Council for Innovation Promotion
C4IP®

The Honorable Andrei Iancu, Co-Chair
The Honorable David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
The Honorable Gary Locke, Board Member
The Honorable Lamar Smith, Board Member
Frank Cullen, Executive Director

November 6, 2025

Via Electronic Submission
Dr. Rajeev Singh Raghuvanshi
Drugs Controller General of India
Central Drugs Standard Control Organization
Bhavan, ITO, Kotla Road, New Delhi -110002

Re: Response to India's Invitation to Comment on Its Drug Approval Regime

Respected Dr. Raghuvanshi:

The Council for Innovation Promotion (C4IP) commends the Central Drugs Standard Control Organization (CDSCO) for initiating a public consultation on how to incentivize drug development in India and for recognizing the lack of level playing field" between the first applicant seeking approval for a new drug and subsequent applicants seeking approval using the first applicant's data.

This initiative reflects CDSCO's deep understanding of the challenge facing innovators who invest significant time and resources in development and clinical testing to bring a new drug to the market. India's commitment to improving the domestic regulatory environment for pharmaceuticals demonstrates both foresight and leadership. Strengthening your drug regulatory procedures will significantly contribute to advancing India's broader goals of encouraging scientific advancements, expanding access to quality healthcare, and cementing your position as a leading hub for biopharmaceutical research and clinical innovation.

C4IP is a bipartisan coalition dedicated to promoting strong and effective IP rights, driving innovation, boosting economic competitiveness, and improving lives everywhere. Our co-chairs are two former Under Secretaries for Intellectual Property and U.S. Patent and Trademark Office (USPTO) Directors: Andrei Iancu, who served in the first Trump administration, and David Kappos, who served in the Obama administration. Our board includes two retired judges from the Court of Appeals for the Federal Circuit: former Chief Judge Paul Michel, who was appointed by President Reagan, and former Judge Kathleen O'Malley, who was appointed by President Obama. Our board also includes two distinguished public servants: Gary Locke, former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China under President Obama; and Lamar Smith,

former U.S. Representative for Texas's 21st congressional district and Chairman of the House Judiciary Committee.

We welcome the opportunity to engage constructively as India weighs growth-oriented reforms to improve its drug regulatory framework by setting forth policies that we believe have worked well in the United States. Our country has addressed the "lack of level playing field" referred to in your Notice through regulatory data protection (RDP) and data exclusivity, and we will set forth the rationale for why this is a best practice below.

Robust RDP ensures that valuable clinical trial and safety data submitted by an originator company cannot be used by another firm to obtain marketing approval for a defined period, typically five to 10 years. It does not extend a patent or block generic competition indefinitely. Rather, it provides temporary protection for the data itself — the product of years of research, testing, and regulatory review — in light of the significant investments needed to generate that data.

Clinical trials account for the majority of drug development costs. Without a reliable drug regulatory framework, subsequent applicants can rely on this data at little cost, gaining an immediate regulatory advantage without investing in research or clinical validation. This dynamic discourages both domestic and international innovators from conducting trials in-country or introducing new products in markets that lack predictable data protection.

Addressing this imbalance between first and subsequent applicants has been a central focus of reforms worldwide. The United States adopted data protection provisions through the 1984 Hatch-Waxman Act, which helped balance medical advancement with timely generic entry. The reform provided five years of data protection for new small-molecule drugs and, later on, through the Patient Protection and Affordable Care Act, 12 years of data protection for biologics.

The results were transformative. Predictable RDP encouraged investment, supported public-private partnerships, and laid the foundation for America's biotechnology revolution. Today, the U.S. biopharmaceutical sector generates over $340 billion in economic output and supports over 1 million jobs, while 90% of prescriptions are filled with affordable generics.

Other countries, including Japan, Canada, and South Korea, as well as the European Union, have also realized substantial economic gains after implementing modernized drug regulatory frameworks. Their experiences demonstrate that predictable data protection strengthens national research capacity, manufacturing capability, and regulatory integrity.

As India evaluates potential reforms to its data protection framework, we recommend that it consider adopting a similar RDP framework to reward and incentivize the first applicant of a new drug to seek regulatory approval in India.

By establishing predictable data exclusivity rules, a strengthened regulatory framework creates a transparent and balanced system: drug developers can recoup their investment, and generic manufacturers retain the ability to enter the market later with their own data or after the exclusivity period expires. Adopting such a system will promote innovation and, ultimately, strengthen competition, expanding access to affordable medicines.

A balanced framework that ensures a level playing field in the use of clinical and bioequivalence data would directly benefit Indian scientists, startups, and universities. Investors and research institutions would gain greater confidence to conduct clinical trials and launch new products in India. India's role in global research collaboration would also expand, facilitating valuable technology transfer and knowledge exchange. By recognizing and safeguarding the value of data generated through early-stage research, such a framework would create stronger incentives for domestic drug development, not merely for manufacturing and formulation work.

Greater clarity and predictability around data use would also encourage investment in studies addressing India's own public health priorities, including diseases that are often underrepresented in global research. At the same time, it would strengthen the quality and reliability of locally generated evidence that underpins regulatory decisions and patient trust.

India has rightly earned its place as the pharmacy of the world. Building on that foundation, a transparent and equitable data-governance system — aligned with global best practices — would position the country as a leader in drug discovery and clinical research, reinforce its reputation for quality and trust in global health partnerships, and complement the government's broader digital-governance and transparency initiatives.

This, together with enhanced cooperation between regulators, universities, and industry to expand training and technical expertise, would reinforce India's R&D capacity and bolster its biopharmaceutical workforce, while ensuring transparent oversight and public trust.

India has demonstrated formidable success as a global supplier of medicines. Strengthening its procedures for intellectual property associated with new drugs represents a natural next step — one that will empower Indian scientists and entrepreneurs to bring more discoveries to market and continue competing on the world stage.

The experiences of other nations show that well-designed data-protection policies stimulate research, attract investment, and expand patient access in the long term. By taking this step, India can build on its proven strengths to drive the next phase of biopharmaceutical growth — creating high-value jobs, strengthening its innovation economy, and enhancing its global competitiveness.

We respectfully commend CDSCO for engaging stakeholders in this important process and stand ready to provide any additional information that may assist in shaping an effective, forward-looking regulatory framework in India.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)