A Review on Economic Perspectives of Biotechnology Vaccines Development

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Abstract - Biotechnology has transformed the discipline of biomedical sciences globally benefitting human welfare through vaccine development. Biotech companies have unique needs when it comes to creating vaccine product brands and raising interest and awareness for them. The market is the influence of the success of the product. Biotechnology companies are facing the reality that greater emphasis must be placed on delivering products to markets as companies become increasingly evaluated on their profitability. The current review focusses on Potential risks related to markets and technologies. This article unveils the foundational themes of biotechnology economy, analyzing its ecological, educational, and sustainable dimensions. It also reflects on the evolving dynamics of the emerging industry and discusses future directions for ecotourism research and practice.

Keywords -Ecotourism, Biodiversity Conservation, Environmental Sustainability, Ecological Awareness, Nature-based Tourism

INTRODUCTION

Biotechnology is a fusion technology that combines biological sciences with technological applications, making it highly significant in various fields. It utilizes biological systems, organisms, or their components to develop products suitable for commercial and educational purposes [1]. In the healthcare sector, biotechnology allows researchers to manipulate DNA in innovative ways to study gene functions, which is why it is often referred to as genetic engineering [2].

Vaccines, one of the key outcomes of medical biotechnology, are biological preparations created using both live or inactivated organisms, or their components. This branch of biotechnology has made substantial advancements, with vaccine development being one of its major achievements. The development and approval of biotechnology-based vaccines follow a rigorous scientific process, beginning with preclinical studies and progressing through phase I to III clinical trials to ensure efficacy and safety at optimal doses. Even after a vaccine receives licensure and is introduced to the market, ongoing surveillance (post-licensure vaccine safety monitoring) continues to ensure its safety and effectiveness. [3]

Biotechnology plays a pivotal role in healthcare and clinical medicine, particularly in the production of therapeutic proteins and pharmaceuticals, which are essential for developing various vaccines and treatments. [3]

GROWTH PROSPECTS OF INDIAN BIOSIMILARS AND VACCINES INDUSTRY

The Positively Contributing Factors also considered as Internal factors comprises Strengths and weakness. The Strengths (S) factors include Young and aspiring workforce, Cost competitiveness, High efficacy, low cost and akin safety level; growing demand in healthcare, Affordable, low-cost biosimilars make medication cost-effective in a price-sensitive Indian market, Reduced cycle in synthesis and regulatory compliance compared to innovator molecule, Innovation, R&D focus in innovative therapeutics as key player at global scale, Government regulatory assistance to produce biosimilars, Government initiatives to foster confidence and encourage investment.

The Weaknesses (W) include Poor Industry-Academia alliance, Low government funding to industry, Complex regulatory compliance process; lack of confidence in regulatory bodies and policy makers leading to high corporate cost in approval, Physicians not prescribing biosimilars; low awareness among the doctor and patient, Higher price compared to conventional generic drugs, Pharmacovigilance to

monitor efficacy and safety needed for possible immunogenicity, Altered production process may alter biosimilars' property, Batch-wise uniform production is a challenge; needs skilled manpower, and validated and verifiable SOP

The External factors include Opportunities (O) like Green-field, favourable emerging global biosimilars market, Fast-growing biopharma trade; US $300 million, Indian biosimilar market anticipated to be worth US $40 billion by 2030, Over next few years, patent protection of many biologics expire, Vast prospect for cost-effective Indian biosimilars; biologics company start-ups booming, Biosimilar to cost 20–30% less than biologicals,low cost makes it affordable and accessible as demand grows, Government pledges to fund up to US $1.3 billion on API-based pharma business, Making APIs locally appear doable in next couple of years; to drive developing biotech-based medicines in India for the world, Efforts of DBT and BIRAC to support Indian biotech industry would benefit biologics industry, Government strategies focus on globally-acceptable legislation, entrepreneurship, industry-academia and public-private partnerships and investment avenues for business house, investor and other agencies.

The Threats (T) include Stronger Chinese and Korean influence, Bargaining power of Indian companies with international patent litigations; patent litigation stifles smaller company from getting into biosimilars business, Lack of a comprehensive regulatory framework, for biosimilars development, Tough approval process for pharama companies, to enter global market, Delay in clinical trials approval, new pharma pricing policy, uniform code for sales and marketing practises, compulsory licencing, product quality, regularity uncertainty, reluctant to prescribe, and production complexity, Substantial competition from branded biologics than the tough competition as posed by small-molecule generics.

Building a vaccine research ecosystem in India

The Department of Biotechnology has over the last 3 decades focused on building coherence and connectivity between diverse disciplines and brought together variegated skills across sectors to enhance synergy. Towards this, it has worked on building human resource (HR) and infrastructural capacities and helped in building an enabling environment, thereby preparing India to take up affordable product development. In addition to academic research, DBT has established various initiatives towards advancing biotechnology sector in India, such as establishing biotech clusters;promoting entrepreneurial culture through funding and support to Small and Medium Enterprises (SMEs) and start-ups; building national and international research collaborations/partnerships; enabling innovation ecosystem through establishment of incubation centres and innovation parks; and promoting industry academia partnerships for accelerated product development.

The organic growth scenario of Indian bioindustries:

Triggering Factor	Beneficiary Organisation	Speciality Area
Scientists or local individual from various industrial sectors	• XCyton Diagnostics (Bengaluru) • GangaGen (Bengaluru) • Shanta Biotechnics (Hyderabad)–now part of Sanofi • Cytogenomics (Bengaluru) • Bigtec (Bengaluru) • Brilliant Bio Pharma Private Limited • (Hyderabad)	• Diagnostics • Antimicrobials • Biogenerics, diagnostics, contract • Research • Bioinformatics • Bioinformatics • Veterinary Vaccines
Companies venturing into biotech	• Serum Institute of India (Pune) • Biocon (Bengaluru) • Infosys (Bengaluru); Tata Consultancy • Services (Mumbai) • Zydus Cadila • Bioogical E (Hyderabad) • Intas Pharmaceuticals (Ahmedabad) • Emcure–Gennova (Pune) • Panacea Biotec (New Delhi) • Wockhardt (Mumbai) • Dr. Reddy's Laboratories (Hyderabad)	• Vaccines, biosimilars • Generics, biologics, biosimilars • Bioinformatics • Generics, biologics, biosimilars • Vaccines. Biologics • Generics, biogenerics, contract • Manufacturing • Biosimilars, Novel Vaccines • Generics, vaccines • Generics, biologics, vaccines

	• GVK Biosciences (Hyderabad) • Jubilant Biosys (Bengaluru)	• Generics, vaccines, biosimilars, biologics • Generics, biogenerics • Bioinformatics, contract research
Academic scientist to bioentrepreneur	• Bangalore Genei (Bengaluru) • Avesthagen (Bengaluru) • Strand Life Sciences (Bengaluru) • Microtest Innovations (Bengaluru)	• Reagents supply, contract research • Plant biotech, diagnostics, nutraceuticals, • contract research • Bioinformatics • Diagnostics
Industry professionals or academic scientists from overseas	• Molecular Connections (Bengaluru); CellBhat Biotech (Bengaluru) • Bharat Biotech International (Hyderabad) • Genotypic Technologies (Bengaluru) • Connexios Life Sciences (Bengaluru) • Ocium Biosolutions, Mapmygenome • (Hyderabad)	• Bioinformatics, systems biology • Diagnostics • Vaccines, Biosimilars • Bioinformatics, contract research • Systems biology • Bioinformatics, Diagnostics

Novel Innovative Vaccines for Emerging and Neglected Diseases That Could Impact SDGs – Selected Promising Projects

DENGUE

Sanofi's CYD-TDV vaccine has entered the market after 20 years of development. However, due to evidence showing serostatus-dependence, the World Health Organization (WHO) recommends pre-screening individuals before vaccination, which complicates operational use. Beyond this, at least two other vaccines are currently in Phase III clinical trials, with results expected in the next 3–4 years. These developments indicate significant progress in combating dengue but highlight operational and regulatory challenges.

PNEUMOCOCCAL VACCINE

Merck: V114, a next-generation pneumococcal vaccine, is undergoing evaluation in two Phase III clinical trials, aiming to improve protection against pneumococcal diseases.

Pfizer: Another leading pharmaceutical company is testing its own advanced pneumococcal vaccine in a Phase III trial, aiming to enhance immunogenicity and coverage.

RSV Vaccine

Novavax: ResVax RSV is a maternal immunization vaccine designed to protect infants from respiratory syncytial virus (RSV). Currently in a Phase III study, this vaccine represents a crucial step toward reducing RSV-related infant mortality worldwide.

HUMAN PAPILLOMA VIRUS(HPV) VACCINE:

VGX-3100: This vaccine targets cervical dysplasia caused by HPV. It is now in Phase III clinical trials, with promising results expected to pave the way for addressing a major global health challenge.

MALARIA

GSK/path: The RTS,S malaria vaccine has finally been registered after a staggering 28 years of development. This vaccine provides hope in the ongoing battle against malaria, especially in regions where the disease burden remains high.

DIARRHEA

Takeda Pharmaceuticals: In its Phase II trial, the bivalent norovirus vaccine candidate demonstrated good tolerability and immune responses that persisted for a year. Following these encouraging results, one of the formulations has advanced to Phase III studies, signifying a potential breakthrough in preventing diarrheal diseases.

INFLUENZA

Sanofi Fluzone: A well-established influenza vaccine currently marketed to reduce seasonal flu cases.

University of Washington School of Medicine: Pioneering research is underway for a universal DNA influenza vaccine, which could revolutionize the fight against influenza by providing broader and longer-lasting protection.

HIV

National Institute of Allergy and Infectious Diseases (NIAID): The VRC01 vaccine is progressing through Phase IIb and III trials. This project aims to overcome barriers by achieving over 50% efficacy, improved safety, and reduced adverse effects. Success would mark a significant improvement compared to the previous 31% efficacy seen in the Thailand trial, potentially revolutionizing HIV prevention efforts.

Adjuvants

Company	Class	Indications
Alum	Mineral salts	Broad use in vaccines
MF59	Novartis	O/W emulsion, Influenza (Fluad)/pandemic flu
AS03	GSK	O/W emulsion + α-tocopherol, Pandemic flu (Pandemrix)
AS04	GSK	MPL + alum, HBV (Fendrix), HPV (Cervarix)
Liposomes	Crucell	O/W emulsion, HAV, Flu (EU)

Adjuvants play a critical role in enhancing the efficacy of vaccines by improving immune responses. For example, MF59 and AS03 have been effectively used in influenza and pandemic flu vaccines, respectively, demonstrating their potential to bolster immune defenses.

Top Countries in Patent Deposits for Adjuvants for Vaccine Compositions

Country	Zika	Dengue	HIV/AIDS	Influenza	Total
China	1	1	9	80	91
USA	2	4	11	47	64
South Korea	0	0	7	17	24
UK	0	0	4	16	20

This table highlights the global focus on adjuvant development, particularly in China and the USA, which lead in patent filings for diseases such as Zika, dengue, HIV/AIDS, and influenza. These numbers underscore the competitive and collaborative nature of vaccine innovation.

Organic Growth Scenario of Indian Bio-industries

Triggering Factor	Beneficiary Organisation	Specialty Area
Scientists/local individuals	XCyton Diagnostics, GangaGen, Shanta Biotechnics	Diagnostics, antimicrobials, bioinformatics
Companies venturing into biotech	Serum Institute, Biocon, Infosys, Zydus Cadila, etc.	Vaccines, biosimilars, generics
Academic scientist to bioentrepreneur	Bangalore Genei, Avesthagen, Strand Life Sciences, etc.	Diagnostics, contract research
Industry professionals/ academic scientists from overseas	Molecular Connections, Bharat Biotech, Connexios Life Sciences	Bioinformatics, diagnostics, systems biology

India's bio-industrial ecosystem benefits from a diverse range of players, including scientists, startups, and multinational corporations. These organizations contribute to innovations in diagnostics, bioinformatics, and biosimilars, driving the sector's growth.

CONCLUSION

Biotechnology companies face unique challenges as they strive to deliver innovative products while maintaining profitability. Risks associated with technology and market dynamics must be realistically evaluated. Key obstacles include Complex product feature sets that require clear communication to diverse audiences, Shortened development timelines,

demanding efficient resource management and Global rollouts with varied regulatory and market requirements.

These challenges underscore the importance of strategic planning, strong branding, and collaboration within the biotech sector.

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