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GLOBAL PHARMA continues to see potential in investing in R&D IN INDIA

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Innovative biopharmaceutical companies around the world continue to strive to accelerate the pace of innovation and deliver effective medicines to patients quickly and efficiently. By investing more time, energy, and resources in collaboration across the R&D ecosystem and leveraging more sophisticated research and manufacturing tools, these companies in India continue to invest in R&D and advance the science forward.

The global pharmaceutical industry is an important aspect of the world economy today, providing about one trillion US dollars in revenues annually. The American pharmaceutical industry accounts for about 40 per cent of these revenues. However, China is fast catching up as having the fastest growth in the industry. European pharmaceuticals have also shown high revenues in prescription sales.

The US based Johnson & Johnson is at the top of the list with a sales revenues of about $17.8 billion in the first quarter of 2017 while Pfizer's sales stood at $12.8 billion. Swiss based Novartis made $11.54 billion in revenues in the first quarter while Roche went ahead with $13.02 billion in the same period. French pharmaceutical company Sanofi made $9.42 Billion while Germany based Bayer made $10.67 billion in the first quarter of 2017. GlaxoSmithKline (GSK) made a revenue of $9.58 billion with Abbott following behind with a sales revenue of $6.3 billion in 2017 Q1.

Many of these pharmaceutical companies have global operations in different countries including India for conducting research and development. Manufacturing innovative pharmaceutical medicines, vaccines and consumer healthcare products are the basic research activities of these companies. Over the years, companies have invested in state-of-the-art manufacturing facilities in India that extend across a wide range of pharmaceutical and healthcare categories.

Pharmaceutical companies such as GlaxoSmithKline, Abbott, Novartis, Sanofi, Eli Lilly, Johnson & Johnson have invested a lot over the years in setting up R&D centers in India. It began with the earliest center coming in 1971 by GSK while the latest R&D center was established by Abbott in 2012.

These pharmaceutical companies have dedicated R&D centers in India for treating many debilitating diseases and conditions. These mainly include oncology (GSK, Sanofi, Novartis, Johnson & Johnson, Eli Lilly), diabetes (GSK, Abbott, Sanofi, Eli Lilly), infectious diseases (GSK, Abbott, Novartis, Johnson & Johnson), cardiovascular diseases (GSK, Abbott, Sanofi, Novartis), to name a few.

“The biopharmaceutical industry is at a pivotal time in medical discovery, which has enormous potential to further revolutionize the treatment of costly and debilitating diseases like Alzheimer’s, cancer, heart diseases, and hepatitis C, to name a few. India’s large biopharmaceutical industry has now reached a scale and scientific-technological sophistication which makes Indian firms important global players”, said Sanjeev Sethi, Head of Global Injectable Operations, Mylan Pharmaceuticals Private Limited.

In recent years, many new treatment options have emerged that are having a profound impact on the lives of patients. Many of these advances transform what were once considered fatal illnesses into manageable conditions and, in some cases, may even cure a disease. Often new medicines fill an important unmet need or provide an effective alternative where there previously were none. Many recent advances also facilitate adherence to treatment, halt disease progression, and help prevent serious complications. This enables patients to live longer, healthier lives.

“Scientific and technological advances and growing understanding of the underlying mechanisms of disease are fueling the development of new treatments and cures for patients. At the same time, the costs, time, and complexities of biopharmaceutical research have also increased, introducing additional challenges in the research and development (R&D) process”, commented Tarun Puri, Medical Director, Eli Lilly and Company (India) Pvt. Ltd.

The R&D process constantly adapts and changes as new science emerges and as the policy environment also shifts and changes. Growing complexity of clinical trials, uncertainty concerning intellectual property (IP) rights, changing coverage and reimbursement requirements from payers, and continued challenges related to capital and investment are driving an increasingly complex and costly R&D process.

Forces changing the R&D process in India Complexity of Science

Scientists’ ever-deepening understanding of the biologic causes of disease yields new opportunities while also changing numerous aspects of the drug development process. Personalized medicine offers enormous potential to revolutionize the treatment paradigm. But the complex nature of the development process for these exceptionally precise treatments and diagnostic tests requires changes in how medicines are identified, studied, and manufactured.

Dr. Rashmi Hegde, Medical Director at Abbott India Limited shared her views on this thought. “At Abbott, we are focused on continually changing the way medicine is practiced. At the forefront of patient care is personalized medicine which tailors medical treatments to individual patients. Abbott is also taking the use of personalized medicine beyond oncology to areas such as infectious diseases. We are proud to have received approval for the first U.S. FDA-approved hepatitis C genotyping test as well”, she said.

Research on Complex Diseases

Science has always been, and always will be, about exploration, but with exploration comes the inevitable setbacks inherent in the research of complex diseases. “Over the past decades, we have achieved tremendous efforts in biomedical research and have progressed in controlling infectious diseases for instance. However, as people live longer, they now suffer from more complex and chronic diseases, such as diabetes, cancer or cardiovascular diseases”, said Dr. Mubarak Naqvi, Medical and Regulatory Affairs, Sanofi India Limited.

Similar thoughts were shared by N. Rajaram, Country Head & General Manager, Pharmaceutical Operations, Sanofi India Limited. “The challenge people living with diabetes face today is to keep their glucose levels under control. Nearly 50 per cent of people living with diabetes remain uncontrolled. Sanofi India is proud of its strong legacy in diabetes management. We have a diversified portfolio of oral and insulin therapies, including Lantus and Amaryl that have been supporting people in diabetes management for over a decade. We have brought two new molecules to Sanofi India portfolio - Lyxumia and Zemiglo, which is our step forward in developing new solutions for people with type 2 diabetes.”

Regulatory Environment

The regulatory requirements and growing complexity of clinical trials translate into more numerous and more complex eligibility criteria. This primarily involves study enrollment, increased site visits and required procedures, longer study duration, and more rigorous data collection requirements.

“Though India makes up 16 per cent of the world’s population and 20 per cent of the world’s disease burden, less than 1.4 per cent of global clinical trials are carried out in the country. Of the 7,000 known rare diseases, treatment is available for only around 500. Drug prices are also very high. We should be concerned about pricing to ensure that people get access to decent healthcare in India”, said Dr. Vrishali Desai, Regulatory Affairs, GlaxoSmithKline Pharmaceuticals.

Dr. Shiva Murthy Nanjundappa, Head, Regulatory affairs and Quality, Novo Nordisk India Pvt Ltd emphasized on the need for access and affordability of drugs to serve the larger population of hemophilia patients in India. “Last year in April, Novo Nordisk launched NovoEight in India for the treatment and prevention of bleeding in people with hemophilia A (congenital factor VIII deficiency)”, he added.

Incorporating the Patient Perspective

Biopharmaceutical companies are working on integrating patient perspectives into the drug development process. Patient views are incorporated on the outcomes that matter most to them, in terms of quality of life, day-to-day impact, and new therapy’s benefits and risks. This allows researchers to develop medicines that achieve outcomes that are more meaningful for patients.

“I don’t think there is any area of what we do today which will not undergo a radical change. Digital mode is making the patients’ lives easier, improving adherence and increasing specificity, such as digitally targeted medicines”, said Dinesh G, Metabolics Marketing Head, Novartis India Limited. “The Novartis Indian Metabolics team launched a patient support program (PSP) for those living with diabetes in India. The PSP called Prayaas (the Hindi word for ‘endeavor’) diagnoses over 2,000 patients per month during their health camps. The program has established itself as the flagship diabetes PSP across Asia, the Middle East and Africa”, he highlighted.

Intellectual Property

Adequate IP rights and their enforcement remains a challenge. New threats to the strength and enforceability of patents as well as the repeated calls to reduce the data exclusivity period for innovative biologics are increasing business uncertainty. This is particularly affecting established and emerging biopharmaceutical companies, and negatively impacting their ability to make long-term R&D investment decisions.

Aditya Basu, Manager, Novozymes South Asia Pvt. Ltd. said that sudden regulatory shifts will affect MNC drug companies who make long-term investments in innovation. “Novartis currently conducts more than 50 clinical trials in India across all its therapeutic segments. Things have improved in consistency with rest of the world and the regulatory environment has got better now from both intellectual property and clinical trials’ perspective and such environment enables MNCs to invest with certainty over longer periods of time”, he added.

Innovative biopharmaceutical companies around the world continue to strive to accelerate the pace of innovation and deliver effective medicines to patients quickly and efficiently. By investing more time, energy, and resources in collaboration across the R&D ecosystem and leveraging more sophisticated research and manufacturing tools, these companies in India continue to invest in R&D and advance the science forward. But even more important, with the ever expanding drug development pipeline and continued high levels of R&D investment, potential new medicines continue to offer tremendous promise and hope for patients.