chain, exposed and exacerbated by the coronavirus pandemic, have led major markets to pursue localization policies aimed at bolstering domestic production capacity. But any significant transformation promises to take many years.

Talking about active pharmaceutical ingredient supply, Jain pointed out that “API reliance of the world is very high on one source,” explaining that Europe, the US and India have to come together if there is only one supplier for a product. “We have to have multiple suppliers.”

Pointing out the lack of diversity in the supply chain, Jain said that “you can't be dependent only on one supplier for a particular product.” He reiterated that “co-

ordination between Europe, India and US is very important for a resilient supply chain.”

However, when asked if India and China will be able to retain their positions as the main manufacturing hubs if a more diversified supply chain is in place, Jain said that “it will not happen overnight.”

“Initially companies have to be given some kind of incentive,” said Jain. “Like in India, there is going to be incentives for local production of API, the US is talking about giving incentives for local production, Europe is talking about local production.” He continued, “but there has to be a balance because everything cannot be locally produced.”

Jain suggested that whenever there is only one supplier for a particular API, governments should encourage companies to produce such APIs through incentives. “It will not happen overnight; it will not happen in a year. It is a long shot. Which is why it is important to start,” said Jain.

Furthermore, Jain predicted that the impact of India’s Production Linked Incentive scheme would not be visible for another three to five years. (Also see "[India Approves 16 Applications Under PLI Scheme](#)" - Generics Bulletin, 23 Apr, 2021.)

Calling the PLI scheme a “long-term initiative” to boost domestic manufacturing of raw materials and increase self-reliance, Jain insisted that “it should be viewed as a long-term investment to expand India’s pharmaceutical manufacturing capabilities.” (Also see "[IPA’s Jain Predicts 3-4 Weeks To Meet Indian Shortages](#)" - Generics Bulletin, 29 Apr, 2021.)

Key Lessons From COVID-19

Talking about how industry worked together with regulators during the pandemic, Suzette Kox, secretary general of the IGBA, said that it was worth highlighting that significant efforts have been made by regulators to implement regulatory flexibilities and new ways of working.

“We realised early that the generics industry had to play a very important role,” Jain said, talking about the generics industry’s role in the pandemic. “Supply of generics medicines is the most critical thing, because though vaccines are important, patients may suffer from other ailments.”

Talking about the second wave of the pandemic, Jain said “it was very difficult to predict the demand [for medicines]. So, the supply chain agility, the logistical agility and co-ordination became very important.”

He added, “We have been able to maintain the supplies of the medicines by and large. But in some parts of the world, we realised that there had been shortage of some of the COVID drugs, [so] we ramped up the production.”

“So, one of the learnings is that the stockpiling of critical medicines is very important around the world,” said Jain. “Second, oxygen has become a major issue in India,

Indonesia and other parts of the world. So, oxygen supply has to be maintained because that is a major cause of fatalities.”

Kox pointed out that the entire industry – including originators, the off patent sector and vaccine companies – recently participated at an International Coalition of Medicines Regulatory Authorities industry virtual workshop on enabling manufacturing capacity in the COVID-19 pandemic. “This exchange will continue,” said Kox.

Furthermore, Kox insisted that increasing manufacturing capacity was “very important,” which needs regulatory greenlights, which needs harmonization.

“Harmonized Regulatory Approaches Are More Important Than Ever”

“Harmonized regulatory approaches are more important than ever,” said Kox. “It will accelerate access to the market and support the resilience of the supply chain.”

Talking about the recent launch of the US Food and Drug Administration’s generic drug cluster for harmonization and for common standards, Kox said, “We applaud regulatory harmonization initiatives.” She added, “Promoting regulatory co-operation and mutual recognition agreements, as well as the convergence of regulations through initiatives, such as International Council for Harmonization and the one now recently started by US FDA, are an integral part of the purposes of the association.”

Furthermore, Kox said, “Convergence of regulatory requirements, harmonization and reliance are indeed key to streamline the development of generics, complex generics and biosimilars as they support also the sustainability of our industry, and thereby increased access to high quality generics and biosimilars.”

Kox said that over the past four years, the IGBA has been nominating company experts to 26 ICH expert working groups, thus demonstrating its commitment to harmonization.

Increasing Adoption Of Generics, Biosimilars, Value-Added Medicines

On the subject of how to drive uptake, Jain said there was “a lot happening as many patents expire,” so there would be “significant adoption for many of these products. Generic companies will be keen on it and the government will try to expedite it because of the pressure on healthcare costs.”

“Some companies will also try and extend product patents like [AbbVie’s] Humira (adalimumab),” suggested Jain.

From a patient point of view, Jain said that we will see a faster approval of products and a better pathway for approvals. “However,” he said, “approval alone is not enough.”

Jain insisted that educating patients about off-patent products was important, as patients will not adopt a product just because the patent expires. Apart from low prices, he indicated, adoption of generics depends on education, awareness and patient sensitivity.

Talking about the challenges to generics, biosimilars and value-added medicines adoption, Jain said that the cost of products was high wherever the insurance systems are not available. Moreover, according to Jain, other challenges include delays in approval processes, patent challenges and education and awareness issues.

“The role of innovative companies and generic companies is very important to address the unmet needs of medicines. And the role of the government is very important as well,” said Jain.

Talking about challenges to biosimilar adoption specifically, Kox said “countries are in different stages of adoption of biosimilars, hence the measures needed to increase uptake are country-specific.” She insisted on information and awareness about biosimilars as well as the positive clinical experiences that are paramount for stakeholders everywhere, since they will be the key driver for biosimilars growth.

She continued, “In Europe the total clinical experience with biosimilar medicines exceeds two billion patient treatment days. Other markets are clearly opening up too.” Furthermore, “biosimilars have been used now in more than 121 million days of patient therapy in the US,” Kox added.

However, she pointed out that “the regulatory pathway is obviously also very important.” She insisted that “we need a regulatory framework which allows global development of biosimilars and avoids duplication of studies.”

In the first week of November, the IGBA will be launching its second Global Biosimilars Week, a social media campaign where it will engage directly with stakeholders, confirmed Kox, following an inaugural event last year. (Also see "[IGBA Kicks Off Biosimilars Week](#)" - Generics Bulletin, 16 Nov, 2020.)

“Since encouraging professional awareness and general knowledge that promote the quality, safety and efficacy of biosimilars is one of the key purposes of the association,” she highlighted, “IGBA is supporting its member associations in their educational efforts on biosimilars.”

“The UK MHRA move is a milestone and a logical next step in the biosimilar medicines regulatory framework.”

In May, the IGBA applauded the UK Medicines and Healthcare products Regulatory Agency’s recent biosimilar guidance revision that will see the agency break ground by

not typically requiring comparative efficacy data as part of the biosimilar licensing process.

Updated guidance on the UK's new licensing pathway for biosimilars – which will typically not require comparative efficacy data – has been published by the MHRA after a stakeholder consultation, receiving a warm welcome from the off-patent industry both locally and internationally.

“This evolution of the regulatory pathway is driven by the growing clinical evidence with biosimilars after more than 15 years on the market and billions of treatment days of experience, as well as improvements in regulatory processes, analytical science and characterization technology,” said Kox.

“The UK MHRA move is a milestone and a logical next step in the biosimilar medicines regulatory framework,” she commented. “We hope that the same updated scientific and regulatory approach will be included in the World Health Organization guidelines on evaluation of similar biotherapeutic products, currently under revision.”

“We need also a global implementation roadmap to progress this science-based efficiency in order to accelerate equitable access for patients around the world,” insisted Kox.

In the second part of this interview, to be published shortly in Generics Bulletin, Jain and Kox discuss the importance of digitalization to the off-patent industry.