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India Hopes to Ease Regulatory Pathways for Biosimilars

(Source: An article by Vibha Ravi for Scrip Citeline)

While India has played a critical role in lowering cost of medicines across the world with generics, it is now preparing to move on to the next stage of development which includes increased focus on biosimilars. This will require an easing of clinical development norms and a new approach to regulatory procedures, and the country is ready to take on the challenge.

From a waiver of Phase III trials for biosimilars to simplification of regulatory processes for cell and gene therapy development, executives from leading Indian firms have recently called for changes.

Concurrently, officials noted that venture capital (VC) funds need to play a bigger role to encourage novel modalities, just as they have done in China. Likewise, companies should direct discovery efforts to disease areas like cancer and rare diseases.

During a panel discussion at the Indian Pharmaceutical Alliance (IPA)'s 9th global pharmaceutical quality summit, Ravi Shankara, senior general manager, biopharma, at Sun Pharma said "each biosimilar will hit the Indian market at the right time" post patent expiry.

While Shankara didn't specify which companies intend to launch the biosimilars and when, he said companies are working very aggressively to develop biosimilars that would be available at a fraction of the cost of biologics to Indian patients. Launch of medicines such as *Keytruda (pemrolizumab)* would be a significant event for a country with an increasing cancer burden.

With global sales of US$6.9 billion in the first quarter of 2024, Merck & Co., Inc.'s *Keytruda* retained its title as the best-selling drug, a position it has held every quarter since the start of 2023. As of March 2024, it was approved for 27 indications overall in the European Union. In India, it is approved for treatment of triple-negative breast cancer (TNBC) and renal cell carcinoma (RCC) in adults, among at least 14 indications across different kinds of tumors. It is currently imported for use in the country.

Terming regulatory expectations a "sensitive topic", Ipca's senior vice president and head of biosimilars, Sanjeev Gupta

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In Brief...

- **Pfizer Inc.** has announced that it has selected a once-daily, modified-release formulation of its oral glucagon-like peptide-1 (GLP-1) receptor agonist *danuglipron* to advance in development. The decision is based on the results of an ongoing pharmacokinetic and safety study evaluating immediate- and modified-release formulations of *danuglipron* in healthy adults. *Danuglipron* is the most advanced asset in Pfizer's obesity pipeline. Separately, Pfizer's chief scientific officer, *Mikael Dolsten, M.D., Ph.D.* is leaving the company after 15 years. Pfizer is in the process of finding his replacement.
- **Viatris** has completed the divestiture of its over-the-counter business to **Cooper Consumer Health**, a European over-the-counter drug manufacturer and distributor. The completion of the OTC divestiture, the largest of the divestitures that the company previously announced, is a major milestone in the execution of the company's strategic plan to considerably simplify the organization in order to increase focus on areas with the greatest potential to accelerate growth, patient impact and shareholder value, Viatris said.

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Alta Pharmaceuticals

Alta Pharmaceuticals Ltd. Joins IFPW as the Newest Wholesale Member

IFPW is pleased to announce that Alta Pharmaceuticals Ltd. has joined IFPW as its newest wholesale member organization. Alta Pharmaceuticals is a modern company with its eye on the future. Alta focuses on sustainable upward development in the pharmaceutical sector and has extensive knowledge and experience in wholesale of pharmaceutical products, medical devices, food supplements and cosmetics. It is one of the leading distributors of medical products to the wholesale and retail market in Bulgaria.

Alta Pharmaceuticals Ltd. was founded in 2007 with business activities related to the import of medicinal products, medical devices, food supplements, medical cosmetics, as well as their distribution to pharmacies and wholesalers of medicines. The company also performs activities related to the analysis of the medicinal products' market and the pharmaceutical sector. Alta is committed to excellence and strives to provide the highest quality products and services to the Bulgarian market. In addition to services related to classic distribution, Alta Pharmaceuticals also offers services related to pre-distribution - (3PL) according to the requirements of the Good Distribution

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India *(cont'd.)*...

said the complexities of molecule development along with complicated approval procedures cause delays in new drugs reaching patients.

"We have to deal with two bodies – the RCGM [Review Committee on Genetic Manipulation] for preclinical and non-clinical trials and the DCGI [Drugs Controller General of India] for Phase I to III trials," he said.

He also observed that Phase III trials are no longer required for biosimilars in a few countries and so should the case be in India. Globally, the Biosimilars Forum, a trade association of biosimilar sponsors, wants the U.S. Food & Drug Administration (FDA) to drop blanket comparative efficacy study and clinical pharmacokinetic study requirements and has asked for a risk-based approach to mandating immunogenicity studies.

Similarly, the European Medicines Agency is considering a more "tailored" approach to the assessment of new biosimilar medicines, with a focus on whether to waive the requirement for comparative efficacy studies when the biosimilar shows a high degree of similarity to the reference drug.

Reiterating a long-standing demand of the industry, Gupta inquired if the Indian regulator could harmonize dossiers required for biosimilars approvals with those required by other agencies in the U.S., United Kingdom, Japan and Europe to cut the submission burden on companies.

Meanwhile, Dhananjay Patankar, former vice president, pharmaceutical and biologics at Syngene International, a Biocon subsidiary, asked for greater regulatory easing for new molecules.

Patankar also urged regulators to encourage use of contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) for research on novel molecules.

In 2023, globally six of the top ten new biologics were from new modalities like RNA, and cell and gene therapies, indicating the need for India to follow suit. Also, upstream and downstream processes for manufacture of biologics need to be scaled up and integrated for a thriving industry.

Pointing out that the use of artificial intelligence (AI) also necessitates rapid changes and responses, Ratnesh Jain, managing director, Mumbai Biocluster and associate professor at the Institute of Chemical Technology (ICT) said "Just as the US changes rapidly, we also need to amplify efforts"

If Indian pharma companies wish to progress the discovery of novel molecules, they need to incorporate drastic changes and transform every five to ten years on the lines of technology companies, the panelists felt.

Alta Pharmaceuticals *(cont'd.)*...

Practice. Since 2015 Alta Pharmaceuticals is a shareholder in the leading Armenian pharmaceutical company – Alfa Pharma. Since 2021 the company operates in Northern Macedonia, Albania and Kosovo. It also has a successful strategic partnership with SUBRA®pharmacy chain.

"As members of IFPW, Alta is particularly enthusiastic about the prospect of engaging with fellow members through various events, seminars, and networking opportunities. The exchange of ideas and experiences with other esteemed members will undoubtedly enrich our perspective and drive our continuous improvement. Furthermore, we are eager to contribute to the vibrant business community that IFPW fosters, sharing our knowledge and collaborating on initiatives that promote economic growth and development. We believe that together, we can achieve remarkable success and foster a strong, collaborative environment for all members," stated Alta's CEO, Todor Dotchev.

IFPW warmly welcomes Alta Pharmaceuticals Ltd. to IFPW, and looks forward to its insights and perspectives on the Eastern European pharmaceutical market.

In Brief (cont.)

- Pharmaceutical companies aren't taking full advantage of the captive audiences that can be found on various social media platforms, according to a survey of healthcare providers. The providers surveyed by marketing agency **MedFluencers**, represent more than a dozen specialties. Nearly 90% said they believe the pharma industry is underutilizing social media as a method of communication. Survey respondents suggested that patients may be getting a significant portion of their health information from online content, as 85% of the doctors surveyed said they'd had patients mention social media posts during their appointments.
- **Rite Aid** has reportedly been cleared to exit bankruptcy after winning court approval for its restructuring plan that will prevent the chain from liquidation by handing control of the business to key creditors. The restructuring plan cuts approximately US$2 billion in debt and gives Rite Aid access to about US$2.5 billion in exit financing to fund a turnaround plan which has been named *"Rite Aid 2.0"*.
- According to sources within **Bayer**, the company will continue to cut managerial positions in Germany, Japan, the United Kingdom, Belgium and the Netherlands through this year as part of the Bayer's reorganization. The company has already cut approximately 40% of its managerial positions in the U.S. and has also implemented downsizing measures in Canada, Mexico, Italy, Australia and the Nordic countries.
- Japanese health minister *Keizo Takemi* requested executives from 13 generic makers to consolidate their products to revamp the industry, proposing approximately five companies as the target number of manufacturers handling each active pharmaceutical ingredient (API). He stressed the need to restructure the sector into one that limits the number of entrants so as to leverage "economies of scale", noting that five companies per API could be the rough consolidation target. Separately, Indian drugmaker **Biocon** will make a full-scale entry into the Japanese market with its generic API business. The company currently handles four APIs in Japan through traders but will set up a local office during the current fiscal year and increase the number to nearly 20 by FY2025.
- **GSK** has moved its corporate headquarters from the West London suburbs to Central London. Approximately 3,000 staff members will work through a hybrid working model from the company's new location on Oxford Street. The move follows a "comprehensive search" of potential new headquarters sites across London.

(Sources: Company Press Releases, Drug Store News, FiercePharma, JIHO, and Scrip Intelligence)