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Regulators should align to formulate standards for the approval of generic and biosimilar medicines: Sudarshan Jain

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Shahid Akhter ETHealthWorld August 18, 2021, 07:40 IST



Shahid Akhter spoke to **Sudarshan Jain**, Chair, [International Generic](#) and [Biosimilar](#) Association (IGBA) & Secretary General, [Indian Pharmaceutical Alliance](#) (IPA), to know more about the challenges and opportunities in the [generic](#) and biosimilar medicines.

How has been the contribution of the global generic and

The global Generic and Biosimilar medicines industry has significantly contributed in enhancing access and improving global health outcomes. Today, Generics represent 60-80% of all medicine volume sales in key markets globally, with penetrations in many countries at even higher levels (e.g., 90%+ in the US, 80%+ in Australia, 90%+ in India and 85% in Jordan). This scale coupled with the industry's ability to maintain cost-effective prices has enabled the industry to significantly expand reach and access of several therapies globally. For example, generic HIV therapies have helped increase treatment coverage 3-fold since 2010 in Eastern and Southern Africa and reduce the number of deaths by 44%.

Despite the many challenges in the [COVID 19](#) pandemic, the generic medicines companies have risen to the occasion by quickly adapting and acting with agility to scale manufacturing. During the outbreak of COVID-19, this industry was providing most of the medicines needed in [Intensive Care Units](#) to ventilate critically ill COVID patients. For example, several Indian companies quickly adapted to repurposed drugs for treatment of COVID 19. The industry has been providing most of the quality medicines dispensed around the world, especially for increasingly prevalent chronic diseases at affordable prices and is therefore a strong contributor to health outcomes globally.

The generic and biosimilar medicines industry will continue to play this important role in the healthcare ecosystem across the world not only in pandemic time but beyond as well. The IGBA's Vision Report has highlighted the contribution of the industry and also laid down the steps to be taken going forward in order to be sustain growth.

What are the challenges the industry is experiencing currently and how does it plan to overcome the same?

While the industry has established itself as a dependable partner for the global healthcare industry but is facing few challenges that could hinder its growth. One of the challenges the industry faces is high level of pricing pressures for both generics and biosimilar products.

Secondly, Regulatory hurdles are slowing access to generics & biosimilars. While regulatory processes for generics are well established, there remain hurdles: For example, evidence generation required in inhalation and long-acting injectables and need for market-specific reference samples.

Another challenge the industry is encountering is that supply and manufacturing networks continue to be under pressure. Covid-19 has increased a push for localisation/on-shoring which may increase both complexity and costs and bears

Additionally, new modalities and technologies in the innovation pipeline are increasing the risk profile of investments (e.g., 1000+ pipeline assets focusing on cell/tissue therapies). These will require new scientific and technical capabilities, as well as a re-think of business models (e.g., new therapies targeted for smaller populations). The industry will require a completely new set of capabilities and substantial investments for success in these emerging areas.

The pharma companies are building their pipelines in generics and biosimilars in emerging markets as the emerging markets remain considerable part of global pharma market. However, these markets are challenging in terms of volatile economic fundamentals, push towards local manufacturing and non-convergent regulatory requirements. In such cases, streamlining and simplification of regulatory guidelines will be critical to enable speedy access to markets, while ensuring adequate quality and efficacy. Furthermore, global supply chain disruptions of raw materials and disruption in traditional commercial models can also pose hurdles for the industry.

The generic & biosimilar companies have started exploring strategic new and emerging opportunities while strengthening their core capabilities across value chain. Subsequently, support from the government in policy decision and international collaborations will play a critical role in the industry's development.

How do you see the industry shaping in India?

India is the 3rd largest by volume and 13th largest in value terms and contributes 20 % of generic market. Indian pharmaceutical sector supplies over 60% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. With respect to biosimilar, the Indian domestic biosimilar market was estimated to have generated US\$576 million in 2019. Moreover, the industry exports to most of the countries globally and has significant footprints in all the highly-regulated developed markets.

The [Indian pharmaceutical industry](#) has played a key role in maintaining supply chain resilience throughout the pandemic. The generic and biosimilar industry will be key in expanding the global market share of the Indian pharma sector in terms of value and volume in years to come. In order to sustain the impetus, Indian companies would need to move up the value chain and invest in R&D and enhancing manufacturing capabilities and related technical competence. Moreover, support from policymakers will help Indian companies to have larger access in developed markets like the US and Europe. Going forward, Innovation, R&D, digitalisation, and Quality will be critical. Global reach is key for Indian

What are steps taken by the industry to accelerate the growth in the space of innovation and R&D?

Generic and Biosimilar medicines industry is a key driver for reach of high quality and affordable medicines across the globe. The last decade witnessed the launch of many New Molecular Entities (NMEs) in markets such as the US. The generic industry helped to make the products available to the larger population across the world.

As we move towards the future, the healthcare and pharma industry in India will have to move up the value chain and expand its presence in the innovation space which continues to account for 2/3rd of the global pharmaceutical market value. The Indian Pharmaceutical Industry is at an inflection point like the Indian IT industry which blossomed in the 1990s-2000s. The pharma sector has the potential to grow to a value of USD 120-130 Bn by 2030 from its current value of USD 43 Billion. The key drivers in achieving this growth will be building a strong innovation-based pipeline with potential breakthroughs in next-generation products (non-generics) coupled with a robust growth in international markets such as USA and Europe and large, under-penetrated markets such as China and Japan.

How can simplified regulatory process expedite growth of the generic and biosimilar industry?

For a sustained growth of generic and biosimilar industry, it is a pre-requisite to have a regulation and policy framework that enables speedy and cost effective access to market, fair pricing and protection of patient safety. In this context, the focus should be on - Simplification of guidelines in line with advancements in science to allow for speedy and cost-efficient access of Biosimilars as well as complex Generics. Convergence of approval pathway across markets is another critical aspect while easing of regulatory approvals will help move up towards innovation, especially in India.

Regulators across major markets should align to formulate streamline standards for the approval of generic and biosimilar medicines. We need a regulatory framework which allows global development of biosimilars and avoids duplication of studies. The UK MHRA's recent guidelines for biosimilars, in this context, is a milestone and a logical next step in the biosimilar medicines' regulatory framework. We hope that the same updated scientific and regulatory approach will be included in the [WHO](#) guidelines on evaluation of similar biotherapeutic products (SBP), currently under revision. We also need a global implementation roadmap to progress this science-based efficiency in order to accelerate equitable

At IGBA, the aim is to promote regulatory cooperation to enable reliance on evaluation and mutual recognition agreements that will not only help industry but also enable speedy access of medicines for patients. IGBA has been supporting its members and taking educational efforts on biosimilars. In the first week of November 2021, we are launching our second Global Biosimilars Week, a social media campaign where we will engage directly with stakeholders.

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