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IPA's Jain Predicts 3-4 Weeks To Meet Indian Shortages

Current IGBA Chair Also Insists On Global Collaboration For Vaccine

by Akriti Seth

Speaking exclusively to *Generics Bulletin*, Indian Pharmaceutical Alliance secretary general Sudarshan Jain says that India's needs for COVID drugs like favipiravir, remdesivir and tocilizumab will be met "in the near future." Current IGBA chair Jain also talks about global collaboration by governments and donors for equal vaccine distribution through the Access to COVID-19 Tools Accelerator.

As India struggles with the second wave of COVID-19, patients have been repeatedly flagging the shortages of COVID drugs like remdesivir and favipiravir, as daily reported cases rose to 379,275 on 29 April 2021.

Speaking exclusively to *Generics Bulletin*, Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance and current chair of the International Generic and Biosimilar Medicines Association, insisted that against this backdrop "companies have stepped up the production and all efforts are being taken to meet the increased demand."

"Favipiravir should be available in the near future," Jain assured. "Remdesivir and tocilizumab will take some time as the production cycle for remdesivir is three to four weeks and tocilizumab is imported from Roche, Switzerland." (Also see "*Gilead Scales Up Remdesivir Production To Meet Indian Demand*" - Generics Bulletin, 27 Apr, 2021.)

Industry Steps Up To Help India

Noting the efforts of the industry, Jain said, "The pandemic in the beginning resulted in disruptions of supply chain operations but the industry quickly worked and addressed it. No drug

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shortages were reported domestically, and Indian pharma companies were also able to meet the global demand."

Acknowledging that "there has been exponential increase in the COVID-19 cases in India in the last three months," Jain said, "there used to be around 8,000 cases in early February which has risen to around 40 times reaching over 350,000 cases per day in the last one week." This "has led to a significant demand of COVID drugs, namely favipiravir, remdesivir and tocilizumab."

"Co-operation and collaboration between the industry and government will play a pivotal role in dealing with this public health crisis," insisted Jain.

Through Second Wave

By Akriti Seth

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As India sees a consistent rise in daily cases and deaths due to COVID-19, the off-patent industry is stepping up to make drugs affordable and available. Zydus Cadila is seeking approval for virafin, while Natco has applied for molnupiravir approval. Vaccine production and availability has also come under focus.

Read the full article here

Talking about the government efforts being taken to address the shortages, Jain said, "Government and industry are seized of the matter and all out efforts are being undertaken to improve the supply situation."

> ***"Co-operation and collaboration between the industry and government will play a pivotal role in dealing with this public health crisis."***

'We Will Not Be Able To See The Outcome Of The PLI Scheme Immediately'

Jain also discussed the latest Indian efforts to boost domestic production of active pharmaceutical ingredients, intermediates and key starting materials.

Recently, the Indian government's ministry of chemicals and fertilisers approved 16 drug production applications under the country's Production Linked Incentive scheme. (Also see "*India Approves 16 Applications Under PLI Scheme*" - Generics Bulletin, 23 Apr, 2021.) Commenting on the approvals, Jain said, "the Indian pharmaceutical industry welcomes the

government's initiative and active steps towards the PLI scheme."

However, when asked about India's dependency on imports of basic raw material, Jain said, "we will not be able to see the outcome of the PLI scheme immediately."

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."

Recalling the purpose of introducing the PLI scheme, Jain said, "The goal of the scheme is to promote and increase domestic manufacturing of key starting materials, drug intermediates and APIs, making global manufacturing champions in the country and thereby reducing India's reliance on other countries for pharmaceutical raw materials."

"Additionally, [the PLI scheme] will stem the infusion of investment and employment generation. Considering the potential of the scheme, we can expect more API production approvals in the future," he added, as the government notification on PLI Scheme on APIs/KSM mentions a list of 41 APIs, KSMs and drug intermediaries that are being considered.

India's Generics Industry At Forefront Of The Pandemic

"The pandemic has thrown unprecedented challenges at us," said Jain. "However, we believe that it has also given us, the generic pharmaceutical industry, the opportunity to rise to the occasion and ensure access to quality and affordable medicines to people across the world."

"The generic industry has been at forefront of the pandemic and has worked relentlessly to ensure uninterrupted supply of life-saving medicines," he said.

However, since the second wave of COVID-19 is much stronger, impacting both the young and the old and also the entire families, Jain insisted that India's integrated approach of testing, tracking, treating and vaccination will play an important role along with a thrust on COVID appropriate behaviour.

"The industry is committed to supply affordable, high quality medicine and has demonstrated the consistent supplies in the most difficult times," Jain said, insisting that the Indian pharmaceutical industry has truly lived its reputation as the 'Pharmacy of the World.'

IGBA Extends Support To ACT-A Global Collaboration For Equal Vaccine Distribution

In his capacity as this year's chair of the International Generic and Biosimilar medicines Association (Also see "*Who's Hired? IGBA Names IPA's Jain As Chair*" - Generics Bulletin, 11 Jan, 2021.), Jain insisted that "global solidarity, collaboration and co-operation constitute altogether

the fastest and most effective way to defeat the pandemic and to get our economies back to full operation."

"That's why the Access to COVID-19 Tools Accelerator coalition was formed to support the development and equitable distribution of tests, treatments, and vaccines the world needs to fight COVID-19," he highlighted. "To meet ACT-A's vision and mission, IGBA calls upon governments and donors to urgently increase the financing of ACT-A's activities."

The global initiative was launched last year by the World Health Organization and is aimed at speeding the development and production of essential health technologies for addressing the coronavirus pandemic, as well as ensuring "equitable global access" to these technologies. (Also see "*IGBA Backs Global Coronavirus Initiative*" - Generics Bulletin, 28 Apr, 2020.)

"To meet ACT-A's vision and mission, IGBA calls upon governments and donors to urgently increase the financing of ACT-A's activities."

While creating manufacturing capacity in all parts of the world may not be possible or sustainable as it would need building infrastructure and creating supply chains, Jain insisted that creating regional hubs could meet the requirement. "Unprecedented initiatives are ongoing to make this happen," he said.

"It is also critical that trade in medicines continues to flow unimpeded as a closely connected, diverse and resilient pharmaceutical supply chain is the best means to ensure that patients and health care systems have access to a secure and consistent supply of pharmaceuticals and other COVID-19 tools," Jain said.

He noted that to support the deployment of COVID-19 tools, it was crucial to also invest time and resources in supporting and building robust health systems to manage public health crisis like COVID-19 as well as for the future.

"Governments in different parts of the world are already investing in research and development whereas all pharma companies have risen to the occasion in an unprecedented manner to combat the pandemic," Jain said. "Voluntary licensing for novel anti-COVID-19 therapeutics and repurposing of drugs are other crucial elements in treatment for COVID-19."

"Nobody is safe until everybody is safe."

Talking about the IGBA's role during the pandemic, Jain said that the association "plays an important role in providing a platform for exchange, support and co-operation between our international member associations, which proves to be very valuable during the ongoing health crisis."

"Nobody is safe until everybody is safe," insisted Jain.

Increased International Regulatory Co-operation And Convergence Required

According to Jain, the development of new trade agreements and implementation of free trade agreements are constantly monitored, by the IGBA, "given the impact of FTAs on generic and biosimilar medicines markets."

Talking about the importance of increased collaboration and simplification of regulatory procedures, Jain said that the time had come to "make now a big leap towards increased international regulatory co-operation and convergence."

"Within the same spirit, IGBA continues to strengthen its relationship with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use," he added. "In the last four years, IGBA nominated scientific experts to 26 ICH expert working groups."

When it comes to biosimilars, Jain said that IGBA was building on its 2020 work regarding streamlining biosimilar development. (Also see "*IGBA Calls For 'Streamlining' Of Global Biosimilars Process*" - Generics Bulletin, 30 Sep, 2020.) "The WHO consultation of the revised Similar Biological Products guideline constitutes an excellent opportunity to build upon the extensive clinical experience gained with biosimilar medicines and biologics manufacturing changes," he noted, "and to move towards a more tailored clinical development program while maintaining at the same time the scientific rigor needed to support approval."

As IGBA prepared for a second 'Global Biosimilars Week' in the fall – following the inaugural event last November (Also see "*IGBA Kicks Off Biosimilars Week*" - Generics Bulletin, 16 Nov, 2020.) – Jain insisted, "Raising worldwide awareness on biosimilars also needs further efforts in order to increase access to biologic treatments."