

## IGBA focusing to promote enabling regulatory environment for generic and biosimilar industry

*Yash Ved, Mumbai, Friday, August 6, 2021, 08:00 Hrs [IST]*

The International Generic and Biosimilar Medicines Association (IGBA) is focusing to promote an enabling regulatory environment for the generic and biosimilar industry which can be fostered by increased collaboration and simplified and efficient regulatory procedures, stated Sudarshan Jain, chair, IGBA and secretary general, Indian Pharmaceutical Alliance (IP Alliance).

Jain added that there is a need for regulation and policy framework which allows global development of biosimilars and avoid duplication of studies, that enables speedy and cost-effective access to market, fair pricing and protection of patient safety through simplified guidelines and approval process.

"The UK MHRA's recent guidelines for biosimilars is a more streamlined 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," added Jain.

IGBA aims to promote regulatory cooperation and efficiency, information-sharing, confidence building, convergence, and harmonization of standards for the approval of generic, value added, and biosimilar medicines. This will ultimately enable reliance and mutual recognition agreements.

IGBA's Vision Report has highlighted industry's contribution and laid down the steps to be taken going forward in order to sustain growth. It is aimed at providing a roadway to the industry for navigating future opportunities and challenges, during Covid-19 and beyond.

It presents the industry stakeholders with strong insights that will be fundamental for the industry's growth and support them in improving patient outcomes across geographies. The findings and recommendations are based on concrete discussions with industry leaders and their outlook towards the future of the industry.

IGBA strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. IGBA provides a common platform for exchange, support and cooperation, and deliberation between our regional and local member associations.

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