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IGBA Sets Out Industry Vision To 2030

Comprehensive Whitepaper Highlights Headwinds And Opportunities

by David Wallace

A whitepaper setting out a comprehensive vision for the off-patent industry to 2030 has been launched by the IGBA. Highlighting the industry's current contribution to healthcare, it also sets out a path ahead for the generics and biosimilars sector, pointing out headwinds as well as opportunities.

The International Generic and Biosimilar Medicines Association has set out its vision for the off-patent industry over the next ten years in a comprehensive whitepaper that highlights the key role played by generics and biosimilars in healthcare and explains the latest industry trends, as well as looking ahead to identify significant headwinds and tailwinds for the sector from now until 2030.

Under the title of "A Vision for the Global Generic and Biosimilar Medicines Industry," the *whitepaper* seeks to underline "the strong contribution of this pharmaceutical sector to global health outcomes and economies, the opportunities, challenges and disruptions for the industry, its 2030 vision as well as actions needed to achieve this vision," the IGBA said.

"The whitepaper is the result of extensive input from 14 generic and biosimilar medicines companies and IGBA member associations," the organization explained, pointing to "input from Alvotech, Apotex, Aurobindo Pharma, Celltrion, Cimed, Dr Reddy's Laboratories, Hikma, Insud Pharma, Intas Pharmaceuticals, Polpharma, Sandoz, Sawai Pharmaceutical, Sun Pharma and Teva."

"This whitepaper is mainly meant to be a reference for industry, which never ceases to evolve, but also for all stakeholders, who are an important part of the increasingly complex healthcare ecosystems," the IGBA said, adding that it was aiming to support "global recovery efforts to rethink, build and secure a future which addresses the inequalities in healthcare, while

supporting sustainability."

Industry Is At A Crossroads

As well as acknowledging the current context of the COVID-19 pandemic, the whitepaper emphasizes the off-patent sector's key contribution to the healthcare sector worldwide, representing "60%-80% of all medicine volume sales in key markets globally, with penetrations in many countries at even higher levels," as well as broadening patient access to medicine via "industry's ability to maintain cost-effective prices."

Describing the off-patent sector as "a growing industry with strong fundamentals, but facing several discontinuities," the document notes that the generics industry is worth around $390bn, "making it nearly a third of the $1.20trn worldwide pharmaceutical market."

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"It is noticeable, however, that the industry's growth trajectory has slowed and it seems the industry is now at a crossroads," the whitepaper states. "Sustained and substantial price erosion – often triggered by consolidated buying power and shifts in regulatory policies – is putting strong pressure on margins and sustainability of the industry in many markets."

"Competition in the industry also continues to rise, with boundaries between various categories of unprotected products and the companies active in the field becoming more and more dispersed. Global supply chains are coming under threat driven by disruptions due to the pandemic and protective policies being adopted in several geographies."

"At the same time, sustained pipeline of innovation opportunities, uptick in adoption of biosimilars and digitally supported expansion of access/offerings suggest ample opportunities for the industry to continue to grow and drive global health and economic outcomes," the whitepaper observes.

"Given the opposing forces," the IGBA cautions, "concerted action from the industry and supporting stakeholders will be critical to help the industry to maintain its contributions to the healthcare system and economies globally."

Tailwinds And Headwinds Identified

Key tailwinds for industry identified by the whitepaper include "underlying socio-economic fundamentals" that will generate sustained growth in demand for healthcare, while the IGBA also sees a "continued trajectory in the innovation pipeline" in terms of significant loss-of-exclusivity opportunities.

At the same time, the "biosimilars opportunity is finally coming to fruition," the IGBA says. Meanwhile, digital technologies will be "a key enabler to help industry deepen reach and further strengthen operations," the whitepaper suggests, urging "continuous innovation to sustain value creation opportunities."

Moreover, it points out, "beyond the traditional definitions of generics and biosimilars offerings, the industry is increasingly finding relevance of its core capabilities across a number of adjacent opportunities," including consumer health, digital therapeutics and contract development and manufacturing.

"While each of these areas require specific capability augmentation for success, several of these present interesting opportunities to enhance access for patients," the whitepaper points out.

> *"The limited number of supply sources, particularly for active pharmaceutical ingredients/key starting materials has emerged as a risk for the industry's supply chain."*

On the other hand, several significant headwinds are identified by the document. These include "sustained price pressures" stemming from continuing price erosion, as well as regulatory hurdles for generics and biosimilars that are slowing down access.

The whitepaper also points to the vulnerability of off-patent industry supply chains that has been highlighted by the pandemic, with pressure continuing to be felt. (Also see "*Pandemic Perspectives: Cracks In Global Supply Chain Lead To Localization Trend*" - Generics Bulletin, 15 Mar, 2021.)

"The limited number of supply sources, particularly for active pharmaceutical ingredients/key starting materials has emerged as a risk for the industry's supply chain, and the pandemic has put additional spotlight on this topic given the short supply of COVID-related products which were prioritized for local requirement," the document states. "In response, many governments

have strengthened their efforts to build local manufacturing competency and on-/near-shore supply for a variety of medicines.

“While these moves have the potential to accelerate localized production in a number of markets, such policies combined with already existing push for local manufacturing across several markets face the risk of spilling over into protectionist trends, which can have significant impact on overall product access and economic viability.”

Other industry headwinds cited by the whitepaper include “new modalities and technologies in the innovation pipeline increasing the risk profile of investments,” with the shift away from oral solid products to more complex small-molecule opportunities and biosimilars representing “a significant scale-up in capabilities and investments for the industry, given the complex nature of these developments and more stringent clinical trials requirements.”

On emerging markets, the whitepaper says that while these “represent a traditional growth opportunity and a key playing ground for improved access to medicines, they also present severe competitive and structural market challenges for generics and biosimilars companies.”

Citing “intense local competition” that makes it challenging to build a presence in emerging markets, the paper says that volatile economies and currencies along with increasing price controls are combining with local manufacturing requirements and non-harmonized regulatory approaches to make it difficult for companies to effectively focus on these markets. And “moves around partnerships or acquisitions in the past have also seen mixed successes limited overall growth performance for players in these markets.”

Finally, the report identifies as a major headwind for industry a “gradual shift in commercial models and channel dynamics,” with changing procurement processes and channel disruption meaning that “generics companies will need to develop effective trade management skills and portfolio strategies that enable attractive value bundles for new customers and partners, while at the same time thinking about innovations in commercial models to de-risk against some of these emerging competitive moves.”

Four Pillars And Seven Key Actions Support Strategy To 2030

Setting out four pillars that it said would support its vision to 2030, the IGBA said the off-patent industry must become “an industry embedded in an end-to-end healthcare ecosystem, benefiting patients and institutions globally by providing access to cost-effective and high-quality modern medicines and healthcare solutions, while enabling sustainable economic contributions for all stakeholders.”

The four pillars of the organization’s strategy are for the industry to:

- Expand patient access to high-quality and affordable medicines across traditional and emerging modalities;
- Step up to become a confident, well-respected strategic partner to institutions globally;
- Broaden role to help form end-to-end healthcare ecosystems along the entire continuum of care; and
- Enable sustained economic contributions for economies, healthcare systems and all stakeholders.

To accomplish these objectives, the IGBA identified seven key actions necessary for industry. These are to:

- Secure impeccable quality and agility in the supply chain while strengthening the cost position even further;
- Balance portfolio choices across technology/complexity with a high focus on driving R&D efficiency and capability;
- Re-imagine commercial models to be ready for disruption;
- Embed digital and analytics as a core capability along the entire value chain;
- Scale "step-outs" – presences in adjacent segments – beyond the core with a purposeful reallocation of resources;
- Drive systematic M&A and partnerships to support aspirations; and
- Embed agility and new capabilities, while welcoming post-pandemic working models.

Support from other industry stakeholders such as regulators, government and associations would be essential to achieve these goals, the IGBA said.

"To help industry achieve its 2030 vision," summarized IGBA secretary general Suzette Kox, "we need efficient, supportive and consistent regulatory frameworks, equitable patent and litigation systems fostering innovation while enabling access, open international borders and secure trade flows as well as encouragement for investment in new technology and innovation."

Concluding that "the generic and biosimilar medicines industry has played and continues to play

a crucial role in the ongoing COVID-19 public health crisis and in the overall healthcare ecosystems," IGBA chair Sudarshan Jain said "the IGBA 2030 vision reflects our efforts to ensure that this industry can continue to contribute deeply to enhancing reach and access to high quality and cost-effective therapies globally. They are needed more than ever."