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Comparative Study of Biopharmaceutical Innovation Policies: India and the European Union

Naim Uddin[1*]
Research Scholar, Department of Law,
MJP Rohilkhand University, Bareilly
Advocatenaim1982@gmail.com

Prof. (Dr.) O. P. Rai[2]
Principal, Bareilly College, Bareilly
droprai17@gmail.com

Abstract:
Biopharmaceutical innovation has become a critical determinant of national health security, economic growth, and technological advancement in the contemporary global order. This paper presents a comprehensive comparative study of biopharmaceutical innovation policies in India and the European Union (EU), examining how divergent regulatory philosophies and institutional frameworks shape research and development outcomes. The EU represents a highly integrated and harmonized innovation ecosystem, characterized by centralized regulatory oversight through the European Medicines Agency, robust intellectual property protection, and extensive public funding mechanisms such as Horizon Europe. Using a qualitative doctrinal and comparative policy analysis, this study evaluates regulatory approval processes, intellectual property regimes, innovation incentives, and market access mechanisms in both jurisdictions. The findings indicate that while the EU's policy framework offers greater regulatory certainty and innovation-specific exclusivities, India leverages intellectual property flexibilities and cost-efficient manufacturing capabilities to foster a competitive biopharmaceutical sector. The paper argues that strategic policy learning, regulatory cooperation, and calibrated intellectual property governance can bridge existing gaps and enhance innovation capacity without undermining public health objectives. Ultimately, the study contributes to the discourse on comparative pharmaceutical governance by highlighting pathways for sustainable and inclusive biopharmaceutical innovation in both developed and emerging economies.

Keywords: Biopharmaceutical Innovation; Comparative Policy Analysis; India; European Union; Intellectual Property Rights; Pharmaceutical Regulation; Research and Development; Public Health.

INTRODUCTION

Biopharmaceutical innovation has emerged as a central policy priority for states seeking to address complex public health challenges, ensure preparedness against pandemics, and secure long-term economic competitiveness in an increasingly knowledge-driven global economy. Advances in biotechnology, genomics, and personalised medicine have transformed the pharmaceutical sector from one primarily focused on chemical synthesis to a research-intensive industry dependent on high-risk investment, sophisticated regulatory oversight, and strong intellectual property (IP) protection. Governments across the world now view biopharmaceutical innovation not merely as a commercial activity but as a strategic public good, closely linked to national health security, industrial policy, and international trade commitments[3]. The global biopharmaceutical industry is characterised by high research and development (R&D) costs, lengthy product development timelines, and significant regulatory uncertainty. It is estimated that the development of a single innovative biologic medicine can take more than a decade and require investments running into billions of dollars[4]. These structural features necessitate active state intervention through regulatory frameworks, fiscal incentives, public funding mechanisms, and market exclusivity regimes to correct market failures and stimulate innovation. Consequently, biopharmaceutical policy has become an area where law, economics, science, and public health intersect in particularly complex ways.

Against this backdrop, India and the European Union (EU) present compelling and contrasting case studies for comparative analysis. The EU represents one of the most mature and institutionalised biopharmaceutical innovation ecosystems in the world. Its regulatory framework is characterised by a high degree of harmonisation across Member States, centralised marketing authorisation procedures, and a dense network of innovation incentives coordinated at both the supranational and national levels. The European Medicines Agency (EMA) plays a pivotal role in ensuring regulatory consistency, scientific rigour, and market integration across the Union[5]. In parallel, the EU has developed an elaborate system of IP protection, data exclusivity, supplementary protection certificates, and targeted incentives for niche areas such as orphan drugs and advanced therapies[6].

India, by contrast, occupies a distinctive position as both a major global supplier of affordable medicines and an emerging hub for biopharmaceutical innovation. Historically recognised as the "pharmacy of the developing world," India's pharmaceutical sector has been shaped by policies emphasising access, price control, and generic competition[7]. However, over the past two decades, India has undertaken significant legal and policy reforms to reposition itself within the global innovation landscape. Compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), increased public investment in biotechnology, and the gradual strengthening of regulatory capacity have signalled a strategic shift toward innovation-driven growth[8]. Yet, this transition remains marked by persistent tensions between incentivising innovation and safeguarding public health imperatives. A comparative study of India and the EU is particularly instructive because it illuminates how jurisdictions at different stages of economic development respond to common structural challenges in biopharmaceutical innovation. While the EU operates within a high-income, research-intensive context, India represents a large emerging economy balancing innovation aspirations with developmental and distributive concerns. The contrast between these systems enables a nuanced examination of how regulatory design, IP governance, and innovation incentives interact with broader socio-economic objectives. Moreover, both jurisdictions are influential actors in global pharmaceutical governance, shaping international norms through trade negotiations, regulatory cooperation, and standard-setting processes[9].

The scope of this study is deliberately focused on four interrelated dimensions of biopharmaceutical innovation policy:

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regulation, incentives, intellectual property, and competitiveness. First, regulatory frameworks are examined as foundational determinants of innovation outcomes. Efficient, predictable, and scientifically robust regulatory systems are essential for reducing uncertainty, accelerating market entry, and ensuring patient safety[10]. The paper analyses how regulatory approval processes in India and the EU differ in terms of institutional design, procedural timelines, and adaptability to emerging technologies such as biologics, biosimilars, and gene therapies.

Second, the study evaluates innovation incentives, including public funding, fiscal measures, and public–private partnerships. Biopharmaceutical innovation is particularly sensitive to policy signals due to its capital-intensive nature and high failure rates[11]. The EU's extensive use of framework programs, collaborative research funding, and innovation clusters is contrasted with India's evolving ecosystem of government grants, biotechnology parks, and startup-focused initiatives. This comparison highlights differing state strategies for mobilizing private investment and fostering translational research.

Third, intellectual property governance is analysed as a central legal mechanism shaping innovation behaviour. Strong IP protection is often justified as a necessary condition for recouping R&D investments, yet excessive exclusivity can impede access to essential medicines[12]. The EU's layered system of patent protection, data exclusivity, and supplementary protection certificates is examined alongside India's use of TRIPS-compliant flexibilities such as strict patentability standards and compulsory licensing. This dimension is critical for understanding how legal choices reflect broader normative commitments to innovation, competition, and public health.

Finally, the paper situates regulatory, incentive, and IP frameworks within a broader analysis of competitiveness. Biopharmaceutical competitiveness is not solely determined by innovation outputs but also by factors such as manufacturing capacity, integration into global value chains, and responsiveness to global health needs[13]. By comparing India's strengths in cost-efficient production and biosimilars with the EU's leadership in novel therapeutics and advanced research, the study seeks to identify complementarities as well as structural asymmetries between the two systems.

In undertaking this comparative analysis, the paper aims to contribute to the growing body of scholarship on pharmaceutical governance and innovation policy. Rather than adopting a purely descriptive approach, it critically evaluates how different policy choices shape innovation trajectories and distributional outcomes. The central argument advanced is that neither the EU's highly protection-oriented model nor India's access-driven framework offers a complete solution in isolation. Instead, context-sensitive policy learning and regulatory cooperation between developed and emerging economies are essential for fostering sustainable and inclusive biopharmaceutical innovation in an interconnected global landscape.

BIOPHARMACEUTICAL POLICY IN INDIA

India's biopharmaceutical policy landscape is shaped by a combination of legislative frameworks, regulatory institutions, intellectual property laws, and innovation incentives that collectively aim to balance public health objectives with industry competitiveness. This section examines India's regulatory framework, its intellectual property regime, and the primary innovation incentives deployed to foster research and commercialisation in biopharmaceuticals.

A. Regulatory Framework

Role of Central Drugs Standard Control Organisation (CDSCO)

The Central Drugs Standard Control Organisation (CDSCO) is India's apex regulatory agency for pharmaceuticals, biologics, vaccines, and medical devices. Often likened to the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA), the CDSCO operates under the Ministry of Health and Family Welfare and is responsible for approval of new drugs and clinical trials, establishing quality standards, and coordinating with state drug regulators for enforcement under the Drugs and Cosmetics Act, 1940[14]. The head of CDSCO, the Drugs Controller General of India (DCGI), serves as the central licensing authority overseeing drug approvals, including import, manufacture, and distribution of pharmaceutical products and biologics[15]. The CDSCO's mandate also includes the conduct and oversight of clinical research, ethics committee registration, post-market surveillance, and adverse event reporting.[3] In recent years, CDSCO has undertaken significant reforms to streamline processes for biopharmaceutical development and regulatory compliance.

A key component of India's regulatory architecture is the New Drugs and Clinical Trials Rules, 2019 (NDCTR 2019), promulgated to replace earlier rules under the Drugs and Cosmetics Act and provide a modernised approval mechanism for new drugs, biologics, and clinical trials[16]. The NDCTR 2019 consolidates approval procedures for new drugs and investigational products, ethics committee governance, bioavailability/bioequivalence studies, and clinical investigation pathways. Features include standardized application formats, specific registration pathways, and defined processes for ethics committee registration and clinical trial permissions[17].

Despite these reforms, stakeholders have pointed to ongoing challenges in regulatory predictability and timeliness. Industry voices argue that while CDSCO's stringent review standards prioritise safety and efficacy, they may also result in longer review timelines and uncertainty for innovative biologics compared with regulatory agencies in high-income jurisdictions[18]. Some innovators report that simultaneous filing and parallel review mechanisms with global regulators are not always accommodated, which can hinder India from achieving regulatory harmonisation with markets such as the EU[19]. Additional concerns relate to coordination between central and state regulators, which can sometimes result in disparate enforcement practices and bureaucratic complexity for approvals and manufacturing licenses[20]. The government has also initiated moves toward digitalisation of regulatory workflows. For example, CDSCO has launched online registration systems for Clinical Research Organisations (CROs) through the Sugam Portal, aimed at reducing administrative burden and enabling digital submissions and renewals[21]. Related digital reforms are anticipated under proposed regulatory innovation policies that envision single-window digital interfaces for submission, tracking, and automated review of applications for biologics and advanced therapies[22]. Such measures are expected to enhance transparency, build predictability, and reduce approval times, critical enablers of biopharmaceutical innovation.

Beyond clinical trials and drug approvals, CDSCO's regulatory coverage includes quality standards, Good

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Manufacturing Practice inspections, pharmacovigilance, and integration with adverse event reporting systems like the Pharmacovigilance Programme of India (PvPI)[23]. Recent initiatives have sought to harness technology for safety monitoring, for example, requiring QR codes at pharmacies to facilitate real-time reporting of adverse drug events[24]. These quality and post-market mechanisms reflect the regulatory ecosystem's responsibility not only for pre-market approvals but also for continuous lifecycle oversight of biopharmaceutical products.

India's regulatory framework, anchored by CDSCO and the NDCTR 2019, seeks to balance public health protection with innovation-relevant efficiency. While significant modernisation efforts have been undertaken, gaps remain in harmonisation, digitalisation, and administrative predictability when compared to more established regulatory systems.

B. Intellectual Property Regime

TRIPS Compliance

India's intellectual property (IP) regime plays a fundamental role in shaping incentives for biopharmaceutical innovation, particularly given the high costs and risks associated with drug discovery and development. Historically, India's patent legislation restricted patent protection to processes rather than products, which facilitated the growth of a robust generic industry but limited exclusivities for innovative medicines[25]. However, India's accession to the World Trade Organization (WTO) and compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) led to substantial revisions of the Patents Act, 1970[26]. Under these revisions, product patents, including for pharmaceuticals and biotechnological inventions became available, aligning India with international standards.

TRIPS compliance introduced a patent term of 20 years and data protection obligations, theoretically enhancing the incentives for innovation by granting exclusivity to novel molecules and biologic entities. Nevertheless, India's implementation remains calibrated to preserve access and affordability, reflecting public health priorities. For example, the country incorporates strict patentability criteria, particularly concerning obviousness and incremental changes, to prevent evergreening of patents that could unduly extend exclusivity without significant therapeutic advances. Even with these TRIPS-compliant protections, the Indian patent regime maintains built-in safeguards to balance monopolistic exclusivity against public interest. Compulsory licensing provisions, for instance, permit the government to authorise third-party production of patented inventions in circumstances of public health need or non- availability at reasonable prices, a mechanism used sparingly but symbolically to underscore access imperatives.

Patent Linkage and Post-Grant Oppositions

One area of ongoing debate involves patent linkage, which connects regulatory approval decisions (for marketing authorisation) with the patent status of the underlying invention. While explicit "patent linkage" systems whereby regulators defer approval of generics until patent expiry are well established in some high-income jurisdictions, India does not have a formal linkage regime embedded in law. Rather, regulatory agencies may consider patent information in extraordinary cases, but explicit legal mechanisms tying patent enforcement to regulatory approval remain limited and contested. Proponents argue that clearer linkage mechanisms could protect innovators from premature generic entry, while critics caution against such linkage raising drug prices and impeding access without commensurate innovation gains.

India's patent opposition framework is another critical feature shaping its IP environment. The Patents Act, 1970 provides for both pre-grant and post-grant opposition proceedings, allowing interested parties to challenge patent applications at two distinct stages. Under Section 25(1), pre-grant opposition can be filed after publication of a patent application but before grant, enabling third parties to contest on grounds such as lack of novelty or obviousness. Post-grant opposition under Section 25(2) permits similar challenges within a defined period after patent grant, providing a mechanism for public accountability and quality control of patents. These opposition procedures serve as cost-effective alternatives to full litigation and can deter overly broad patents that might stifle competition. However, critics also claim that aggressively used opposition mechanisms can create uncertainty and delay for genuine innovators seeking exclusivity in high-risk areas like biopharmaceuticals.

There are broader debates about whether India's IP environment sufficiently incentivizes breakthrough innovation. Some scholars and industry stakeholders argue that while the legal structures are TRIPS compliant, enforcement challenges, limited patent term extensions, and the absence of data exclusivity provisions (comparable to those in the EU or U.S.) reduce innovation incentives for high-risk biologic research.[23] Others note that innovations rooted in India's rich traditional knowledge or biodiversity may face additional complexities within the global patent ecosystem, suggesting opportunities for tailored IP strategies that protect indigenous discoveries while promoting equitable innovation.

C. Innovation Incentives

Promoting biopharmaceutical innovation in India requires more than regulatory clarity and patent protections; it also depends on effective innovation incentives that mobilize research funding, nurture entrepreneurial ventures, and link academia with industry.

The Department of Biotechnology (DBT) and the Department of Science & Technology (DST), both under the Ministry of Science and Technology are pivotal in directing public funding toward biopharmaceutical research and development. DBT's strategic initiatives include grant programs, mission-mode projects, and infrastructure support aimed at developing high-impact technologies such as biologics, bio-manufacturing, and vaccine platforms. Its policies emphasise commercialisation of research, translational science, and human capital development, often through biotechnology research parks, incubators, and collaborative consortia with international partners.

Examples of DBT's targeted funding include joint calls for proposals on precision biotherapeutics (such as mRNA therapeutics and monoclonal antibodies), aligned with broader bio-manufacturing policy goals. DBT also implements unified digital platforms (e.g., DBT- SAHAJ) that facilitate access to high-end research infrastructure across institutions, reducing duplication and enhancing collaborative R&D.[28] Meanwhile, DST complements these efforts through funding for basic and interdisciplinary research, innovation ecosystems, and technology development programs that support early-stage scientific discoveries relevant to biopharmaceutical innovation. Despite these public funding mechanisms, challenges persist. India's total R&D expenditure as a percentage of GDP remains below global averages for research-intensive economies, limiting the scale of high-risk, long-horizon

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innovation projects. Furthermore, there are concerns over a "valley of death" in funding where translational research fails to attract sufficient investment between proof-of-concept and commercialisation, especially for biopharmaceutical ventures requiring costly clinical trials.

The Indian government provides a range of tax incentives aimed at stimulating innovation and investment in research-driven sectors. These include deductions for R&D expenditure under the Income Tax Act, favourable depreciation rates for scientific equipment, and incentives for firms engaged in biotechnology and life sciences. Specific fiscal measures allow companies undertaking approved scientific research to claim weighted deductions on qualifying R&D expenditure, effectively lowering the after-tax cost of innovation investment.[31] Such incentives are intended to encourage both domestic firms and multinational enterprises to deepen their innovation footprints in India. However, tax incentives intersect with broader debates on equitable treatment and administrative clarity. Industry stakeholders sometimes highlight inconsistencies in tax enforcement or qualification criteria that may dilute the effectiveness of R&D incentives, especially for startups and smaller firms that lack dedicated tax planning capacities.

India's Startup India Initiative and ecosystem programs represent another vector of innovation policy support. Designated startups can benefit from tax holidays, simplified regulatory compliance, and access to government-backed funding through schemes such as the Biotechnology Industry Research Assistance Council (BIRAC), a DBT-supported entity that provides early-stage funding, seed capital, and enterprise support. BIRAC's interventions include competitive funding programs (e.g., Biotechnology Ignition Grants, BIPP, SEED) that help startups bridge initial capital gaps and scale nascent technologies.

In parallel, the government has promoted biotechnology innovation clusters and networks of incubators, technology transfer offices, and academic-industry interfaces to nurture entrepreneurial ventures. National strategies envision establishing standalone bio-innovation hubs and linkages across research institutions to enhance technology commercialisation and market adoption. Some of these efforts align with broader BioE3 policy objectives, targeting resilient bio-manufacturing, Bio-AI integration, and capacity building aimed at achieving a projected $300 billion bioeconomy by 2030.

Nonetheless, structural gaps remain in converting innovative ideas into globally competitive products. Fragmented infrastructure, limited late-stage venture capital, and the need for stronger industry-academia collaboration are recurrent themes in policy critiques. Addressing these requires not only policy instruments but also ecosystem maturity that supports sustained investment, risk capital, and commercial pathway acceleration for breakthrough biopharmaceutical innovations.

India's biopharmaceutical policy framework presents a multifaceted blend of regulatory governance, IP law adaptation, and incentive instruments aimed at bolstering innovation while ensuring equitable access. The CDSCO's regulatory modernization through NDCTR 2019, ongoing digital reforms, and public safety initiatives reflect important strides toward coherent governance. India's TRIPS-compliant IP regime, while balancing access imperatives, continues to spark debate around linkage mechanisms and global competitiveness. Meanwhile, public funding, tax incentives, and startup-oriented programs provide critical support for early-stage innovation, though persistent funding gaps and ecosystem weaknesses suggest the need for continued policy refinement.

India's approach underscores a broader ambition: to move beyond its generics-dominant identity toward a more innovation-driven biopharmaceutical sector that contributes meaningfully to global health solutions, domestic capacity building, and sustainable economic growth. This evolution will hinge on coherent policy implementation, regulatory foresight, and targeted investments that align scientific excellence with entrepreneurial dynamism.

BIOPHARMACEUTICAL POLICY IN THE EUROPEAN UNION

The European Union (EU) has developed one of the most structured policy regimes in the world for biopharmaceutical innovation. With a highly coordinated regulatory architecture, integrated market access procedures, and a layered set of intellectual property (IP) and incentive mechanisms, the EU seeks to balance patient access with scientific competitiveness and industrial growth. This section examines the EU's regulatory framework, IP regime, and innovation support mechanisms in detail.

A. European Medicines Agency (EMA)

At the heart of the EU's biopharmaceutical regulatory architecture is the European Medicines Agency (EMA), established in 1995 and operational under EU law to support the scientific evaluation, supervision, and safety monitoring of medicines. The EMA is a decentralized agency of the EU whose scientific committees conduct evaluations for marketing authorization and provide guidance on benefit-risk assessments for human and veterinary medicinal products across Member States[27].

The EMA's mandate encompasses:

- Evaluation of marketing authorization applications via scientific committees (e.g.,
- **Committee for Medicinal Products for Human Use (CHMP)**).
- Post-marketing pharmacovigilance and safety surveillance.
- Scientific advice and protocol assistance for developers, including formal consultation mechanisms early in the development process (e.g., PRIME designation to support priority medicines)[28].

The EMA's centralised scientific evaluation is essential for ensuring a harmonised risk–benefit review across the bloc, forestalling fragmented national decisions that could impede cross- border innovation and market deployment[29]. While Member States maintain national competent authorities, the EMA functions as a supranational scientific hub that consolidates expertise and regulatory standards.

Centralized vs. Decentralized Procedures

The EU employs multiple approval pathways designed to streamline medicine authorisations and ensure broad market integration:

Centralised Procedure: Under Regulation (EC) No. 726/2004 and implemented through the EMA, the centralised procedure grants a single marketing authorisation valid across all EU Member States. This pathway is compulsory for:

- Medicines derived from biotechnology processes.
- Orphan medicinal products (rare disease therapeutic agents).
- Advanced Therapy Medicinal Products (ATMPs) such as gene and cell therapies.

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ISSN: 1053-7899
Vol. 36 Issue 1, Jan-June 2026, Pages: 1729-1736

- Medicines containing new active substances for HIV/AIDS, cancer, diabetes, neurodegenerative diseases, and certain other serious conditions[30]

The centralized process improves efficiency and reduces duplicative national assessments by providing a one-stop scientific evaluation and authorization that applies EU-wide31. Optional centralized review is also available for products deemed significant innovations or of public health interest, reinforcing the framework's flexibility.

Decentralized Procedure: For products not mandated or opting into the centralized pathway, the decentralized procedure allows applicants to seek simultaneous marketing authorization in multiple Member States based on one assessment dossier, coordinated among national regulators. Member States mutually recognize scientific assessments and share evaluations to reduce regulatory burden.

Mutual Recognition Procedure (MRP): In cases where a medicine already has national approval in one Member State, other Member States can recognize that approval to authorize the product without independent re-evaluation. These multiple pathways strike a balance between regulatory harmonization and subsidiarity, recognizing the diverse capacities and legislative traditions of Member States while fostering wider access across the Single Market.

Overall, the EU's regulatory architecture reflects a multi-tiered system designed to promote consistent scientific standards while avoiding unnecessary duplication or market fragmentation. This structure has been instrumental in supporting integrated market access for innovative biopharmaceuticals and enhancing regulatory predictability for developers.

B. Intellectual Property Framework

A robust intellectual property regime is fundamental to biopharmaceutical innovation given the high scientific risks and substantial development costs involved. In the EU, IP protection for pharmaceutical products operates through both patent extensions (Supplementary Protection Certificates) and data exclusivity regimes, which collectively extend exclusivity beyond basic patent terms to reward innovation.

Supplementary Protection Certificates (SPCs)

A Supplementary Protection Certificate (SPC) is a legal instrument that extends the protection conferred by a patent for a medicinal product that has received regulatory marketing authorization. SPCs are intended to compensate for the time lost during the lengthy clinical trial and approval phases, which can significantly erode effective patent life. Under current EU rules, an SPC can extend a patent right for a maximum of five years beyond the expiry of the corresponding patent. An additional six-month extension is possible if the product has completed an agreed-upon Paediatric Investigation Plan (PIP), designed to encourage the development of medicines for children. The SPC regime thus serves as a critical incentive for biopharmaceutical innovators by enhancing the duration of exclusivity, allowing originators to recoup R&D investments and command market returns longer. SPCs have been central to maintaining Europe's attractiveness for high-risk, high-reward pharmaceutical R&D relative to global competitors.

Recent policy discussions suggest potential reforms to the SPC framework aimed at simplifying issuance and enhancing consistency, including moving toward a centralized SPC system that cuts across Member States. Such reforms could further streamline protections and reduce administrative hurdles.

Data and Market Exclusivity Rules

Beyond patent-based mechanisms, the EU provides regulatory data protection and market protection, which function independently of patent law to reward clinical research investment. Under the current legislative framework:

- Innovative medicinal products receive eight years of data exclusivity, during which generic or biosimilar applicants cannot rely on the originator's pre-clinical and clinical data in their authorization submissions.
- An additional two-year period of market protection follows, during which generic or biosimilar products may obtain authorization but cannot enter the market until the exclusivity expires.

In practice, these provisions establish a ten-year baseline exclusivity period for regulatory protection. This period can extend up to eleven years if an authorized product obtains approval for a new therapeutic indication that offers significant clinical benefit compared to existing therapies. Orphan medicinal products designed for rare diseases affecting no more than five persons per 10,000 in the EU benefit from specific exclusivity incentives. Sponsors of orphan medicines can receive ten years of market exclusivity (distinct from data and market protection) during which no similar products targeting the same condition may be marketed. Fee reductions and scientific protocol assistance further support orphan product development. The EU's data and market protection regime thus provides regulatory exclusivity that functions alongside SPCs to create a dual-layered incentive for innovation. These protections are significant drivers of investment in novel therapeutic development across the EU.

Notably, recently negotiated reforms to the EU's pharmaceutical legislation (the so-called "pharma package") reaffirm these core protections but recalibrate certain elements to balance innovation incentives with access and competition goals. For example, the baseline exclusivity structure under the provisional deal provides eight years of data protection and one year of market protection, with potential extensions tied to unmet medical needs and other criteria. These reforms reflect an evolving equilibrium in the EU's IP policy seeking to maintain sufficient exclusivity to encourage investment, while ensuring access and cost-effective competition through measured adjustments.

C. Innovation Support

Beyond regulatory and IP exclusivity, the EU employs innovation support mechanisms that leverage public funding, collaborative research programs, and targeted incentives to stimulate biopharmaceutical R&D. Key among these are Horizon Europe and the Orphan Drug Regulation.

Horizon Europe

Horizon Europe is the EU's flagship research and innovation framework program for 2021– 2027, with an overall budget of roughly €95.5 billion. A substantial portion of this funding supports health research, including biopharmaceutical innovation, advanced therapies, and translational science.

Horizon Europe's Health cluster funds initiatives on:

MSW MANAGEMENT -Multidisciplinary, Scientific Work and Management Journal
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Vol. 36 Issue 1, Jan-June 2026, Pages: 1729-1736

- Personalized medicine and therapeutic development.
- Innovative clinical trial methodologies.
- Biotechnologies that address priority health needs.
- Research infrastructures and partnerships to catalyse cross-disciplinary innovation.

The program also fosters cross-border collaboration between academia, industry, and public research institutes, thereby integrating fragmented national efforts into larger European value chains. Horizon Europe's grants, networks, and co-funded projects reduce financial barriers for early-stage research and enhance the EU's scientific capacity to compete globally. Horizon Europe thereby acts as a broad innovation ecosystem enabler, undergirding foundational science and commercial translation across biopharmaceutical domains.

Orphan Drug Regulation and Incentives

The EU Orphan Medicinal Products Regulation (Regulation (EC) No. 141/2000) provides a suite of incentives to encourage the development of medicines for rare diseases, conditions historically underserved due to limited commercial market potential. Under this regime:

- Medicines intended for rare conditions can obtain orphan designation, unlocking incentives such as reduced fees and specialized protocol assistance.
- Once authorized, an orphan medicine receives ten years of market exclusivity (distinct from other protections), during which similar medicinal products cannot be marketed for the same indication.
- Sponsors also benefit from scientific guidance aimed at optimizing clinical development pathways and regulatory submissions32.

The long market exclusivity period combined with fee waivers and support has helped drive a significant increase in orphan product development in the EU, with hundreds of designated products and over 200 approved therapies across rare diseases reported33. These incentives are critical for addressing unmet medical needs where small patient populations would otherwise offer limited return on investment Ongoing legislative reforms propose updates to the Orphan Regulation, including graduated exclusivity periods and targeted adjustments to better balance innovation rewards with access. For instance, proposals suggest recalibrating exclusivity durations based on unmet need levels and criteria for continuous supply across Member States[34].

Comparative Tables

Table 1: EU Regulatory Approval Pathways

Procedure	Scope	Authority	EU-wide Validity
Centralized	Biotechnology, ATMPs, orphan drugs, and new active substances for key diseases	EMA + EC	Yes
Decentralized	Multi-country marketing authorisations	National Authorities (coordination)	Selected MS
Mutual Recognition	National approval recognition	National Authorities	MS accepting recognition

Table 2: EU Innovation Incentives and Protection Types

Incentive/Protection	Duration	Primary Purpose
Data Exclusivity	8 years	Protect clinical data from use by generics
Market Protection	2 years (+ possible additional year)	Delay generic/biosimilar commercialization
Supplementary Protection Certificate (SPC)	Up to 5 years (+6 months PIP)	Extend patent life for pharmaceutical products
Orphan Market Exclusivity	10 years	Protect orphan medicine markets
Horizon Europe Funding	Variable grants/projects	Support R&D innovation networks

The EU's biopharmaceutical policy ecosystem reflects an integrated regulatory architecture designed to harmonise scientific evaluation across Member States, a robust IP framework that extends exclusivity through SPCs and data/market protection, and innovation support mechanisms such as Horizon Europe and the Orphan Drug Regulation that catalyse research and commercialization efforts. These policy instruments collectively enhance the EU's capacity to nurture advanced therapeutic innovation while attempting to balance access, competition, and industrial competitiveness.

As the EU advances reforms under the evolving pharmaceutical legislative package, these structures continue to adapt to global scientific trends, patient needs, and competitive pressures demonstrating an ongoing commitment to fostering a dynamic and sustainable biopharmaceutical innovation ecosystem.

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COMPARATIVE ANALYSIS: INDIA AND THE EUROPEAN UNION

This section provides a concise yet analytically robust comparative assessment of biopharmaceutical innovation policies in India and the European Union (EU). The comparison is structured around four key dimensions: regulatory stringency versus speed, effectiveness of innovation incentives, market access conditions, and innovation outcomes. Together, these dimensions capture how policy design translates into practical innovation performance.

1. Regulatory Stringency vs. Speed

Regulatory systems in biopharmaceuticals must reconcile two competing objectives: ensuring patient safety through rigorous evaluation and facilitating timely market access for innovative therapies.

The EU regulatory framework, anchored by the European Medicines Agency (EMA), is characterized by high regulatory stringency combined with procedural predictability. Centralized authorization ensures uniform scientific assessment across Member States, reducing duplication and regulatory fragmentation. Although the EU approval process is stringent, predefined timelines, scientific advice mechanisms, and accelerated pathways (such as PRIME) enhance regulatory speed for priority medicines. As a result, regulatory certainty in the EU is relatively high, which is particularly attractive for innovators developing complex biologics and advanced therapies.

India's regulatory system, led by the Central Drugs Standard Control Organization (CDSCO), has historically emphasized public health protection and affordability. While recent reforms under the New Drugs and Clinical Trials Rules, 2019 have improved clarity and transparency, regulatory speed remains uneven. Approval timelines for innovative biologics may be longer and less predictable compared to the EU, partly due to evolving institutional capacity and coordination challenges between central and state authorities. Consequently, India's regulatory environment is often perceived as moderately stringent but procedurally less predictable, particularly for first-in-class products.

2. Effectiveness of Innovation Incentives

Innovation incentives play a decisive role in mitigating the high costs and risks associated with biopharmaceutical R&D. The EU's incentive structure is comprehensive and layered. It combines strong intellectual property protections (SPCs, data and market exclusivity) with direct public funding through Horizon Europe and disease-specific incentives such as orphan drug exclusivity. These mechanisms collectively create a highly attractive innovation environment for novel therapeutics, particularly in areas of unmet medical need. Evidence suggests that such incentives have significantly increased investment in biologics, rare disease therapies, and advanced medicinal products within the EU.

India's innovation incentives are comparatively targeted and developmental in nature. Public funding through the Department of Biotechnology (DBT), Department of Science and Technology (DST), and BIRAC primarily supports early-stage research, startups, and translational innovation. Tax incentives and startup programs lower entry barriers but offer limited long-term exclusivity rewards. While effective in nurturing a vibrant startup ecosystem and incremental innovation, India's incentive framework is less effective in attracting large- scale investment for high-risk, novel biopharmaceutical R&D.

3. Market Access

Market access determines whether innovation ultimately translates into patient benefit and commercial viability. The EU offers seamless market access through its centralized authorization system, allowing approved medicines to enter all Member States under a single license. However, post-authorization access is influenced by national pricing and reimbursement decisions, which can introduce variability in actual patient access timelines. Despite this, the EU's large, integrated market provides innovators with scale and commercial predictability.

India's market access environment is shaped by price controls, procurement policies, and affordability considerations. While regulatory approval allows nationwide marketing, price regulation under instruments such as the National List of Essential Medicines can significantly constrain revenue potential for innovative products. This makes India less attractive as a primary launch market for novel biologics, although its large population and manufacturing strengths offer long-term strategic value.

4. Innovation Outcomes

Innovation outcomes reflect the cumulative impact of regulation, incentives, and market access on the production of new therapies. The EU demonstrates strong innovation outcomes, particularly in novel biologics, orphan drugs, and advanced therapies such as gene and cell treatments. High patent filings, EMA approvals, and global first launches indicate a robust innovation ecosystem supported by coherent policy design.

India's innovation outcomes are asymmetric. The country excels in generics, biosimilars, vaccines, and cost-efficient manufacturing, making it a global leader in affordable medicines. However, the number of globally novel biopharmaceuticals originating from India remains limited. Innovation outcomes tend to favour incremental and process innovation rather than breakthrough therapeutics.

The comparative analysis reveals that the EU's biopharmaceutical policy framework prioritizes innovation depth, supported by strong regulatory harmonization and exclusivity-based incentives, whereas India's framework prioritizes innovation breadth and access, leveraging cost efficiency, public funding, and IP flexibility. Neither model is universally superior; rather, they reflect context-specific policy choices aligned with economic capacity and public health priorities. Strategic policy learning and regulatory cooperation between India and the EU could help bridge gaps, combining Europe's innovation-intensive model with India's access-driven strengths to foster more inclusive global biopharmaceutical innovation.

RECOMMENDATIONS

Drawing from the comparative analysis, this study proposes targeted and actionable policy recommendations for India, the European Union, and joint cooperation, aimed at strengthening biopharmaceutical innovation while preserving public health objectives.

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A. Recommendations for India

India should prioritize strengthening regulatory capacity and predictability in its biopharmaceutical governance framework. While recent reforms under the New Drugs and Clinical Trials Rules, 2019 mark progress, further investments are required in regulatory infrastructure, scientific expertise, and digital review systems within the CDSCO. Establishing clearer timelines for approvals, expanding accelerated pathways for innovative biologics, and enhancing coordination between central and state regulators would improve regulatory confidence for innovators.

On the incentive side, India should move beyond early-stage funding dominance and develop mechanisms to support late-stage and translational biopharmaceutical research. This may include risk-sharing public–private partnerships, milestone-based funding for clinical trials, and selective exclusivity incentives for first-in-class biologics addressing unmet medical needs. Strengthening technology transfer offices and fostering deeper industry–academia collaboration will also be critical to converting scientific research into globally competitive products.

B. Recommendations for the European Union

For the EU, policy refinement should focus on greater flexibility within regulatory harmonization, particularly for startups and small and medium enterprises (SMEs). While the centralized EMA framework ensures scientific rigor, compliance costs and procedural complexity can disproportionately burden smaller innovators. Tailored regulatory guidance, reduced fees, and simplified authorization pathways for SMEs could improve innovation inclusivity without diluting safety standards.

In parallel, ongoing reforms to intellectual property and exclusivity regimes should maintain a careful balance between innovation incentives and timely access. Targeted use of exclusivity extensions linked to demonstrable therapeutic benefit, coupled with early access and adaptive licensing models, can ensure continued investment while responding to affordability concerns.

C. Joint India–EU Initiatives

At the bilateral level, India and the EU should pursue regulatory cooperation and mutual learning. Joint scientific advisory platforms, shared clinical trial data standards, and collaborative research funding particularly in vaccines, antimicrobial resistance, and neglected diseases can generate synergistic innovation outcomes. Such cooperation would also strengthen global preparedness for public health emergencies and reinforce equitable innovation governance.

CONCLUSION

This comparative study demonstrates that biopharmaceutical innovation policies in India and the European Union are shaped by distinct economic capacities, regulatory philosophies, and public health priorities. The EU's policy framework emphasises regulatory harmonisation, strong intellectual property protection, and extensive innovation incentives, resulting in robust outcomes in novel biologics and advanced therapies. India, in contrast, has developed a policy model oriented toward affordability, access, and cost-efficient innovation, achieving global leadership in generics, biosimilars, and vaccine manufacturing while gradually expanding its innovation ambitions. The analysis underscores that neither model is inherently superior; rather, each reflects context-specific trade-offs between innovation depth and access equity. Importantly, the growing convergence of global health challenges: pandemics, antimicrobial resistance, and chronic diseases demands policy approaches that transcend traditional divides between developed and emerging economies. Strategic regulatory cooperation, adaptive intellectual property governance, and inclusive innovation incentives can enable both India and the EU to strengthen their biopharmaceutical ecosystems while contributing to global public health goals.

This study highlights that sustainable biopharmaceutical innovation must be grounded in balanced governance, one that rewards scientific risk-taking, ensures patient safety, and guarantees equitable access. As global health interdependence deepens, lessons drawn from the Indian and EU experiences offer valuable guidance for designing innovation policies that are not only economically efficient but also socially responsive and globally just.