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"AI, one of the most promising technologies, can revolutionise quality control in pharma manufacturing and supply chain"

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Germany headquartered life sciences company Bayer operates as Bayer Zydus Pharma, a joint venture between Bayer and Zydus Cadila in India. The focus of the pharmaceuticals division in India is on prescription products, especially for cardiology and women's healthcare and on specialty therapeutics in the areas of oncology, haematology and ophthalmology. The division also comprises the radiology business, which markets diagnostic imaging equipment together with the necessary contrast agents. As the company globally invests 18 per cent of its net sales back into R&D, Bayer views India as an important location to support drug development for its global pipeline. In an interaction with BioSpectrum, Manoj Saxena, Country Division Head, South Asia for Pharmaceuticals, Managing Director, Bayer Zydus Pharma sheds more light on the company's plans to launch new drugs in India.

How big is the Indian market for Bayer?

The growing incidence of non-communicable diseases (NCDs) is a concern for India. There is a need to provide patients with NCDs access to medications and cutting-edge healthcare solutions and this is where Bayer aims to contribute. India is a strategic market for Bayer Pharma and we have been introducing new drugs in the country at the same time as in European countries and sooner than in other parts of the world. Against this background, last year, we launched Kerendia to prevent progression of chronic kidney disease in people with diabetes (CKD). We also launched Verquvo to fill a gap in the present treatment for worsening heart failure. Another case in point is the launch of Nubeqa, an innovative drug for prostate cancer, the fifth-leading cause of mortality associated with cancer in men.

Which new products are in the pipeline for the Indian market?

In the women's healthcare segment, we plan to introduce a hormonal pill towards the end of this year. We will continue to strengthen our cardiovascular and women's health portfolio with our late-stage pipeline assets such as asundexian and elinzanetant. We are also committed to increase access to our already-launched products in India. To that end, Bayer is

actively leveraging technology and digitalisation to connect rural communities with broader health networks, to improve health access and literacy related to significant diseases. We apply tiered pricing in India to make our products more accessible.

Our Center of Excellence for Pharmaceuticals in Hyderabad caters to the growing global demand for Data Sciences and Analysis (DS&A) and Oncology Data Analytics (ODA). This enables Bayer Pharmaceuticals to focus not only on excellence in the execution of clinical trial deliverables but also to contribute to industry-leading solutions in analytical trends and methodologies. In India, the company has 17 projects in ongoing Phase II, III and IV clinical trials across a range of potential therapeutic modalities and indications, with a focus on oncology, cardiovascular, diabetes, ophthalmology, and women's health. Our vision is to ensure that the Indian population is better represented in innovation. The Hyderabad centre is crucial for creating job opportunities in the country, especially given the talent pool in data and analytics. Bayer has also collaborated with several technology partners, like TCS, Accenture, Wipro, etc. to support our efforts in the areas of pharmacovigilance, clinical trials and drug development.

What are the current regulatory challenges in India?

We believe the regulations can be made more transparent and predictable, especially for Intellectual Property Rights (IPR) and stability around drug pricing. We welcome measures such as the New Drugs and Clinical Trials (NDCT) 2019 rules which have played a huge role in making India a favourable clinical trial destination by giving global companies like us the ability to conduct clinical trials for our expansive pipeline. We currently have 17 clinical trials across phase II, phase III, and phase IV. This has increased at least three times in the past three years. Additionally, the government's efforts through policies like 'Make in India' and Production Linked Incentives (PLI) scheme also act as incentives for innovation in the country. An increased representation of experts in the subject committees responsible for drug approvals will lead to more enriching conversations about a drug and its requirements. This is especially true for niche modalities that require stakeholders and medical practitioners who specialise in them. In terms of upholding international quality standards, there is a need for regulatory compliance and collaboration within our own space to overcome bottlenecks.

Being the President-elect of the Organization of Pharmaceutical Producers of India (OPPI), how do you want to see the pharma sector five years down the line?

OPPI is actively working to address India's healthcare challenges through collaborations and advocacy. We collaborate with industry stakeholders, government bodies, and patient groups to create a sustainable, accessible, and quality-driven healthcare ecosystem. We are committed to bridging the gap between innovation and accessibility and ensuring that patient-centric care is at the forefront of our sector. At OPPI, we envision the pharmaceutical sector to flourish over the next five years with a strong focus on innovation, quality, and global collaboration.

We are committed to collaborating with regulatory authorities to establish a clear, consistent, and transparent framework that will foster an environment conducive to innovation. Additionally, strengthened IP protection, achieved through balanced policies, will incentivise R&D investments and drive innovation. Sustained investments in workforce training and education will meet the demands of research, development, and manufacturing. In a bid to boost environmental sustainability, it is imperative for the industry to adopt sustainable practices. There is a need for self-regulation, and proactive engagement in the industry to ensure high standards of quality and ethics.

Quality remains a concern for the pharma companies in India. What measures has Bayer undertaken to mitigate the crisis?

We make investments in strong quality management systems and carry out exhaustive risk analyses. We comply with international standards, such as Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) to ensure that our manufacturing, clinical trials, and testing meet the necessary standards for quality and safety. We are also committed to improving accountability, traceability, and transparency throughout the supply chain. Employee training, as well as proactive manufacturing process monitoring, can support the maintenance of high-quality standards. Investments in training programmes for our employees to improve their technical proficiency and comprehension of quality control methods are necessary. As 50 per cent of our total revenue comes from products made in India, we make sure that all our manufacturing collaborations also undergo the rigorous process of quality control. It is essential for the industry at large to collaborate and engage in a knowledge exchange on ways to improve overall quality measures.

What new technologies have been adopted by Bayer to ensure that quality remains intact till the last mile?

We believe artificial intelligence (AI) is one of the most promising technologies, which can revolutionise quality control in pharma manufacturing and supply chain. Through AI-powered algorithms, it has become possible to analyse large datasets quickly and identify defects and anomalies in the manufacturing process and supply chain. Quality control can be automated and done far more quickly and accurately than before. We are investing in AI across our entire pipeline, from early discovery to late-stage development. We are partnering with technology leaders such as Google Cloud and biotech leaders such as Recursion Pharmaceuticals, Inc. to access new areas of innovation.

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