

# Biologics And Biosimilars In India: The Imperative Shift With Insights From Ivf Treatments



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## Abstract

India's pharmaceutical industry is undergoing a strategic transition from small-molecule generics to complex biologics and biosimilars. This shift is driven by rising disease burdens, patent expiries, and the need for affordable advanced therapies. The pharmaceutical landscape is shifting toward biologics, with biosimilars offering cost-effective alternatives. India, traditionally strong in generics, is now transitioning into biologics to address rising healthcare costs and complex diseases. The global pharmaceutical industry is shifting from small-molecule drugs to biologics, with biosimilars emerging as cost-effective alternatives. India, historically dominant in generics, is now transitioning into biologics and biosimilars to address rising healthcare costs and complex disease burdens. This paper explores the necessity of this shift, focusing on In Vitro Fertilization (IVF) as a case study. IVF treatments rely heavily on biologics such as recombinant follicle-stimulating hormone (rFSH), which significantly increase treatment costs. Evidence suggests that biosimilars offer comparable efficacy and safety while improving affordability, making them crucial for expanding access in India.

**Keywords:** Biologics, Biosimilars, India, IVF, Fertility Treatment, Pharmaceutical Industry, Healthcare Access etc.

## 1. Introduction

Biologics represent a new frontier in medicine, offering targeted therapies for chronic and life-threatening conditions. Biosimilars, as cost-effective alternatives, play a crucial role in expanding access. India, known globally for its generics industry, is now positioning itself to become a major player in biologics. The shift is particularly relevant in high-cost treatment areas like IVF, where biologic drugs are essential but often unaffordable for a large segment of the population. Biologics are large, complex molecules derived from living organisms and represent a major advancement in modern medicine. However, their high-cost limits accessibility, particularly in developing

countries like India. Biosimilars, highly similar versions of approved biologics, offer a pathway to reduce costs and improve access.

India’s pharmaceutical sector is uniquely positioned to lead this transition due to its strong manufacturing base and experience in generics. The IVF sector provides a compelling example of how biosimilars can transform access to specialized healthcare. As we know, biologics are complex, life-saving drugs derived from living systems, widely used in treating chronic diseases and infertility. However, their high-cost limits access in developing countries like India. Whereas biosimilars provide a solution by offering similar therapeutic outcomes at lower costs. India’s transition toward biologics is both a healthcare necessity and an economic opportunity.

## 2. Biologics and Biosimilars: Conceptual Framework

### 2.1 Biologics

Biologics are complex molecules produced using living systems. Biologics are produced through biotechnology and include hormones, monoclonal antibodies, and recombinant proteins. These therapies are inherently complex and exhibit variability due to their biological origin. In IVF, biologics such as recombinant follicle-stimulating hormone (rFSH) are used to stimulate ovarian function (2).

### 2.2 Biosimilars

Biosimilars are highly similar versions of approved biologics with no clinically meaningful differences in safety or efficacy. They offer:

- Lower cost
- Comparable therapeutic outcomes
- Increased patient access

Biosimilars are not exact copies but are “highly similar” to reference biologics, requiring rigorous comparability studies to demonstrate equivalent safety and efficacy. They play a critical role in improving affordability and access to advanced therapies globally (3).

**Table1.** Examples of Marketed biosimilars in the IVFsector

Sl No.	Biosimilar Name	Reference Product	Molecule (API)	Indication in IVF	Manufacturer	Approved Region
01.	Ovaleap	Golan-f	Recombinant Human FSH (Follitropin alfa)	Controlled Ovarian stimulation	Teva Pharma B.V./Theramax	Europe
02.	Zyfol	Golan-f	Recombinant Human FSH	Infertility treatment	Zydus Life Sciences	India
03.	Folisurge	Golan-f	Recombinant Human FSH	Ovarian stimulation	Intas Pharmaceuticals	India

04.	Folitime	Golan-f	Recombinant Human FSH	Controlled Ovarian stimulation	Intas Pharmaceuticals	India
05.	Bemfola	Golan-f	Recombinant Human FSH (Follitropin alfa)	Ovarian follicle development	Gedeon Richter PLC/Finox Biotech	Europe Australia
06.	Primapur	Golan-f	Recombinant Human FSH	Ovarian stimulation	IVFarma	Russia

### 3. The Need for a Shift in India

#### 3.1 Growing Healthcare Demand

India is experiencing increasing rates of chronic diseases and infertility. Lifestyle changes, delayed parenthood, and environmental factors have contributed to growing demand for assisted reproductive technologies. IVF demand is rising rapidly, but treatment costs remain a barrier (4).

#### 3.2 Economic Opportunity

Indian pharmaceutical companies such as Biocon and Dr. Reddy's Laboratories are investing in biosimilars to tap into global markets while addressing domestic needs.

The biologics market is expanding rapidly, and biosimilars are becoming essential for sustainable healthcare systems. India's entry into this segment allows:

- Global market penetration
- Domestic cost reduction
- Technological advancement
- Patent expirations creating entry points
- India's manufacturing advantage

#### 3.3 Patent Expirations

Many biologics used in reproductive medicine are losing patent protection, enabling biosimilar entry and price competition.

#### 4.1 Role of Biologics in IVF

IVF treatment relies heavily on biologics, including:

- Recombinant FSH (ovarian stimulation)
- Human chorionic gonadotropin (hCG)
- Luteinizing hormone (LH)

These drugs stimulate ovarian follicle growth and are essential for IVF success. FSH is particularly critical, as it stimulates ovarian follicle development and directly influences IVF success rates.

## **4.2 Emergence of Biosimilars in IVF**

Recent years have seen the development of biosimilars of rFSH (e.g., follitropin alfa biosimilars). These drugs:

- Are structurally and functionally similar to originators
- Follow the same dosage and administration protocols
- Require stringent regulatory approval

Studies confirm that biosimilar rFSH demonstrates comparable efficacy and safety to original biologics.

## **4.3 Cost and Accessibility Impact**

Biologics constitute a major portion of IVF costs. Biosimilars can:

- Reduce drug expenditure significantly
- Increase treatment accessibility
- Expand IVF adoption beyond high-income groups

## **4.4 Clinical Considerations**

Clinical and real-world studies indicate the following:

- Biosimilars must demonstrate equivalence in ovarian response and pregnancy rates
- Physician confidence is essential for adoption
- Regulatory oversight ensures safety and quality

A large proportion of IVF practitioners report no significant difference in outcomes between biosimilars and originators, though awareness and confidence are still evolving (3).

## **4.5 Cost Barrier in India**

An IVF cycle in India can cost ₹1.5-2.5 lakh or more, with medications contributing up to 40-60% of the total expense. Imported biologics further increase costs. Globally, cost pressures have driven the adoption of biosimilar FSH due to patent expirations and affordability concerns (3).

# **5. Challenges in India's Biologics Transition**

## **5.1 Regulatory Framework**

Biosimilars require extensive clinical trials and comparability data, making approval more complex than generics. Approval processes governed by the Central Drugs Standard Control Organization require continuous strengthening to match global standards.

## **5.2 Manufacturing Complexity**

Biologics production involves:

- Advanced biotechnology infrastructure
- Skilled workforce
- Stringent quality control

### **5.3 High Investment Requirements**

Development timelines are long and capital-intensive compared to generics. Developing biosimilars requires significant capital, long timelines, and clinical validation.

### **5.4 Adoption Barriers**

- Limited awareness among clinicians
- Concerns regarding interchangeability
- Need for real-world evidence

## **6. Policy and Strategic Recommendations**

### **6.1 Strengthening Regulatory Frameworks**

India should align with global standards to ensure faster approvals and international acceptance.

### **6.2 Investment in Infrastructure**

Provide incentives for biologics research and infrastructure. Example:

- Biotech parks
- Skilled workforce development
- Advanced manufacturing facilities

### **6.3 Promote public-private partnerships**

Collaboration between academia and industry can accelerate innovation.

### **6.4 Enhancing Awareness**

Educational initiatives for doctors and patients will increase biosimilar adoption. Educate clinicians about biosimilar efficacy and safety.

### **6.5 Expanding Insurance Coverage**

Including IVF and biologic therapies in insurance schemes can improve accessibility.

## **7. Conclusion**

India's shift toward biologics and biosimilars is both necessary and strategic. The IVF case highlights the transformative potential of biosimilars in reducing costs and expanding access to advanced treatments. With appropriate regulatory support, investment, and awareness, India can emerge as a global leader in biosimilars while addressing critical domestic healthcare challenges (5). The IVF example demonstrates how biologics dominate high-cost therapeutic areas and how

biosimilars can democratize access. India's transition is not merely industrial but socio-economic, directly affecting healthcare equity.

## 8. References

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