STRENGTHENING THE INNOVATION ECOSYSTEM FOR BIOPHARMACEUTICALS IN INDIA

INVEST INDIA ROUNDTABLE REPORT

OCTOBER 2019

EXECUTIVE SUMMARY

Invest India convened a roundtable with representatives from government and industry on October 18, 2019 to discuss opportunities to strengthen India's innovation ecosystem. The roundtable focused on identifying potential policy opportunities to catalyze innovation in the biopharmaceutical sector – with the dual benefits of increasing patient health and safety, while also promoting investment and job creation in the sector. The roundtable participants identified and recommended a number of important policy reforms to expedite progress and bolster India's biopharmaceutical sector, which are outlined in this report.

RECOMMENDATIONS FROM THE ROUNDTABLE

International Harmonization with Global Regulatory Best-Practices

Creation of Standard Operating Procedures for the Approval of New Drugs

Formation of Single-Window Regulatory Tracking Department

Increase Transparency in Central and State Regulators

Strengthen Academic-Industry Linkages

INTERNATIONAL HARMONIZATION WITH GLOBAL REGULATORY BEST PRACTICES

Opportunity

The adoption and consistent implementation of the broad suite of internationally harmonized technical and regulatory guidelines that are developed and maintained by the International Council for Harmonization (ICH) is a foundational step in creating a strong regulatory framework. India's Central Drugs Standard Control Organization (CDSCO) has recently taken important foundational steps to become an active observer to the ICH Assembly, the association's main governance body. It is important to note that China became a full member of the ICH in June 2017, following active participation in the ICH as an observer and implementation of the Tier I guidelines. China's elevation within ICH enables the country to have a prominent voice in shaping ICH regulations as it pursues domestic regulatory reforms that continue to attract global investment and promote innovation.

Roundtable Discussion

In the roundtable, participants discussed the importance of strengthening the exchange of regulatory best-practices with global peers. To do so, India should become an observer at the Pharmaceutical Inspection Convention (PIC), participate in ICH, and closely collaborate with regulatory agencies of countries with large markets. As the ICH continues to develop new guidelines that will govern future innovation, it is important for India to have an influential voice in the ICH's scientific and technical consensus-building process utilized to draft new guidelines. Roundtable participants affirmed that these steps enable India to create a robust business environment, promote the growth of the biopharmaceutical sector, and improve healthcare for Indian patients. These steps are important to improve the quality perception of Indian drugs and expedite approvals of new drugs.

Recommendations to the Government of India

To ensure India has a seat at the table in shaping the ICH's pro-innovation frameworks, CDSCO should immediately begin to position itself to become a full ICH member by becoming active in ICH's governance and expert working groups through the steps outlined below.

- Build on positive steps over the past year, including DCGI's participation in ICH in June 2019.
- Appoint CDSCO subject matter experts to participate in ICH working groups, such as those focused on clinical trials and generics.
- Establish a CDSCO plan to implement ICH guidelines.
- India to become an observer at the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

> *"We applaud the important steps the Indian government has taken over the past year to participate in global standards conversations. These efforts are critical to the growth of India's pharmaceutical sector, as well as health and safety of Indian patients."*

CREATION OF STANDARD OPERATING PROCEDURES FOR NEW DRUGS

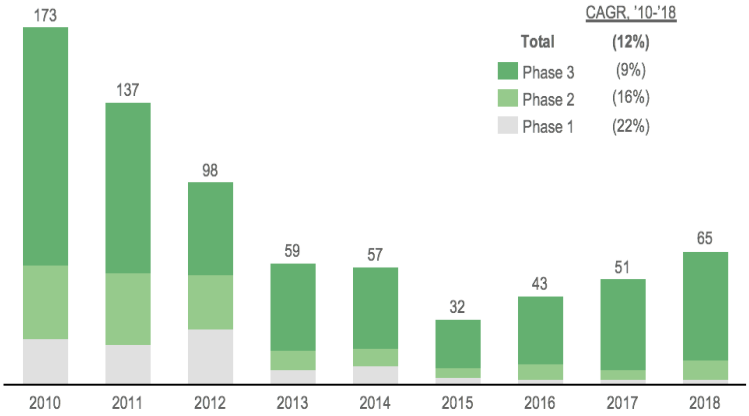
Opportunity

As India take steps to increase development of innovative and life-saving drugs, it will be critical for the government to develop a robust and transparent system to conduct clinical trials in India. Clinical trials are important to determine the impact of new potential treatments, and the absence of defined service-level agreements has created significant delays in the approvals of clinical trials in India. Globally, regulators commit and adhere to defined timelines for response, as well as provide a recourse in the event of a delayed response. For example, there is a defined six-month approval timeline for priority new drugs in China, as well as automatic approval in the event of no response from regulators.

Roundtable Discussion

At the roundtable, participants discussed the importance of creating new Standard Operating Procedures (SOPs) to streamline the multiple processes currently involved in the approvals of new drugs and innovative drugs. Alongside these SOPs, it will also be important to set enforceable timelines for each stage. This may also include removal of processes not required or processes which can be combined to reduce the timelines.

Industry funded clinical trials in India by development stage, 2010 to 2018



	2010	2011	2012	2013	2014	2015	2016	2017	2018
% Phase 1	13%	15%	28%	12%	16%	13%	7%	6%	5%

Recommendations to the Government of India

Reduce complexity in approval process

- Reduce the number of overlapping approvals for new drugs.
- Increase the speed of approval for large animal studies by empowering the Institutional Animal Ethics Committee (IAEC) without additional approval from the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).
- Establish accelerated approval pathways for innovative products in alignment with global best practices, such as adoption of ICH standards.

Strengthen consistency and quality of review

- Establish clear SOPs and timelines for each process stage.
- Improve consistency from expert committees in the approval guidance.
- Advance adoption of ICH harmonized guidelines and standards.

FORMATION OF SINGLE-WINDOW REGULATORY TRACKING DEPARTMENT

Opportunity

To ensure fast and efficient approval of new life-saving medicines, India would benefit from the creation of a single-window regulatory tracking department. Currently, the lack of a dedicated project management office for new dugs has limited transparency and delayed timelines for approval of drugs and medicines. Globally, leading regulatory bodies such as the U.S. Food and Drug Administration and the China's National Medical Product Administration have dedicated project managers that serve as a single point-of-contact for industry.

Roundtable Discussion

In the roundtable, participants noted there are currently multiple authorities involved in the drug approval process, and the process is not uniform across authorities. Additionally for different types of drugs, separate approvals are required for initiating R&D activities, as well as import and export approvals.

Going forward, India has the opportunity to ensure clear division of regulatory responsibilities between the central government and the states, with a harmonized legal interpretation of the enforcement functions.

Additionally, it was unanimously suggested that India should take steps to create a centralized regulatory body for the clearance of all regulatory approvals under a single window system. Participants recommended that the Indian government create a dedicated Union Ministry of Pharmaceuticals to simplify policy-making, increase the speed of the product approval, and expedite investment.

6

Agencies involved in the regulatory approval of biosimilar drugs in India

32

Steps required for regulatory approval of biosimilar drugs in India

34-75

Months duration before approval of biosimilar drugs in India

Recommendations to the Government of India

- Create a single-window regulatory tracking department or a similar suitable format, each for regulatory processes and innovative drugs.
- Enhance transparency and collaboration with industry in the approvals process.
- Implement pre-submission discussions systematically and increase transparency and visibility on the review status.
- Shift the proof of burden to the sponsor, rather than reviewers, to reduce risk-averseness in the process.

INCREASE TRANSPARENCY IN CENTRAL AND STATE REGULATORS

Opportunity

One of the most significant challenge facing biopharmaceutical applicants seeking marketing approval in India is that regulatory and manufacturing approvals are not transparent or coordinated between federal and state agencies. Four years after a new medicine is approved by the Central Drugs Standard Control Organization (CDSCO), Indian law allows state regulators to approve third-party manufacturers to commercialize copies of innovator products – regardless of whether those products infringe on an innovator's patent. Experience in competitive markets globally demonstrates that the approval of patent infringing follow-on medicines often results in irreparable harm to patients, innovators, and other producers.

Roundtable Discussion

As the Indian government takes steps to improve the business environment, there is a clear opportunity to improve the transparency and coordination of regulatory and manufacturing approvals in the pharmaceutical sector at the central and state levels. In the roundtable, participants discussed the importance of ensuring all biopharmaceutical manufacturers, relevant Indian authorities, and the broader public have timely notice of marketing and manufacturing applications filed with central and state regulators through the SUGAM portal. This is a critical step to increasing innovation, improving the ease of doing business, and expanding patient access to innovative medicines.

Recommendations to the Government of India

Increase transparency and coordination in regulatory and manufacturing approvals at the central and state levels

- Implement the GSR 19(E) dated January 10, 2019 with the following additions:
  - Require mandatory registration.
  - Require registration from the application stage.
  - Establish specific timelines for each stage.
  - Create mechanism to protect commercially confidential and sensitive data.

Enhance regulatory data protection

- Add suitable provisions to the Drugs and Cosmetics Act 1940 and Rules 1945 to provide for Regulatory Data Protection for new medicines – including new indications, formulations, and combinations.

STRENGTHEN ACADEMIC-INDUSTRY LINKAGES

Opportunity

As India seeks to strengthen the innovation ecosystem and increase development of new drugs and treatments, there is significant opportunity to foster greater cooperation and partnership between academia and industry. This model is used in many competitive economies globally, and further progress in this area will be important for India's progress in strengthening innovation and expanding access to high-quality, affordable medicines.

Roundtable Discussion

Building off the discussion in the July 2018 roundtable, participants reaffirmed their commitment to strengthening academic-industry linkages. A key area of opportunity is strengthening both the incentives for innovation, as well as the intellectual property rights protections. Roundtable participants pointed to global policies that have been effective in fostering greater academic-industry linkages, including the U.S. Bayh-Dole Act and Sweden's "Professor's Rights," where a patent generated by academic research belongs to the scientist, not to the university.

Recommendations to the Government of India

Advance policies to incentivize investment in innovation

- Incentivize private investment in R&D.
  - Re-instate 200% tax exemption on R&D spend.
  - Create tax incentives for use and deployment of start-ups' products and technologies.
- Strengthen ownership of innovation
  - Introduce guidelines for non-statutory compliance legislation in India to promote translational research, such as that similar to the U.S. Bayh-Dole Act or Sweden's "Professor's Rights."

Build domestic capacity

- Increase startup support and expand access to innovation
  - Create dedicated facility to provide information and guidance and fast-track approvals.
  - Create an e-marketplace for technologies developed by startups and academia.

The Bayh-Dole Act: Proven Model for Catalyzing Innovation

A hallmark policy passed with bipartisan support in the United States in 1980, the Bayh-Dole Act facilitates technology transfer from universities to the private sector. Bayh-Dole allows schools and other institutions to own title to the patents arising directly from their research activities and license the rights to the most promising technologies to private sector partners for commercialization. These companies then assume the full risk of development and cost for commercializing the technologies.

Staggering Results

- Commercialization of federally-funded research has increased dramatically -- between 1980 and 2002 alone, U.S. universities generated a **tenfold increase in patents**.
- Technology transfer activity has a **significant impact on the U.S. economy**, with one study finding that between 1996 and 2013, academia-private sector patent licensing across all industries bolstered U.S. GDP by up to USD 518 billion and supported up to 3,824,000 U.S. jobs.

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Government Participants

- **Prof. K. VijayRaghavan,** Principal Scientific Adviser to Government of India
- **Dr. P.D. Vaghela**, Secretary, Department of Pharmaceuticals
- **Dr. Renu Swarup**, Secretary, Department of Biotechnology
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- **Navdeep Rinwa**, Joint Secretary, Department of Pharmaceuticals
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- **Shruti Singh**, Director, Department of the Promotion for Industry and Internal Trade
- **Dr. Anurag Agrawal**, Director, Institute of Genomics and Integrative Biology
- **Nitin K Jain**, Scientist, Department of Biotechnology
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- **Dr. Manish Diwan**, Head of Strategic Partnerships and Entrepreneurship Development, Biotechnology Industry Research Assistance Council
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Industry Participants

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Industry Participants

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