

# Generic giants to biotech frontiers: mapping India's pharma trajectory—part II

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## Abstract

The Indian pharmaceutical industry produces affordable, high-quality generic drugs for global and domestic markets. The Indian government supports this sector by focusing on policy reforms to improve access to cost-effective medicines. While policy reforms have aided progress, persistent gaps in quality control, regulatory efficiency, and research and development (R and D) investment continue to hinder sustained leadership. To remain more globally competitive, the industry must strengthen its manufacturing capabilities and increase the use of a more generic active pharmaceutical ingredients and biotech products. Furthermore, the industry and the Indian government must jointly address and resolve the challenges inherent in the existing roadmap for regulatory affairs, intellectual property rights issues, and quality control. Enhanced collaboration between the government and industry is essential to boost R and D, expand the production of biologics and biosimilars, and ensure the speed of sustainable growth through increased interaction and resolution of issues hindering progress. There is also a need to intensify and strengthen R and D in specific areas, as outlined in the paper, in addition to other areas identified nationally and internationally.

**Keywords:** Biosimilars, generic APIs, Genome India, Indian pharmaceutical industry, intellectual property, nano-formulations, quality control issues, regulatory reform, viral vectors

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## INTRODUCTION

In the first part of the review,<sup>[1]</sup> efforts were concentrated on identifying the more vibrant individual pharmaceuticals manufacturing companies in the country and in selecting and recognizing the active pharmaceutical ingredients (APIs) produced in the country as also those that are imported to enable the policy-makers to strengthen policies in the directions that strengthen the industry

and the country further. Inadvertently, financial information on one major company, namely, M/s Intas Pharmaceuticals Ltd. (<http://www.intaspharma.com/>), was omitted, likely because this company is not a listed entity. This company would stand out with an estimated turnover of approximately Rs 23,000 crores and an estimated net profit of around Rs 3200 crores during 2024, making it one of the top-five pharma manufacturing companies in India. Taking these figures into consideration, there would be approximately a 5% difference in the upward direction for the estimated

Received: 29-Jul-2025

Accepted: 30-Jul-2025

Published: 29-Sep-2025

| Access this article online   |  |
|--|--|
| <b>Quick Response Code:</b><br> | <b>Website:</b><br><a href="https://journals.lww.com/mgmj">https://journals.lww.com/mgmj</a> |
|  | <b>DOI:</b><br>10.4103/mgmj.mgmj_211_25  |

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**How to cite this article:** Ghosh PK. Generic giants to biotech frontiers: mapping India's pharma trajectory—part II. *MGM J Med Sci* 2025;12:558-73.

turnover and profitability of all Indian companies, as reported earlier.

In this part of the review, the quality control issues requiring improvement for enhancement of the performance of the industry; the limitations of the existing laws on intellectual properties; and the current regulatory hurdles and delays for the fast introduction of generic APIs and intellectual property right (IPR)-expired biologicals so that the industry becomes more stronger and achieves a more dominant position in the international generic pharmaceutical market, have been discussed. Furthermore, there is a need to intensify and strengthen research and development (R and D) in specific areas, in addition to other existing areas that have been identified nationally and internationally. The selected specific areas where more R and D is required to acquire skills and abilities for applications have been highlighted in this review.

### QUALITY CONTROL ISSUES

Finished APIs and pharmaceutical formulations are released for use only after being thoroughly checked for quality against established standards. India has its pharmacopeia, where standards for each pharmaceutical drug are established. The latest version of 2022 has introduced 3152 drug monographs. The standards laid down there will help deliver quality medicines within and outside India.<sup>[2]</sup> The drugs manufactured and marketed can be of pharmacopeia standards as well as non-pharmacopeia standards, but they must adhere to some defined authoritative standards. Generally, Indian pharmaceutical products have earned a high reputation for their quality in both national and international markets.

However, there have been multiple instances of drug recalls in the Indian pharmaceutical industry, affecting both local and international markets. In some instances, it was discovered that certain companies were producing counterfeit medicines bearing the names of renowned pharmaceutical companies. In other instances, poor-quality formulations were introduced into the market. Medicines were also recalled because it was later revealed, after the product was marketed, that there was a labeling error. Several formulations sold in the US market were recalled later due to quality issues. In one instance, an eye drop exported was linked to causing a drug-resistant microbial infection. In another instance, the World Health Organization (WHO) revealed that cough syrups exported to Gambia by an Indian company were of sub-standard quality and were linked to the deaths of over 60 children. Several other examples of quality issues in pharmaceutical

formulations by Indian companies have come to light.<sup>[3]</sup> Consequently, the industry has often become entangled and continues to be repeatedly caught up in controversies related to quality issues, both in the local and international markets.

Deviations in the quality of marketed formulations are unintentional, except in rare cases. While companies act quickly whenever such issues arise, they also continuously take steps to minimize the prevalence of such incidents and instances. Such incidents and issues must not tarnish the goodwill of this important Indian industry.

The Government of India has recently given close attention to the industry to take measures that minimize the recall of drugs from the market. In March 2025, the Union Minister of State for Chemicals and Fertilizers in a written information in the Rajya Sabha mentioned<sup>[4]</sup> and highlighted that the Central Drug Standard Control Organization (CDSCO) of the Ministry of Health and Family Welfare had taken several measures to ensure the quality, safety, and efficacy of medicines in the country.

In this context, it is emphasized that strengthening regulatory oversight for establishing improved manufacturing practices and adherence to current Good Manufacturing Practices (cGMP); improving the quality control issues of drugs and pharmaceutical produced, requiring enhanced audits and inspections of the manufacturing units by the regulatory authorities; enforcing strict and decisive measures when deviations are noticed from standards; establishment of clear and specific regulatory guidelines for testing of inputs and finished products; effective post-market surveillance to monitor drug quality and safety after they are released for use are some of the major steps to be implemented and their adherence monitored continuously by the CDSCO. The CDSCO would also need to foster a strong, quality-oriented culture within manufacturing companies and enforce regular training for personnel on cGMP and quality assurance procedures.

In the Indian regulatory system, the manufacturing, sale, and distribution of quality drugs and medical devices have been entrusted to the CDSCO and the State-Level Authorities (SLAs). The CDSCO operates at the national level, setting standards, regulating imports, and approving new drugs and medical devices. In contrast, SLAs operate at the state-level. They are responsible for licensing, inspecting, and enforcing regulations related to the manufacturing, sale, and distribution of drugs and medical devices within their respective states. While there must be high levels of cross-talk between the CDSCO and SLAs, this often does

not occur. Moreover, there are sometimes variations in the understanding of the rules by the officers of the two agencies, which result in differences in enforcing regulations at the central and state levels. There is, therefore, a need for periodic meetings between the CDSCO and SLAs to ensure uniformity in approach. There are also variations, such as in the availability of drug inspectors at both the central and state levels, difference in the availability of infrastructures for drug testing, and inadequacy in the availability of legal expertise, which also cause differences in imposing adverse actions on the violators of issues relating to maintaining the quality of drugs and pharmaceuticals by the companies at various locations. These issues need to be continuously evaluated and corrective actions taken to enable both the CDSCO and the SLAs to work more efficiently.

Drug manufacturing companies should also foster a strong, quality-oriented culture within their hierarchy independently. They should attempt to introduce automation that utilizes AI and computer vision for real-time monitoring and detection of contamination or defects. Companies should be encouraged to learn through collaborations with other pharmaceutical companies, regulatory bodies, and research institutions, sharing knowledge and resources to enhance a culture of quality.

### **INTELLECTUAL PROPERTY CHALLENGES AND OPPORTUNITIES IN THE INDIAN CONTEXT**

India had public-friendly patent laws, known as the Indian Patents Act 1970,<sup>[5]</sup> which became effective on April 20, 1972. These laws remained in effect until the first major amendment in December 1994, followed by subsequent amendments made in 1999, 2002, and 2005. These amendments were necessary as India decided to open up its economy in 1991, compelled by the crisis in balance of payment issues.

In the meantime, during the Uruguay Round of Multilateral Trade Negotiations, a global treaty in which India is also a party, the Marrakesh Agreement Establishing the World Trade Organization (WTO) was agreed upon in Marrakesh, Morocco, on April 15, 1994. The WTO was officially established on January 1, 1995. At the Marrakesh meeting, the Agreement on Trade-Related Aspects of IPR (TRIPS), commonly known as the TRIPS Agreement, was also adopted and later became popularly referred to as the TRIPS Agreement of the WTO. The TRIPS Agreement of the WTO is currently the most comprehensive international agreement on intellectual property, aiming to protect and promote trade in knowledge and innovation. TRIPS covers the

protection of various types of IPR, including patents, copyrights, trademarks, and other forms of intellectual property. The WTO's TRIPS Agreement became a legally binding international obligation, requiring WTO member countries to implement and enforce IPR, as outlined in the agreement.

Compliance with the IPR laws of WTO member countries, as mandated by the TRIPS agreement, was intended to protect inventions in the pharmaceutical arena more rigorously by 2005. However, concerns about the consequences of such actions, especially the high cost of medicines, which could impact patient access, led several countries to introduce new IPR laws consistent with the provisions of the TRIPS of the WTO. Still, they made the new laws as public-friendly as possible, instead of drifting toward inventor-friendly laws, by taking into consideration all the provisions and concessions available in the TRIPS of the WTO.

Major concerns before framing TRIPS-compliant IPR laws were to create more flexibility within their provisions, particularly about drugs and pharmaceuticals, including biotech drugs.<sup>[6]</sup>

The new Indian IPR laws<sup>[7]</sup> prevent the evergreening of protection, disallowing the new use of an existing API beyond 20 years. They also allow the patenting of genetic materials, including genes and DNA sequences, only under specific conditions and maintain provisions for compulsory licensing in special situations.

India has made significant progress in developing its generic pharmaceutical industry over time. It is a globally recognized country that helps humanity by providing quality medicines at affordable prices. The current TRIPS-compliant Indian patent laws strongly support the affordability of Indians by encouraging vigorous price competition in the market, leading to lower prices. However, these laws do not favor the development of new high-revenue drugs, which require substantial investment in R and D and a strong environment for protecting inventions through IPR laws.

One of the direct effects of India's current IPR laws is to discourage significant investment in drug discovery by private companies. This mindset is further reinforced when Indian investors see that the costs of developing a new drug are extremely high. The recent estimate of the cost to develop a new drug<sup>[8]</sup> ranges from \$314 million to \$2.8 billion. Since Indian pharmaceutical companies are generally small, risking such large sums is challenging; investing heavily in R and D for new drug discovery does

not guarantee success. Additionally, the long development periods for new drugs make such investments even riskier.

India's current intellectual property laws aim to strike a balance between innovation and affordability. It is therefore surmised that Indian pharmaceutical companies will concentrate on innovating patent-expired drugs to enable their introduction into the market at more affordable prices without compromising on the quality. This situation is expected to continue for another couple of decades until significant government funding for innovation and discovery in the pharmaceutical sector becomes available. A few companies, however, would be driven by their passion for inventing new APIs and would therefore invest in R and D, exploring the invention of one or more. Few such companies would exist.

Indian government investment in R and D has been low compared to that made by many prominent drug and pharmaceutical-producing nations. The total R and D expenditure of India in all sectors as % of its gross domestic product (GDP) was only 0.65% (2020), compared to other major countries<sup>[9]</sup> such as USA 3.59% (2022), China 2.56% (2022), Japan 3.41% (2022), South Korea 5.21% (2022), UK 2.90% (2021), France 2.23% (2022), Germany 3.13% (2022), and Switzerland 3.31% (2021). Of the total amount of money spent on R and D by the Indian government, the expenditure on R and D in the drugs and pharmaceuticals area is, however, higher compared to such investment in other sectors.<sup>[10]</sup>

Most reputable Indian pharmaceutical companies allocate a certain percentage of their total revenue to R and D to remain competitive. In 2023–2024, the R and D expenditure of the top ten Indian pharma companies<sup>[11]</sup> was Rs 137.10 billion, while their total revenue during the same period was Rs 2174.26 billion. The overall average R and D expenditure of these ten companies was approximately 6.3% of their total revenues, while the company-to-company variations in R and D expenditure as a percentage of revenues ranged from 2.58% to 8.19%.

The highest R and D expenditure incurred was by Sun Pharmaceutical Industries, which was about Rs 31.78 billion (about US\$386.15 million). It is stated in this context that, according to recent estimates, the cost of inventing and developing a new drug, as stated earlier,<sup>[8]</sup> has been estimated to vary between US\$314 million and US\$2.8 billion. The present-day Indian pharmaceutical industry can hardly afford such huge investments as success from spending on R and D is not guaranteed.

India has established itself as a significant player in the production and supply of generic drugs, including biopharmaceuticals, to the global market. Indian drugs and pharmaceutical companies are constantly striving to maintain and excel in this leadership position. They are, therefore, busy improving manufacturing processes, as well as developing and introducing patent-expired APIs and their formulations, including biological drugs, by leveraging the latest, cutting-edge innovations. The money for conducting R and D is allocated from the company's profits. For some time, therefore, Indian pharmaceutical companies would have to concentrate on developing innovative, cost-effective processes for manufacturing and supplying generic APIs and their formulations, including biopharmaceuticals, sera, and vaccines, of IPR-expired substances. The development of better manufacturing processes for the deployment of drugs through oral, nasal, buccal, anal, and transdermal delivery is another area of doable R and D, requiring lesser investments with the potential to achieve success.

The Indian government from its Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, has come up with a scheme for "Promotion of Research and Innovation in Pharma MedTech sector (PRIP)" with a total financial outlay of Rs 5000 crores, of which Rs 700 crores are to be spent to establish Centers of Excellence at seven National Institutes Of Pharmaceutical Education And Research, and Rs 4250 crores to accelerate investments in the R and D ecosystem within the sector.<sup>[12]</sup> The goal of the scheme is to transform India into a global powerhouse for R and D in pharmaceutical manufacturing, development, and application in healthcare management. Several other government agencies in India are providing funding for R and D in the field of drugs and pharmaceuticals. The agencies include the Department of Science And Technology, the Council of Scientific and Industrial Research, the Department of Scientific and Industrial Research, and the Department of Biotechnology (DBT). Additionally, the Drug Development Promotion Foundation and the Pharma R and D Fund were established to promote R and D in the pharmaceutical sector. Many state agencies also provide small funds for such developments in their state institutes and universities. These agencies and schemes aim to promote R and D in the pharmaceutical sector and facilitate the development of cost-effective applications.

DBT had established the Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8, Schedule B, Public Sector Enterprise. BIRAC is an interface agency that strengthens and empowers emerging biotech enterprises to undertake strategic research and

innovation. BIRAC was created in 2012. BIRAC has supported over 4800 startups and entrepreneurs. The total investment through BIRAC efforts is estimated to be over Rs 3900 Cr, with an additional Rs 2400 Cr in co-funding from industry and others. This information is available in various scattered BIRAC documents.<sup>[13-17]</sup> It is encouraging to note that DBT, through its BIRAC, has been making sizable investments and efforts to promote biotechnology industrialization through applications. Another noteworthy project worth mentioning is the creation of the National Biopharma Mission (NBM). NBM was launched<sup>[18]</sup> in 2017 by the DBT with a total budget of US\$250 million, of which 50% was co-funded by the World Bank. The NBM was created to enhance and amplify India's capabilities in biopharmaceuticals, vaccines, biosimilars, medical devices, and diagnostics by fostering and nurturing a collaboration between the industry and academia.

These investments would go a long way to strengthening India's development of new and innovative processes in the Indian pharmaceutical sector, while also creating a skilled workforce at Indian institutions and universities.

Such initiatives would significantly strengthen local capabilities and enable the country to make a strong impact in introducing modern biotech products with expired patents much faster than many countries. Such efforts would undoubtedly help India maintain its leadership position in providing multiple modern biotech products with expired patents at affordable prices to the world. The industry can select and leverage various developments that emerge from collaborations, converting them into cost-effective applications.

## REGULATORY ISSUES AND HURDLES

The primary legal framework in India governing the manufacturing and use of drugs and pharmaceuticals as medicines is the Drugs and Cosmetics Act, 1940, and its associated rules, the Drugs and Cosmetics Rules, 1945. These Rules and Regulations cover the issuance of manufacturing licenses, classification of APIs and formulations, quality control issues, labeling and packaging, storage and distribution of medicines, post-marketing surveillance, and advertising issues, among others.

After the expiry of the IPR on APIs and their formulations, generic companies worldwide attempt to introduce these medicines in their respective territories as soon as possible to reap benefits and generate profits. However, companies and business establishments would have to cross several regulatory hurdles and potential delays that can hinder the

prompt introduction, including interpreting the patent validity expiry date and the complexities of regulatory approval procedures, such as the time required for review and approval.

Several factors contribute to delays in drug approvals and market access in India, including a fragmented regulatory landscape, potential issues with clinical trial ethics and quality, as well as challenges related to price controls and patentability. Additionally, delays in inspections and processing, along with a lack of uniform legal interpretation across states, can further impede the process.

The key regulatory hurdles and delays include responsibilities divided between the CDSCO and State Drug Regulatory Authorities (SDRAs) and the interpretations of laws made by the two agencies, which have been found to vary in many states, causing delays. As both the CDSCO and the SDRAs operate independently and the authorities are decentralized, it is necessary to hold intermittent meetings to ensure uniformity in approach and interpretation between the two agencies. Furthermore, the infrastructure for implementing regulations should be comparable in terms of physical and public infrastructure for both the CDSCO and SDRAs. Deficiencies at either agency can lead to inefficiencies. Furthermore, there should be no scope for lobbying by powerful individuals to influence the effectiveness of the independent working of both the CDSCO and SDRAs. Surfacing of the prevalence of spurious and sub-standard drugs in the market poses a significant public health risk and can undermine confidence in the regulatory system. In one recent survey, over 3% of the medicines sold through retail sales were found to be of sub-standard quality,<sup>[19]</sup> and about 0.0245% were found to be spurious drugs. At all costs, both agencies must make strong efforts to minimize the occurrence of such situations.

The need for and the uniformity in the conduct of clinical trials for IPR-expired drugs is another major issue that causes delays. There is a need to ensure a sound and uniform procedure for conducting clinical trials, which should be done ethically to prevent the generation of low-grade data through collusion between drug companies and doctors. The reliability of trial data should be free from issues and factors that may cause unreliability or low compliance.

The author is of the opinion that for the development and induction of new products as well as the first-time introduction of IPR-expired drugs in India, there should be separate regulatory structure within the CDSCO structure, which structure should comprise highly talented scientists constituted by recruiting from the scientific community

of the country who are expected to understand more cogently what R and D is all about and what are its needs. Such a structure should critically evaluate the R and D from the basic stages to the completion of pre-clinical studies, ensuring readiness to transition it to human clinical studies. Avoidable delays must be minimized to ensure rapid scientific progress of such projects. After the projects have made significant progress and are close to approval, the CDSCO may be entrusted with advancing the work. The author identified the main factors and linked actors, as well as the ways to accelerate progress for biotech projects, to become more globally competitive<sup>[20]</sup> (Figure 13.2 of the Reference).

The author believes the current structure can be improved; delays often dampen developers' enthusiasm. Multiple scientific committees comprising capable scientists, technologists, and regulators should be established to understand and appreciate the complexities of R and D, especially in life sciences and modern biotechnology. These committees would facilitate the fast-tracking of project advancement, allowing for their introduction through the necessary phase trials under the Drugs Act. Pre-clinical regulatory structures could be established under the Drugs Act to address various types of inventions, with subject specialists serving on these committees.

### **STRENGTHENING DOMESTIC GENERIC API INGREDIENT PRODUCTION BASE**

The Indian pharmaceutical industry must take decisive steps to maintain its dominant position in the global market. In its efforts to do so, the industry must focus on measures to further strengthen its domestic generic API production base. The defining characteristic of a generic API is that the IPR, specifically patents on the API, have expired, a provision that enables competition and lower prices of the API, determined by the market.

Presently, India manufactures only about 45% of the total number of APIs it consumes for pharmaceutical formulation, according to the author's estimate. The requirements of the remaining quantities are met from imported sources. In a reply to Rajya Sabha question no 181 dated December 5, 2023, it was stated by the Minister of Chemicals and Fertilizers that India had imported<sup>[21]</sup> bulk drugs and intermediates worth Rs 36229.15 Cr, weighing 402,111.18 MT during 2022–2023. The major importing countries from which India imports were, besides China, the USA, Singapore, Italy, Spain, Japan, Germany, Austria, and France. Imports from China

constituted 70.5% of the total value and 74.6% of the total weight of APIs and intermediates imported during the same period.

To reduce India's reliance on imported APIs, the government and industry must take proactive steps to strengthen and boost domestic production. Such measures could include investments in establishing Bulk Drug Parks, offering financial incentives through schemes like the Production Linked Incentive (PLI), and encouraging more R and D efforts through various initiatives. In the previous paragraph titled "Intellectual property issues in the Indian context and potential gains therefrom," the government programs to further activate the Indian pharmaceutical industry have been highlighted. It is expected that these measures will enable India to produce more APIs locally than it currently does.

The Indian pharmaceutical industry is a significant contributor to India's manufacturing gross value added indicator. Therefore, every effort must be made to ensure the industry continues to excel in its performance in the years to come. A study<sup>[22]</sup> conducted on what a roadmap should be for maintaining the status of the Indian pharma industry as an export hub has suggested, among other things, focusing on "Qu RATE mantra," which, according to the study, involves strengthening the industry specifically in areas such as quality, access to the global market, attracting more talent, entrepreneurial innovation, and operating within a stringent regulatory environment. This approach would enable the industry to expand its exports of specialty generics, including formulations and APIs, and boost contract development and manufacturing organization services to facilitate outsourcing drug development and manufacturing to specialized companies. Additionally, there should be increased opportunities for a collaboration between the private sector and government agencies. The measures proposed in the study closely align with actions currently being taken by various government sectors, as mentioned earlier.

Since the Indian pharma industry relies heavily on imports to fulfill its demand for generic APIs, there is a strong need to improve supply chain management to ensure a consistent supply of APIs from imported sources and to expand its API manufacturing capacity domestically.

The global API market in 2023 was estimated at USD 235.39 billion<sup>[23]</sup> and was anticipated to grow at a 6% CAGR from 2024 to 2033. The estimated global API market for 2024 is USD 249.51 billion.

There are various estimates about the current Indian API consumption market. According to one estimate,<sup>[24]</sup> the Indian API consumption market was valued at USD 13.6 billion in 2024 and was projected to grow at an annual rate of 8.1% between 2025 and 2035. Another estimate<sup>[25]</sup> projected that API consumption would reach USD 14.77 billion by the end of 2025, growing at an 8.31% CAGR, and would reach USD 22.02 billion by 2030. Both of these estimates are very close. The current Indian API consumption market is projected to reach USD 13.6 billion by 2024.

Consumption mainly includes the production of locally made pharmaceutical formulations and the export of APIs from India. During 2021–2022, the value of API exports from India was Rs 333 billion, with an annual growth rate of 7.7% from 2018–2019 to 2023–2024.<sup>[26]</sup> The exported APIs were reported at Rs 39632 crores (USD 4.816 billion).<sup>[27]</sup> Indian API consumption for pharmaceutical formulation production involves a mix of local production, imports, and exports. In 2024, API imports in India were reported at Rs 37,722 crores (approximately USD 4.583 billion), with imports accounting for roughly 35% of the total APIs used that year. Based on these figures, the estimated local API production in 2024 is USD 4.246 billion.

The Indian API consumption market is projected to reach USD 13.6 billion by 2024, accounting for a 5.45% share of the global API market, representing significant growth. India produces and sells APIs at more competitive prices than many other countries. Consequently, India is well-positioned to increase its market share in the future. The government's planned steps will support this effort.

### Strengthening the biological production base

India is a major supplier of affordable, high-quality biotech medicines, holding a significant global position. Its products include vaccines, biologics, biosimilars, and biotherapeutic drugs. Specific examples are vaccines and sera, antibiotics prepared through fermentation, certain vitamins and steroids produced via fermentation, and therapeutic enzymes. India accounts for approximately 60% of global vaccine production, making it the world's largest vaccine producer. Indian vaccines are renowned for being affordable, of high quality, and cost-effective. To become a global leader in biopharmaceutical supply, India must focus on strengthening R and D, building a more robust biomanufacturing ecosystem, and ensuring supply chain resilience. This involves fostering innovation, improving technological capabilities, and increasing collaborations with global partners.

### R AND D FOCUSED ON NOVEL VACCINES, INCLUDING MRNA AND PLASMID DNA VACCINE TECHNOLOGIES

The wild animal trade, which involves the trafficking of various animals for use as pets or food, enables disease-producing viruses to jump from animals to humans. This notion has matured from the COVID-19 pandemic, when it was revealed that the wildlife trade in the Wuhan market of China was rampant and may have contributed to the evolution of the COVID-19 RNA virus, which entered human blood. There was evidence of up to 92% genome similarity of coronaviruses<sup>[28]</sup> isolated from pangolins sold in the Wuhan market with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, no exact similarity to SARS-CoV-2 was found among any of these viruses. Scientists have, however, conjectured that the risks of infectious diseases emanating from animals to humans are real.<sup>[29]</sup> Therefore, there is a need to restrict, and even ban, the farming and trading of wild animals for food or pets. India has laws in place to restrict or ban the farming and trading of wild animals, particularly those used for food or pets. More societal restrictions appear to be necessary on the use of animal flesh as food, based on scientific evidence, to promote better human health. Concomitantly, the development of newer vaccines should be prioritized, targeting diseases, especially viral diseases and chronic human diseases, where there has been a noticeable and perceptible rise over the past few decades.

Recently, the use of mRNA vaccines has gained preference over that of existing conventional vaccines due to their higher antigen-presenting efficiencies, higher safety levels, lower manufacturing costs, and ease of rapid development.<sup>[30]</sup> The bottlenecks of instability in mRNA vaccines and their inefficient *in vivo* delivery problems have been addressed and largely resolved.

The development and use of plasmid DNA vaccines have also generated significant interest<sup>[31]</sup> as such vaccines could be used for a variety of similar applications. Their manufacture can be undertaken rapidly, and the products are stable; their efficacy can be enhanced by using appropriate adjuvants.

The first two mRNA vaccines against COVID-19 were developed in India by Gennova Biopharmaceuticals Limited,<sup>[32]</sup> Pune, which were marketed as GEMCOVAC-19 and GEMCOVAC-OM. Other Indian companies, such as Biological E Ltd in Hyderabad, are also interested in developing mRNA vaccines.

Zyodus Cadila developed the first DNA vaccine against COVID-19 in Ahmedabad and was authorized<sup>[33]</sup> for emergency use on August 20, 2021.

India has made some progress toward the use of both mRNA and plasmid DNA vaccines. There is, however, a pressing need to utilize these technologies for the development of new effective and affordable vaccines for protection against several viral diseases such as avian flu (influenza), chikungunya, dengue, hepatitis C, human immunodeficiency virus, Middle East Respiratory Syndrome coronaviruses, herpesviruses other than varicella-zoster virus, respiratory syncytial virus, Ebola filoviruses, zika flaviviruses, and a few more including arthropod-borne viruses. There is also a need to explore whether an effective mRNA or plasmid DNA vaccine can be developed to combat tuberculosis. Furthermore, there is a need to explore the development of mRNA and plasmid DNA vaccines for treating various types of cancer, which are on the rise.

Several issues and factors contribute to the non-availability of vaccines for certain human viral diseases,<sup>[34]</sup> including the virus's inherent characteristics like high mutation rates, complex immune evasion mechanism, long latency within the host for some types, limited replication in cell culture for growing them, challenges in developing effective animal models for testing, and the complexities of clinical trials, particularly in vulnerable populations. There are also regulatory hurdles that require strict compliance with specific regulatory requirements. Furthermore, there may be manufacturing limitations and an imbalance between the development costs and the anticipated sales revenue. The planners would have to make a judgment on which types of vaccines should be developed on a priority basis to maximize benefits to the population and what kind of compensation would attract industry investment.

National programs can be prepared based on data on the incidence of diseases caused by viral and infectious microbial agents, as well as anticipated increases in such diseases. A white paper needs to be prepared at the national level, and future programs need to be outlined.

The author believes that all conventional vaccines will soon be converted into either mRNA or plasmid DNA vaccines as these are anticipated to be more effective, safer, and easier to manufacture with less infrastructure, given the increasing knowledge on resolving the bottlenecks of instability and inefficiency in *in vivo* delivery.

## ENHANCING RESEARCH AND DEVELOPMENT IN SPECIFIC FIELDS, ALONG WITH OTHER NATIONALLY PRIORITIZED AREAS

A few selected areas have been specifically identified and chosen, suggesting the need for conducting intensive research and developmental work over the next two to three decades to maintain and even enhance India's position in the global pharmaceutical industry. These areas are in addition to the areas highlighted in the paper's earlier deliberations. The identified select areas are as follows:

### Artificial intelligence

Artificial intelligence (AI) technology allows machines to mimic human intelligence. Of the four main types of AI, namely, reactive, limited memory, theory of mind, and self-aware, the limited memory AI is most extensively used in drug discovery. Limited memory AI utilizes machine learning and deep learning algorithms. Reactive machines AI is also being used to some extent. The other two kinds of AI might be used in the future. The application of machine learning techniques in medicinal chemistry has been reviewed.<sup>[35]</sup>

In the pharmaceutical industry, the use of AI would improve the overall life cycle of products as AI can assist in multiple ways, from drug discovery to product management. The intelligent use of AI will accelerate the time it takes for new APIs to reach the market. The AI technology is also expected to enhance the quality of products and improve the safety aspects of production processes.<sup>[36]</sup> Indian pharmaceutical industries and Indian drug research institutes must pay close attention to incorporating AI technology into their operations. Furthermore, as scientists in India will be extensively working on similar biologics, there is a need for excellent training on the usage of the AlphaFold technique, an AI system developed by Google DeepMind that enables faster and more accurate prediction of protein 3D structures based on their amino acid sequences. Such expertise may facilitate a deeper understanding of various biological processes.

### API and biological drug development initiatives in India: Suggested directions

India produces a wide range of generic APIs. Not all APIs are considered essential. Each country selects a few APIs and their formulations as essential drugs or medicines. The list of essential drugs<sup>[37]</sup> in India as of 2022 contains only 383 APIs, including biologicals and vaccines. The current model list<sup>[38]</sup> of essential medicines (22nd list, 2021) proposed by the WHO includes just 457 APIs. However, the need to keep a nation healthy involves producing and

providing medicines to treat various conditions, ailments, discomforts, diseases, and defects; thus, the demand for medicines grows nearly exponentially. This situation drives the desire for and the need for new drug development. Not all countries are capable of developing new drugs. Those who can try to maximize profit from the market for these drugs. However, global treaties allow this opportunity to be exploited for a limited time through IPR laws and processes. Most countries only manufacture such drugs after the expiry of IPRs since discovering new drugs is not easy.

In the Indian context, a study by the author revealed that India could discover<sup>[39]</sup> only 16 APIs for the first time in the world from 1900 up to January 2021. Currently, the list may have increased to slightly over 20. Globally, according to the author, fewer than 7000 APIs have been discovered and approved under regulatory laws, of which approximately 6000 APIs are currently in use, while the remaining have become obsolete. Concomitantly, new APIs, biological drugs, and newer methods of personalized treatment utilizing cells, including stem cells from infected individuals, are on the rise, especially in the developed world.

In a recent study, the total number of new and novel APIs, including novel biological drugs, increased phenomenally from 2005 to 2024, rising from 156 in 2005 to an aggregate of 1005 over the entire period.<sup>[40]</sup> The leading discovery countries were the USA, followed by Europe and the UK, Japan, and China. In the years to come, up to 2029, based on estimates of individual medicine consumption in various countries, anticipated large volumes of business in monetary terms are expected to include countries such as the USA, Japan, Germany, France, Italy, Spain, the UK, Canada, South Korea, and Australia. Access to such APIs, biological drugs, and newer methods of personalized treatment will be expensive, and their introduction will be delayed in the developing world. India will, however, continue to remain an important supplier of generic medicines and IPR-expired biologics to the world.

It is difficult to provide an exact number of drugs that have gone off-patent globally between 2016 and 2024 unless the issues are focused upon. In the USA alone, during that period, 54 drugs had gone off-patent.<sup>[41]</sup> As new drug discovery and use are ongoing processes, the number of APIs used and/or manufactured will vary over time. The expiration of IPR allows for the production and use of generic versions of the drugs, resulting in lower prices for these products. Both synthetic and biotech drugs, including some blockbuster ones, are experiencing the expiration of their IPR over time. Efficient pharmaceutical companies desirous of manufacturing

patent-expired drugs soon after the expiry of IPR need to have a strong patent-watch cell that should search the world literature on IPR for APIs and biotech drugs, to select and choose the suitable ones for manufacture and use soon after the expiry of IPR on them. The selection of the right types of APIs and biotech drugs, along with their development in the R and D setup, is necessary to prepare for introducing such products to the market soon after the expiration of their IP rights. The other ways of access to such drugs after the expiry of IPR are to collaborate with companies that can facilitate access to such drugs for use and sale in the market. Companies that can produce such drugs at lower costs would be triumphant. In all such exploration processes, there is an urgent need to prepare a list of APIs and biotech drugs being imported by India and further explore how best conditions can be created in the country to manufacture many of these in India.

## NANO-FORMULATIONS OF BIOACTIVE NATURAL SUBSTANCES

India is endowed with a plethora of natural bioactive principles that contain biologically active compounds, which are obtained from plants, animals, or mineral sources. Such substances, when available in their natural forms, have been used by humanity for centuries to treat various disease conditions, enhance the beauty of the body as cosmetics, improve the bioavailability of nutrients, and stabilize food products in the food industry, among other applications. The efficacy of such substances can be modified and enhanced by converting them into nano-formulations. The nano-formulations of natural products can be presented in various forms, including liposomes, phytosomes, nanoparticles, magnetic nanoparticles, nanosized micelles, and solid lipid nanoparticles, with particle sizes ranging from below 50 nm to approximately 500 nm. While particles with a size range of 10 nm to 1000 nm are considered nanoparticles, formulated nanoparticles with a size range below 50 nm can be more efficacious<sup>[42,43]</sup> for use than native substances. Nano-encapsulation of such substances is anticipated to reduce their particle size, thereby increasing their surface area and enhancing interaction with biological systems, such as living cells and tissues, which may increase their availability at higher concentrations. These are anticipated to enhance their therapeutic or functional effects. A few recent publications have appeared in the literature on nano-encapsulated natural products with enhanced solubility and greater efficacy in specific applications compared to the natural substances.<sup>[44,45]</sup>

It is, therefore, suggested that this area be given higher priority for research by the government as the development of this area holds the potential to yield more efficacious nano-formulations in various types of therapy.

### THE GENOME INDIA PROJECT: GENESIS AND BEYOND

The Genome India Project,<sup>[46]</sup> funded by the DBT, aims to sequence the genomes of 10,000 individuals across India. This information is expected to provide a catalog of genetic variations among Indians, leading to a better understanding of the Indian population's unique genetic diversity. The resulting data are anticipated to aid in research and healthcare advancements.

Whole-genome sequencing is a method that determines the genetic makeup of a specific organism or cell type. A great deal of information can be determined from an individual's genome sequencing data, including the likelihood of developing certain diseases or potential allergies, as well as clues for treatment and even corrections of faulty nucleotide sequences. Therefore, while this dataset provides a starting point, the genome sequence data from only 10,000 individuals are considered insufficient to facilitate the development of groundbreaking inventions in medicine, especially for creating personalized medicines for such a vast human population. The Indian population<sup>[47]</sup> was estimated to be 1.45 billion by the end of 2024 and is anticipated to reach 1.515 billion by the end of 2030 and approximately 1.66 to 1.70 billion by the end of 2050. Achieving 1% coverage by 2030 will require generating over 15 million individual genome sequencing datasets for Indians, which is a monumental task.

Indian efforts are anticipated to represent the genomic data of populations residing in South Asian countries as there has been an incessant movement of populations in this region over thousands of years. The genomic information may assist in understanding the role of population-specific genetic variation, environmental exposures, food intake habits, and ancestral backgrounds of different types of Indian populations in better understanding genetic diseases and disorders, as well as in the development, progression, and therapeutic response to various chronic diseases involving variations in specific nucleotide sequences.

The genome sequencing data shall also contain the exome sequences. Exons are the genome's protein-coding regions. These sequences comprise approximately 2% of the entire genome sequence. In these sequences lie the variants associated with hereditary diseases. Therefore, variations

in these regions need to be studied very critically to identify sequences associated with disease correlates.

The genome of an individual does not remain constant or static in all its cells throughout its lifetime. While most DNA sequences remain unchanged, some changes can occur, especially in somatic cells (cells other than sperm and egg cells). These changes may result from errors in DNA replication or exposure to environmental factors. Recent advances in genomics and proteomics have uncovered noncanonical open reading frames (ncORFs) within regions of non-coding genomic DNA. These ncORFs often encode functional microproteins,<sup>[48,49]</sup> which are crucial for understanding cancer biology, immune responses, and other biological processes. Analyzing the human genome sequence of the same individual at different times could help us gain new knowledge in the coming years.

Sequencing 10,000 genomes is a start, not the finish line. To build personalized medicine pipelines, India needs to build data on at least 15 million genomes sequenced by 2030. The next developmental steps are thought to be as follows

- Scale genome sequencing to 1% of the population.
- Use data to build national bio-banks and drug response models.
- Mandate benefit-sharing with the public on genome-derived drug innovations.

### DEVELOPMENT OF BIOSIMILARS FROM EXPIRED INTELLECTUAL PROPERTY RIGHTS

Biological medicines are essentially proteins and nucleotide sequences of therapeutic and diagnostic value. These are produced primarily by deploying recombinant DNA (rDNA) technologies. Currently, the majority of biological medicines, in terms of value, are based on DNA-encoded proteins. However, it is anticipated that drugs based on nucleotide sequences will be developed rapidly.

Novel rDNA-based proteins are usually protected under IPR. Biosimilar products, or biosimilars, are officially approved versions of the original "innovator" products and can be manufactured by others when the IPR expires.

These proteins can be categorized into four distinct types: replacement protein therapeutics with enzymatic or regulatory functions, protein therapeutics that target specific molecules, protein-based prophylactic vaccines, and protein-based diagnostics. Among these, the first two categories represent a substantial share of the overall value of biologic medicines.

A biosimilar product is a biologic product that has successfully been demonstrated with experimental data to be highly similar to a reference biologic product, which was originally discovered and/or possessed by an agency through IPR, where the IPR was recognized by the World Intellectual Property Organization and/or the US FDA. In India, the official term for a biosimilar product is a “Similar Biologic” product.

By the end of 2024, over 100 biosimilar products will have been approved in India.<sup>[50]</sup> The Indian biosimilars market is experiencing rapid growth and is projected to reach a value of US\$2 billion by the end of 2025. Biosimilar products are used to treat a variety of chronic and severe conditions, including chronic skin and bowel conditions, arthritis, kidney problems, and various types of cancers. Biosimilars provide a more affordable alternative to the original biologic medications.

One report has listed<sup>[51]</sup> that during the next decade, from 2025 to 2034, some 118 biologics will lose IPR protection, which amounts to cost of USD 234 billion. Efforts need to be made immediately to choose and select those that are feasible in India after the expiry of their IPR. This opportunity can be harnessed by companies that are financially strong and have proven capabilities in developing biosimilar products. The choice of biosimilar products to be worked upon shall no doubt depend upon the disease areas, such as cancer and other chronic diseases, where the products would be deployed, having a greater number of patient population, the ability of the entrepreneurs taking up the manufacture of such products, and including resolving difficult manufacturing issues and complexities in clinical trials. Regulatory support and technology support from local efforts, such as the ease of developing transformed cell lines with high cell density in bioreactors, the availability of one-use sterile bioreactors, resins, and columns for the efficient separation of target biologics from contaminants, are other issues that need to be addressed and worked upon.

### **Dementia and the rise in Alzheimer’s disease, a growing concern**

The global elderly population (those aged 65 and over) is estimated<sup>[52]</sup> at around 830 million people in 2025. This number is projected to increase significantly, with an estimated reach of 1.7 billion by 2054. A large portion of such a population is and would be in Asia. Dementia is a disorder found in the aged population. Organizations and institutions with deep expertise in neurology and Alzheimer’s disease (AD) are anticipated to invent effective therapies to contain and postpone the onset of symptoms

of dementia and AD. India needs to identify key areas, select institutions and industries, as well as countries, for collaboration and pursue appropriate programs to delay or prevent the onset of symptoms, if not arrest them, in the elderly population.

Of all the neurodegenerative diseases, such as AD, Parkinson’s Disease, atypical Parkinsonian syndromes, essential tremor, and amyotrophic lateral sclerosis, the largest number of people suffering from neurodegenerative diseases are AD patients. A white paper explores<sup>[53]</sup> how research and collaborations between organizations with deep expertise in neurology and others can accelerate the development of transformative therapies for patients with AD. It is suggested that an Indian white paper on AD needs to be prepared, and R and D action points/programs need to be outlined to enable more effective tackling of the disease in the country.

### **GREATER FOCUS NEEDED TO ACCELERATE ADVANCES IN CANCER THERAPY**

The global burden of cancer is rising rapidly. In 2022, an estimated 20 million new cancer cases and 9.7 million cancer-related deaths were reported. According to the WHO, about 1 in 5 individuals will develop cancer during their lifetime, with 1 in 9 men and 1 in 12 women likely to die from the disease—an alarming reality. Projections indicate that by 2050, the number of cancer cases could exceed 35 million, primarily due to an aging population, lifestyle changes, and increasing levels of environmental pollutants.<sup>[54]</sup>

In terms of new cancer cases, at present globally, the ten most prevalent cancer types are breast, lung, colon and rectum, prostate, skin (non-melanoma), stomach, bladder, kidney, lymphoma, and melanoma.<sup>[55]</sup> The global burden of cancer cases is on the rise.

Cancer cells are caused by mutations. Cancer cells in the body need to be recognized and destroyed by the body’s immune system. Various strategies employed by cancer cells to evade or suppress the immune system, enabling them to survive and proliferate, are being revealed. These include downregulating proteins recognized by T cells (antigens). These include deactivating immune checkpoint inhibitors (ICIs), creating immunosuppressive microenvironments, and interfering with the body’s antigen presentation mechanisms, thereby hindering the activation of immune cells, particularly the ability of T-cells to attack cancer cells.

Activated T-cells of the immune system can destroy cancer cells. T-cell activation occurs through the production of specific cytokines and their subsequent functioning. The cancer cells prevent the cytokine production and cytolytic function of the T-cells, thereby preventing immune activation and immune functioning, and continue to proliferate. The programmed death-1 (PD-1) protein molecules are expressed on activated T-cells, B cells, natural killer cells, monocytes, and dendritic cells. When the PD-1 molecule is locked by its ligands (PD-L1 or PD-L2), signals are transduced, which inhibit T-cell proliferation. One method of treating cancer involves the development and use of molecules<sup>[56]</sup> that bind to PD-1 as ligands, thereby assisting immune cells in becoming activated to destroy cancer cells through various other mechanisms. Several ICIs are known<sup>[57]</sup> besides PD-1, PD-L1, and PD-L2, such as CTLA-4, LAG-3, TIM-3, and TIGIT.

Besides the inhibition of checkpoint proteins, other methods have been developed, such as adoptive and chimeric antigen receptor (CAR) T-cell therapy, as well as cancer vaccinology technology, which are expanding rapidly globally.<sup>[58]</sup>

India is investing in genomic research, strengthening its clinical trial ecosystem, enhancing its information technology infrastructure, and leveraging its digital capabilities, while also intensifying its research capabilities in CAR-T-cell technology.<sup>[59]</sup> These efforts, coupled with increased investment, will enable India to emerge as a significant contributor to cancer treatment technology.

### CAR-T-cell therapy

CAR-T-cell therapy is an immunotherapy. The therapy is primarily used to treat various blood cancers, including certain types of leukemia, lymphoma, and multiple myeloma. The technique involves modifying a patient's T-cells to target and destroy cancer cells more effectively. It involves collecting T-cells, engineering them with a special receptor called a CAR, expanding them in the lab, and then infusing them back into the patient. The incidence of some blood cancers, including certain types of leukemia and lymphoma, may be increasing. By using CAR-T-cell therapy, the overall blood cancer survival rates can be improved due to advancements in diagnosis and this treatment.

This therapy was approved for the first time in 2017 when the US FDA allowed it for the treatment of pediatric and young adult patients with relapsed or refractory acute lymphocytic leukemia.<sup>[60]</sup> As of December 2024, the US FDA had approved six CAR-T-cell therapies, and four others had been approved by other countries, including

one from India.<sup>[61]</sup> Indian CAR-T-cell therapy, known as NexCAR19, developed by ImmunoACT<sup>[62]</sup> in collaboration with IIT Bombay and the Tata Memorial Center, is designed to treat relapsed or refractory B-cell leukemias and lymphomas,<sup>[63]</sup> including B-cell acute lymphoblastic leukemia (B-ALL) and various types of B-cell lymphomas. CAR-T-cell therapy is specifically designed to target CD19, a protein found on the majority of B-cell cancers.

CAR-T-cell therapy is also being explored for the treatment of certain autoimmune diseases<sup>[64]</sup> and potentially infectious diseases.<sup>[65]</sup>

There is a need to intensify R and D in various aspects of utilizing CAR-T cell therapy in India. Since CAR-T cell therapy is essentially a form of immunotherapy, a deep understanding is required to comprehend the body's immune response to the engineered T-cells and their effects on modulating the activities of the brain and central nervous system. The therapy is currently very expensive. India's dominance in this area is expected to reduce treatment costs and make the applications more affordable.

### Need to work on viral-vector cassettes

For containing various deadly diseases, immune system activation is a sound way to research. To activate the immune system, it is essential to select and choose one or more antigens that can trigger the immune response. Viral vectors are crucial antigen delivery vehicles due to their efficiency in delivering genetic material into cells and inducing strong immune responses, making them valuable in various disease treatments, including gene therapy, cancer immunotherapy, and vaccine development against diseases. Viral vectors have high transfection efficiency, can be engineered to target specific cells or tissues, are robust immune responders, and can generate long-lasting immunity. Several viral vectors have been developed and utilized, based on adenoviruses (Ad), adeno-associated viruses, alphaviruses, flaviviruses, herpes simplex viruses, lentiviruses, Newcastle disease virus, poxviruses, picornaviruses, and rhabdoviruses.

Viral vectors have been used to treat both acute and chronic diseases. For treating multiple types of cancer, viral vectors expressing anti-tumor, toxic, suicide, and immunostimulatory genes have been researched.<sup>[66]</sup> In vaccine development against infectious diseases, some viral vectors have been extensively used. Viral vectors have also been used to treat chronic diseases, including hemophilia,  $\beta$ -thalassemia, muscular dystrophy, severe combined immunodeficiency, and sickle cell disease.<sup>[67]</sup> The advantages and limitations of using recombinant viral vector vaccines have also been reviewed.<sup>[68]</sup>

The research on developing and utilizing viral vectors in India is still in its preliminary stage. Non-replicating adeno-viral vectors developed elsewhere have been used to express SARS-CoV-2 viral antigens for vaccination against COVID-19. Some companies are developing viral cassette-based products for use in cell and gene therapy. Several Indian institutes, including the National Institute of Virology in Pune and the Translational Health Science and Technology Institute in Faridabad, are researching vaccine development and gene therapy applications using viral vectors.

There is a need to work intensively on the use of multiple types of viral vector-based products in India. Intensive collaborative projects should be selected and pursued to facilitate the development of viral-vector-based products for novel vaccine development, as well as for treating various chronic diseases, including cancer and arthritis.

## CONCLUDING REMARKS

The Indian pharmaceutical industry is a large, mature, stable, and expansive global leader, recognized as the “pharmacy of the world.” The industry is among the largest generic medicine companies globally. The industry is currently the third-largest by volume and fourteenth by value. The industry is known for producing high-quality, low-cost generic medicines, catering to both domestic and international markets. The Government of India, through its various arms, oversees and promotes the development of the industry, with a sharp focus on ensuring the availability of quality medicines at affordable prices. Yet, with these attributes, the pharmaceutical sector stands at a strategic crossroads.

To remain the king of generics and to evolve into a biotech superpower, several factors and issues require closer critical analysis and steps to improve upon. It is observed and felt that while policy reforms have aided progress, persistent gaps remain in consistently enforcing and adhering to high-quality control standards nationwide. The core issues are as follows:

- Inconsistent enforcement between CDSCO and state regulators (SLAs).
- Insufficient number of drug inspectors and legal experts.
- Recall events driven by labeling errors, contamination, and counterfeit products.

It is recommended that strong efforts need to be made to

- Mandate cross-talk and quarterly alignment meetings between CDSCO and SLAs.

- Invest in AI and computer vision for real-time quality audits.
- Enforce extensive cGMP training across manufacturing personnel.

There are also issues with how CDSCO and SLAs work. The approach of the two essential regulatory structures often results in regulatory gridlock, creating a hidden obstacle for the introduction of novel processes and new drugs. The dual-tier regulatory structure often results in a slowing of the novel drug approval process. There is also divergence in the interpretation between the CDSCO and SLAs, resulting in a slow entry of generic drugs even after the expiry of IPR. The remedies are as follows:

- To create a dedicated, fast-track division within the CDSCO staffed by scientists.
- To develop harmonized SOPs for bioequivalence trials.
- To crack down on trial data corruption and collusion.

There are also aberrations in the existing IPR issues. The existing laws are TRIPS-compliant and are formulated in a manner that prioritizes public access to medicines over profit. These laws, undoubtedly, facilitate the mass production of generics, but they also disincentivize breakthrough drug innovation. The consequences are as follows:

- Only about 20 APIs have been discovered in India in over a century.
- The private sector is not easily willing to invest in high-risk, long-gestation drug discovery.

The way forward is to make -

- Expansion of PLI schemes for bulk drug parks.
- Prioritization of API backward integration in Indian companies.
- Incentivization of API R&D in fermentation and synthesis technologies.
- The government is making a substantial investment, focusing on finding remedies for specific diseases through the discovery of novel APIs and new biologics. There is scope for further investment to be made, linked to India's GDP.
- Establishment of national patent-watch task forces to track expiring IPRs on APIs and biotech drugs, including vaccines and biosimilar molecules. India leads the global market in affordable vaccines and is poised to dominate biosimilars—if it moves fast.
- Leveraging BIRAC and NBM funds to expand biosimilar manufacturing and to develop expertise in various critical components of the technology.

- Promoting enhanced public–private partnerships with innovative policy supports to bridge the affordability gap with innovation.

India has to face the challenge of the future disease-threatened battlefield, dominated by chronic diseases like cancer, autoimmune disorders (including arthritis), Alzheimer’s among the neurodegenerative disorders, and a couple of infectious microbial diseases, and this situation is likely to be aggravated with the rise in the elderly population, resulting from increased longevity. To fight the battle effectively, India must intensify its R and D efforts to acquire more skills in frontier techniques such as CAR-T, mRNA, AI, and nano-formulations, many of which are considered “game-changers in the waiting” in their applications.

### Acknowledgments

The author expresses sincere gratitude to Mrs. Deepali Ghosh, Partner at Sompradip Publishers and Consultants, Block C2B, Flat 5A, Janakpuri, New Delhi 110058, India, for her constant encouragement and support. Special thanks are also extended to Prof. Quamarul Hassan, DVM, PhD, of the RNA and Chromatin Biology Laboratory at the UAB School of Dentistry, Birmingham, AL 35233, USA, for reviewing the manuscript and providing valuable suggestions.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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