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NEWS LETTER
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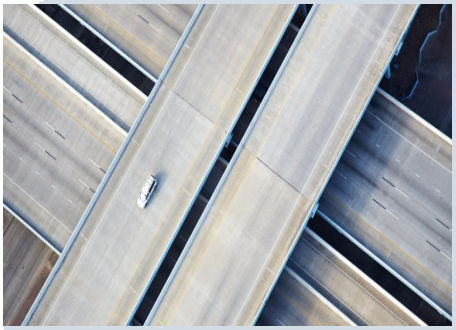
No Turning Back on The Biotech Super Highway



When the country plays host to two global conclaves focussed on bio-pharmaceuticals and life sciences, barely three months apart, it illustrates the opportunities up ahead for both seasoned players and fledgeling ventures. While companies proceed full steam ahead on the biotech highway, there remains much ground to cover, say industry-watchers, in terms of early funding for start-ups or regulatory clarity for the large companies.

Biotech ventures are difficult to establish as there are inherent entry barriers — being capital intensive, needing wet labs, long gestation periods and the absence of early funding, says Jitendra Kumar, Managing Director, BIRAC (Biotechnology Industry Research Assistance Council). And yet, India has 6,755 biotech start-ups, including the 1,391 start-ups added in 2022, says Kumar. This reflects a conducive ecosystem, he says, citing the India BioEconomy Report 2023, that covers a swathe of products and services across bio-industrial, bio-pharma, bio-agri and bio-IT Research segments.

On track

India's bio-economy at $137.2 billion (2022) reflects a healthy growth, says Kumar, adding that the country would get to the $150 billion mark "ahead of the projected 2025" timeline. With a market size of $49.79 billion, bio-pharma accounted for the second largest chunk (36 per cent) of the bio-economy, after the bio-industrial segment (at $58.97 billion or 43 per cent). Also adding to the bio-pharma segment are Covid-linked products and services accounting for $7.66 billion (6 per cent). The IBER report was put together by BIRAC, with the Association of Biotechnology Led Enterprises (ABLE) and was unveiled at the Global Bio-India 2023 conclave, organised by the Department of Biotechnology and its public sector unit BIRAC, in December 2023. February 2024 will witness BioAsia, an annual event from the Telangana government. Some industry players are not comfortable with the IBER's expanded definition of biotech products, but there is consensus that the segment is attracting much domestic and international interest.

Balanced growth

Pushing for balanced growth, Kumar says, be it the North-East, coastal regions, the Himalayas or the Southern States — there are bio-resources everywhere that can be tapped. Therefore, as Bengaluru and Hyderabad taps into bio-pharma, others can look at medicinal plants, etc. But States will have to balance growth with the ecological damage it can cause if left unfettered, he pointed out. Citing the example of saffron, Kumar contends that the opportunity was in developing the molecule in saffron with its medicinal properties and making it synthetically without destroying the ecosystem. Similarly with menthol, he says, adding the "cross-talk" between ecosystems would help discovery at one end and scale-up elsewhere, if required. Companies find scaling -up difficult and would need the help of large pharma firms, for example, to invest or handhold them into taking their products to a larger market, he explains. The Global Bio-India meet saw Japanese drugmaker Takeda sign a three-year agreement with BIRAC to extend its advisory and mentoring support to innovators and entrepreneurs, assisting them from ideation to market deployment of healthcare solutions.

Bio-therapeutics hold out huge opportunities, and Indian drugmakers can help make these otherwise expensive therapies more affordable, says Sudarshan Jain, with the Indian Pharmaceutical Alliance. About $170 billion worth of biologic products are set to go off-patent (2030), opening up an opportunity. And several companies including Reliance, Biocon, Serum Institute, Syngene, Dr Reddy's, Emcure, Intas, are already in the fray, he said, naming a few. Besides an upgraded regulatory framework, Jain said, companies will need to work on product development and market delivery for these specialised products.

Don't look back

Operating in a niche segment, VAV Life Sciences makes lipid nanoparticles (LNP), for example. The LNP technology is considered a breakthrough in vaccine-delivery systems, enabling the development of mRNA-based Covid-19 vaccines at a "blistering pace," its Managing Director Arun Kedia had said when they were catapulted into the spotlight for their work with global mRNA vaccine makers. Urging authorities to look at future-oriented targeted therapies and new drug delivery systems, Kedia says, there are huge breakthroughs to be made in cancer treatment, curing diabetes, targeting multiple sclerosis, thalassemia, lifestyle diseases, etc. But breakthroughs will not be made if one "looks back to make projections," he says, calling for support to companies working in futuristic technologies and therapies. (Source: Business Line)

Bayer Ordered To Pay $2.25 Billion in Latest Roundup Trial

Bayer was ordered on Friday to pay $2.25 billion to a Pennsylvania man who said he developed cancer from exposure to the company's Roundup weedkiller, the man's attorneys said. A jury in the Philadelphia Court of Common Pleas found that John McKivision's non-Hodgkins lymphoma was the result of using Roundup for yard work at his house for a period of several years. The verdict includes $250 million in compensatory damages and $2 billion in punitive damages.

"The jury's punitive damages award sends a clear message that this multi-national corporation needs top to bottom change," Tom Kline and Jason Itkin, McKivision's attorneys, said in a joint statement. Bayer in a statement said it disagreed "with the jury's adverse verdict that conflicts with the overwhelming weight of scientific evidence and worldwide regulatory and scientific assessments, and believe that we have strong arguments on appeal to get this verdict overturned and the unconstitutionally excessive damage award eliminated or reduced."

Bayer added that some previous damages awards had been reduced by more than 90 percent. The verdict comes after five other recent wins late last year by plaintiffs suing Bayer over Roundup, though the company won the most recent such trial in December, as well as a string of earlier trials. In all, it has won 10 of the last 16 Roundup trials.

Around 165,000 claims have been made in the U.S. against the company for personal injuries allegedly caused by Roundup, which Bayer acquired as part of its $63 billion purchase of U.S. agrochemical company Monsanto in 2018. Most plaintiffs, like McKivision, allege that the product caused them to develop non-Hodgkins lymphoma. Bayer has said that decades of studies have shown Roundup and its active ingredient, glyphosate, are safe for human use.

Roundup is among the most widely used weedkillers in the United States, though the company phased out its sales for home use last year. In 2020, Bayer settled most of the then-pending Roundup cases for up to $9.6 billion but failed to get a settlement covering future cases. More than 50,000 claims remain pending. Last year's string of losses produced verdicts against the company totaling more than $2 billion. Bayer is appealing those verdicts, which include large punitive damages awards that are likely to be reduced because they exceed U.S. Supreme Court guidance. The losses had led some investors to question Bayer's legal strategy in defending the Roundup cases. The company said in November that it would continue fighting the cases in court and had "no appetite to write humongous checks" to settle them. The company had even considered a plan to break off its crop science business, in part due to concerns about Roundup liability, though it said earlier this month that it was putting those plans aside for now and focusing on internal reorganization. (Source: Reuters)

Pharmexcil to Promote Exports to Latin American Countries

The Pharmaceuticals Export Promotion Council (Pharmexcil), with the support of the Union Ministry of Commerce and Industry, will be organising the iPHEX-LATAM from Feb 17-28. As many as 105 industry leaders representing 82 leading pharmaceutical companies in the Latin American (LATAM) region, specifically Guatemala, Colombia, and Chile, will attend the meet.

“This is the first such big business delegation in the history of Pharmexcil in which leading American and Indian pharma companies will explore trade and business avenues,“ R Uday Bhaskar, Director-General, Pharmexcil, said. The LATAM region is an emerging export market for Indian pharmaceuticals, currently constituting 6.78 per cent of overall pharma exports ($1.72 billion) in the last fiscal year.

IPHEX-LATAM has invited health ministry officials, drug regulatory agencies, and government procurement agencies of the respective countries to foster a deeper understanding and collaboration between Indian pharmaceutical exporters and the key stakeholders in the LATAM region. There are 33 countries in Latin America, including Mexico, Guatemala, Honduras, Nicaragua, El Salvador, Costa Rica, Panama, Belize, Haiti, Cuba, Dominican Republic, Jamaica, Trinidad & Tobago, Barbados, St Lucia, Grenada, St Vincent & Grenadines, and Antigua & Barbuda, among others. “The significant potential of this region aligns with our goal to achieve the ambitious target of $28.141 billion in pharma exports for fiscal year 2024,“ Bhaskar said.

A series of B2B meetings scheduled during the event will serve as a platform for Indian pharmaceutical companies to engage with their counterparts in Guatemala, Colombia, and Chile, paving the way for concrete partnerships and collaborations, according to Bhaskar. “This initiative is not just about business transactions; it’s about building lasting bilateral ties. By engaging with health ministries, regulatory agencies, and procurement bodies, we aim to create a conducive environment for the sustained growth of Indian pharmaceutical exports in the LATAM region,” Bhaskar said, adding that Pharmexcil’s proactive approach is aligned with India’s vision to be a key player in the global pharmaceutical arena. (Source: Business Line)

India's Pharma Sector Imports Reduced Thanks To The PLI Scheme

A significant reduction in the import of raw materials in the pharmaceutical sector is one of the most notable achievements under the Production Linked Incentive (PLI) scheme, the government said in a document, titled Indian Economy: A Review, written by V. Anantha Nageswaran, Chief Economic Adviser, Ministry of Finance.

The 74-page document presented was a departure from the tradition of releasing the Economic Survey, which may now be released before the full Budget after general elections. The review outlined the nation's economic trajectory over the past decade and forecasts for the future.

The document outlined achievements in healthcare and the 'Make in India' initiative, particularly the success of the PLI scheme in spurring domestic manufacturing and exports across various sectors.

With an investment outlay of Rs 1.97 lakh crore, the PLI scheme has spurred significant production, generating over Rs 8.7 lakh crore in sales and creating employment opportunities for more than 700,000 individuals, Nageswaran said in the document. "The PLI scheme witnessed exports exceeding Rs 3.4 lakh crore, with significant contributions from sectors such as large-scale electronics manufacturing, pharmaceuticals, food processing, and telecom and networking products," he said.

The review also highlighted structural reforms and digital infrastructure development as key drivers of economic growth, citing examples such as the Aarogya Setu and CoWin apps that aided pandemic response efforts and boosted consumption.

Simultaneously, the healthcare sector has also undergone a digital revolution, driven by initiatives like the Aarogya Setu and CoWin apps. These digital platforms played a pivotal role in combating the pandemic, enabling efficient tracking of virus spread and facilitating mass vaccination drives, Nageswaran said.

"Digitalisation directly helped to increase private consumption, both during the pre and post-pandemic phases," he said, adding that the adoption of digital solutions has also revolutionised healthcare delivery, with virtual consultations, digital payments, and e-grocery shopping witnessing a significant uptick, especially during mobility restrictions.

Moreover, government healthcare initiatives such as Ayushman Bharat and e-Sanjeevani OPD services have made healthcare more accessible and affordable to millions. Nageswaran highlighted, "With over 30.3 crore Ayushman Bharat cards issued and 17.4 crore patients availing of e-Sanjeevani OPD services, the impact of these initiatives on public health outcomes is undeniable." Additionally, the establishment of 10,000 Janaushadhi Kendras selling medicines at reduced rates has further enhanced access to affordable healthcare, he said.

In the document, Nageswaran also emphasised that the Indian economy is set to achieve growth rates of 7% or higher for FY24 and potentially FY25, marking a significant milestone post-pandemic. "It now appears very likely that the Indian economy will achieve a growth rate at or above 7% for FY24, and some predict it will achieve another year of 7% real growth in FY25 as well. If the prognosis for FY25 turns out to be right, that will mark the fourth year post-pandemic that the Indian economy will have grown at or over 7%," said Nageswaran. (Source: Business Today)

France's Sanofi to Buy U.S. Drugs Project INBRX-101 For About $2.2 Bln

French healthcare company Sanofi has agreed to buy the drug development project INBRX-101 from its parent company Inhibrx Inc around $2.2 billion, the companies said on Tuesday.

As part of this deal, Inhibrx shareholders will get $30 per share in cash, one contingent value right (CVR) equal to $5 and 0.25 shares in New Inhibrx, a new publicly traded company.

Following the closing of the deal, New Inhibrx will continue to operate under the "Inhibrx" name and will be led by Mark Lappe as Chairman and CEO.

Sanofi will assume and retire Inhibrx's outstanding third-party debts and fund New Inhibrx with $200 million in cash. Sanofi will also retain an equity interest in New Inhibrx of 8%.

The global pharmaceuticals sector has seen a wave of takeover deals in recent months. Last October, Bristol-Myers Squibb said it will acquire cancer drugmaker Mirati Therapeutics for up to $5.8 billion, while in March 2023 Sanofi bought Provention Bio Inc for $2.9 billion. (Source: Reuters)

India's Drug Regulator Goes Paperless, Will Only Accept Soft Copies for Approvals and Licences from February 1

Only emails, pen drives or Google Drive — the country's apex drug regulatory agency will stop accepting paper-based documentation for granting approvals and manufacturing licences for drugs, devices and vaccines, News18 has learnt. To promote 'Digital India', the Central Drugs Standard Control Organisation (CDSCO) has asked its offices across India to accept "only soft copies". The new rule will come into effect from February 1. The regulatory agency, on January 25, "issued instructions requesting all zones, sub-zones, port offices, laboratories to switch over from physical files to e-file for processing of all offline applications for the smooth and efficient functioning of CDSCO's e-office domain".

According to the latest notice, accessed by News18, "all applicants or stakeholders are requested to submit their applications, bulky dossiers, documents, query replies etc...in the form of soft copy..."Many government offices at both the state and central levels are transitioning to digital processes, aiming to enhance transparency in their day-to-day operations. This shift comes in response to challenges such as misplaced files and the creation of duplicate documents for the same issues. For example, the Comptroller and Auditor General of India (CAG) declared on April 1 last year that all audit operations throughout India would transition to digital platforms. It eliminated the need for physical files across its 130 offices. This development ensured seamless record-keeping without the burden of managing vast quantities of physical documents while maintaining transparency and records for eternity.

ALL FUNCTIONS SHIFTED TO DIGITAL APPLICATIONS

The notice explains that the rule applies to stakeholders submitting applications or documents related to WHO Good Manufacturing Practices (WHO-GMP), private testing labs, manufacturing licenses, blood banks, vaccines, DNA forms, veterinary products and other miscellaneous applications – covering the majority of functions of the regulator. The order clarifies that new submissions should be via pen drive or Google Drive. "The bulky dossiers, documents, query replies etc. may also be forwarded through e-mail in the scanned copy, preferably less than 20 MB in pdf format," it said. The order said: "No hardcopy of the application will be accepted by this office from 01 February 2024." "All manufacturers or stakeholders may ensure strict application submission in electronic mode, without which their applications cannot be accepted or processed further," said the notice while adding that "co-operation in the matter in the implementation of e-office to promote digital India is highly solicited." (Source: News 18)

Sun Pharma-Bayer to Market Second Brand of Finerenone in India

Sun Pharmaceutical Industries and Bayer have signed an agreement to market and distribute a second brand of Finerenone in India. The patented drug is used to treat chronic kidney disease associated with Type-2 diabetes mellitus.

Bayer has granted Sun Pharma non-exclusive rights to market and distribute this brand of Finerenone under the brand name Lyvelsa, in India. Finerenone was first launched by Bayer under the brand name Kerendia (2022).

Kirti Ganorkar, Sun Pharma's Chief Executive (India Business), said, the collaboration "would provide patients access to a new treatment, which slows down the progression of chronic kidney disease and reduces the risk of kidney failure associated with Type-2 diabetes." Shweta Rai, Country Division Head, Bayer Pharmaceuticals (South Asia) pointed out that India has a high incidence of diabetes and associated renal and cardiac conditions. In a joint statement.

The companies cited a study by the Indian Chronic Kidney Disease (ICKD) that identified diabetes as the leading cause of chronic kidney disease and end-stage kidney disease in India. Over 40 percent of all patients with diabetes will develop chronic kidney disease, it said. Over 100 million people have diabetes in India, home to the second largest affected population after China.

Despite available treatment options, many patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) progress to kidney failure and premature death, the note said. Finerenone is different from the existing treatments for CKD in T2D patients, in that it acts "by selectively blocking mineralocorticoid receptor (MR) overactivation, which is thought to contribute to CKD progression and cardiovascular damage. "

The pivotal Phase III clinical trial programme of Finerenone involving more than 13000 patients globally was undertaken to investigate the safety and efficacy of kidney and cardiovascular outcomes in patients with chronic kidney disease associated with Type 2 diabetes. Finerenone was approved by the US Food and Drug Administration in July 2021; it received marketing authorization from the European Commission in February 2022, and was subsequently approved in India by the regulators in April 2022, the note said. (Source: Business Line)