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DEPARTMENT OF
SCIENCE & TECHNOLOGY

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

INDIAN PHARMACEUTICAL SECTORIAL SYSTEM OF INNOVATION (IPSSI)

United Nations Industrial Development Organization (UNIDO) &
Department of Science & Technology, Government of India

March 2023

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INDIAN PHARMACEUTICAL SECTORIAL SYSTEM OF INNOVATION (IPSSI) - MEASUREMENT, ANALYSIS AND POLICY RECOMMENDATIONS

UNIDO-DST Survey Report

March 2023 Vienna, Austria

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डॉ. जितेन्द्र सिंह
राज्य मंत्री (स्वतंत्र प्रभार)
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राज्य मंत्री अंतरिक्ष विभाग
भारत सरकार

सत्यमेव जयते

Dr. JITENDRA SINGH
Minister of State (Independent Charge)
of the Ministry of Science and Technology;
Minister of State (Independent Charge)
of the Ministry of Earth Sciences;
Minister of State in the Prime Minister's Office;
Minister of State in the Ministry of Personnel,
Public Grievances and Pensions;
Minister of State in the Department of Atomic Energy and
Minister of State in the Department of Space
Government of India

MESSAGE

I am pleased to extend my warmest congratulations to the Department of Science and Technology (DST) and the United Nations Industrial Development Organization (UNIDO) on the successful completion of the National Manufacturing Innovation Survey (NMIS) 2021-22. The results of the survey provide significant insight into the state of innovation in India's manufacturing sector. The Government of India has been steadfast in its commitment in promoting the competitiveness of Indian manufacturing and increasing its contribution to the GDP. In the past decade, key policies and programmes have been implemented to stimulate innovation, entrepreneurship and the adoption of new technologies. Additionally, large-scale incentive schemes have been introduced to foster growth and innovation in the manufacturing sector, positioning India as a global manufacturing hub.

The findings of the NMIS 2021-22 can add significant value to the Make in India programme objective, and, the more recent Production Linked Incentive (PLI) scheme. These initiatives aim to enhance manufacturing in various sectors, including electronics, pharmaceuticals, and automobiles, and have already demonstrated positive outcomes. The study's recommendations will undoubtedly strengthen our efforts to address the challenges and opportunities in manufacturing that require immediate attention.

I would once again like to applaud DST and UNIDO for their fruitful collaboration in bringing out NMIS reports and offering recommendations for continued growth and success of the Indian manufacturing sector.

(**Dr. Jitendra Singh**)
MBBS (Stanley, Chennai)
MD Medicine, Fellowship (AIIMS, NDL)
MNAMS Diabetes & Endocrinology

Anusandhan Bhawan, 2, Rafi Marg
New Delhi - 110001
Tel. : 011-23316766, 23714230,
Fax. : 011-23316745

South Block, New Delhi – 110011
Tel. : 011-23010191 Fax : 022-23017931
North Block, New Delhi – 110001
Tel. : 011-23092475 Fax : 011-23092716

सत्यमेव जयते

डॉ. एस. चंद्रशेखर
Dr. S. Chandrasekhar

सचिव
भारत सरकार
विज्ञान एवं प्रौद्योगिकी मंत्रालय
विज्ञान एवं प्रौद्योगिकी विभाग
Secretary
Government of India
Ministry of Science and Technology
Department of Science and Technology

FOREWORD

I am pleased to present the National Manufacturing Innovation Survey (NMIS) 2021-22 report on behalf of the Department of Science and Technology (DST), Government of India. The significance of this study lies in the government's prioritization of the manufacturing sector as a critical driver of economic growth and job creation in India, and the launch of several initiatives to catalyse innovation across the industry.

NMIS 2021-22, a follow up of first Indian innovation survey in 2011, is a focused effort to evaluate the state of innovation in India's manufacturing sector. In collaboration with the United Nations Industrial Development Organization (UNIDO), this survey provides a comprehensive understanding of the Indian manufacturing innovation landscape.

The NMIS 2021-22 findings offer valuable insights into the enabling characteristics and barriers to innovation faced by firms, and closely evaluated the performance of states and sectors in terms of producing new products and services. The detailed analysis of the survey results provides valuable insights into the innovation ecosystem in India. I anticipate this report to be of great interest to policymakers, researchers, and practitioners in the field of innovation and economic development.

Furthermore, the findings and recommendations of NMIS offer strong insights for strengthening the scope of the 5th National Science, Technology and Innovation Policy (STIP) (draft), to enable a holistic ecosystem for science, technology, and innovation that includes academia, industry, government, and civil society, with a stronger vision for manufacturing innovation to bolster the Make in India agenda.

I am confident that these reports will serve as an essential resource for all those interested in the state of innovation in India, providing valuable information that can contribute to the development of policies and initiatives that can foster a more innovative and dynamic manufacturing sector in the country.

(S. Chandrasekhar)

Technology Bhavan, New Mehrauli Road, New Delhi - 110016
Tel: 0091 11 26511439 / 26510068 | Fax: 00 91 11 26863847 | e-mail: dstsec@nic.in | website: www.dst.gov.in

Preface by Mr. Ciyong Zou, UNIDO Deputy to the Director General and Managing Director for publication of “the National Manufacturing Innovation Survey 2021-2022”

It is with great pleasure that I introduce the National Manufacturing Innovation Survey (NMIS) 2021-2022 report. Jointly conducted by the Department of Science and Technology (DST) of the Ministry of Science and Technology of India and the United Nations Industrial Development Organization (UNIDO), this report aims at comprehensively assessing the state of manufacturing innovation in India towards the achievement of the 2030 Agenda for Sustainable Development, especially Goal 9, and beyond.

As the only specialized agency of the United Nations mandated to promoting inclusive and sustainable industrial development, UNIDO recognizes the critical role that innovation plays in driving economic growth and job creation in the manufacturing sector. We are proud to partner with the DST in this endeavour to assess the state of innovation in India's manufacturing sector.

The NMIS 2021-2022 is a comprehensive study that provides a detailed understanding of the innovation landscape in India's manufacturing sector through a firm-level and systems analysis of innovation. The firm-level component of the survey examines the performance of firms across states, sectors, and firm sizes in terms of innovation processes, outputs, and barriers, and evaluates the innovation ecosystem that affects the innovation outcomes. The sectorial systems of innovation component provide insights into the collaborative processes between innovation stakeholders in specific industrial sectors, such as automotive, pharmaceutical, textiles, food and beverages, and information and communication technologies (ICT).

The findings of the NMIS 2021-2022 serve as a valuable resource to policymakers, researchers, and practitioners in the field of manufacturing, innovation, and economic development. The report highlights the enabling factors and barriers to innovation in the manufacturing sector and provides valuable insights for strengthening the ecosystem for science, technology, and innovation in India. The recommendations contained in this report will not only contribute to the development of national policies and initiatives but can also guide other countries in the region on ways to foster a more innovative and dynamic manufacturing sector.

I would like to express my sincere appreciation to the DST and the technical advisory committee for their valuable contributions to the NMIS 2021-2022. I also extend my gratitude to all the survey respondents who provided their insights and valuable information for this study serving as a public good. UNIDO is eager to continuing the long-standing collaboration with the Government of India in promoting inclusive and sustainable industrial development.

Ciyong Zou
Deputy to the Director General and Managing Director,
Directorate of Technical Cooperation and Sustainable Industrial Development,
United Nations Industrial Development Organization (UNIDO)

सत्यमेव जयते

वरिष्ठ सलाहकार एवं प्रमुख
नीति समन्वय एवं कार्यक्रम प्रबंधन प्रभाग
विज्ञान और प्रौद्योगिकी विभाग
विज्ञान और प्रौद्योगिकी मंत्रालय
भारत सरकार

डॉ. अखिलेश गुप्ता
Dr. Akhilesh Gupta

Senior Adviser & Head
Policy Coordination & Programme Management Division
Department of Science and Technology
Ministry of Science and Technology
Government of India

PREFACE

The National Manufacturing Innovation Survey (NMIS) 2021-22 is a significant step towards assessing manufacturing innovation in India. The objective of the survey was to evaluate the performance of states, sectors, and firm sizes in terms of innovation processes, outcomes, and barriers, as well as the innovation ecosystem that affects innovation outcomes. The NMIS 2021-22 offers a comprehensive understanding of manufacturing innovation in India from all perspectives.

The Department of Science and Technology (DST), in collaboration with the United Nations Industrial Development Organization (UNIDO), has developed the first Indian Manufacturing Innovation Index (IMII) for guiding decision-making in innovation policy with respect to manufacturing and related services. The significant difference in the IMII score captures the variations in manufacturing across the states.

The "Assessment of Firm-Level Innovation in Indian Manufacturing" report provides a comprehensive and in-depth analysis of innovation activities, outcomes, and barriers in manufacturing firms. Additionally, the NMIS 2021-22 survey produced five reports studying the sectorial systems of innovation within manufacturing sectors, namely, Automotive, Pharmaceutical, Textiles, Food & Beverages, and Information & Communication Technologies (ICT). These reports examine the collaborative processes between innovation stakeholders and the innovation systems available to specific industrial sectors.

The key findings from the study demonstrate that innovation is highly beneficial to manufacturing firms. Over a quarter of manufacturing firms in the country are innovative, and about eighty percent of these firms have used innovations successfully to increase turnover, open new market opportunities, and respond to market and cost pressures. However, the study also reveals that firms face a wide array of barriers to innovation, and innovation activities require perseverance and long-term commitment. Manufacturing firms demonstrate high risk-aversion and lack of entrepreneurial appetite to engage with innovation. Instead of competing for new products that are necessary to compete in the future, firms are still addressing the predominant and immediate demands in the market. These findings call for concerted efforts in strengthening manufacturing policies and bring attention to the need for an innovation strategy for the country, with particular attention to manufacturing.

I would like to express my sincere appreciation to all those who contributed to the creation of this report, including the UNIDO team and the technical advisory committee from DST. We sincerely hope that this report will be of great value as valuable resource and reference note.

(Akhilesh Gupta)

Technology Bhawan, New Mehrauli Road, New Delhi - 110016
Phone: +91-11-26862512 Email: akhilesh.g@nic.in, gakhilesh2008@gmail.com, Website: www.dst.gov.in

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Acronyms

4IR	Fourth Industrial Revolution
7ACA	7-aminocephalosporanic acid
ADP	Advanced Digital Production
ADMA	Ayurvedic Drug Manufacturers Association
AI	Artificial Intelligence
AIIMS	All India Institute of Medical Sciences
AIM	Atal Innovation Mission
AiMeD	Association of Indian Manufacturers of Medical Devices
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
APICF	Assistance to Pharmaceutical Industry for Common Facilities
ARB	Arbitrageur
ASI	Annual Survey of Industries
B2C	Business-to-consumer
BDMA	Bulk Drug Manufacturers Associations
Bio-NEST	Bio incubators Nurturing Entrepreneurship for Scaling Technologies
BIRAC	Biotechnology Industry Research Assistance Council
BNV	Beyond Next Ventures
BPPI	Bureau of Pharma Public Sector Undertakings of India
BTS	Bartlett’s Test of Sphericity
CAGR	Combined Annual Growth Rate
CAP	Creator Accelerator Programme
CARE-DAT	Centre for Advanced Research and Excellence in Disability & Assistive Technology
CBP	Cost-based pricing
C-CAMP	Centre for Cellular and Molecular Platforms
CDRI	Central Drug Research Institute
CDSCO	Central Drugs Standard Control Organization
CEFIPRA	Indo-French Centre for the Promotion of Advanced Research
CEO	Chief Executive Officer
CGMP	Current Good Manufacturing Practice
CIIE	Centre for Innovation Incubation and Entrepreneurship
CLCS-TUS	Credit Linked Capital Subsidy and Technology Upgradation Scheme
CMIE	Centre for Monitoring Indian Economy
CoE	Centre of Excellence
CoPP	Certificate for Pharmaceutical Products
COVID-19	Coronavirus Disease 2019
CPI	Consumer Price Index

CRAMS	Contract Research and Manufacturing services
CRS	Contract Research Service
CSIO	Central Scientific Instruments Organisation
CSIR	Council of Scientific & Industrial Research
CSR	Corporate Social Responsibility
DASI	Data Acquisition Survey Instrument
DASI - V4	Data Acquisition Survey Instrument Version 4
DBT	Department of Biotechnology
DGFT	Director General of Foreign Trade
DI	Drug Intermediary
DISK	Data Information Statistics and Knowledge
DMF	Drug Master Files
DoP	Department of Pharmaceuticals
DPIIT	Department of Promotion of Industry and Internal Trade
DSIR	Department of Scientific and Industrial Research
DST	Department of Science and Technology
DUI	Doing, Using and Interacting
EIC	Established Incubation Centre
EMA	European Medicines Agency
EMPEA	Emerging Market Private Equity Association
EQDM	European Directorate of Quality Medicine
ERP	Enterprise Resource Planning
FAPCCI	Federation of Andhra Pradesh Chambers of Commerce and Industry
FDA	Food and Drug Administration
FDC	Fixed-Dose combination
FDI	Foreign Direct Investment
FICCI	Federation of Indian Chambers of Commerce and Industry
FIC-ISID	Facility for International Cooperation for Inclusive & Sustainable Industrial Development
FITT	Foundation for Innovation and Technology Transfer
FTCCI	Federation of Telangana Chambers of Commerce and Industry
GDP	Gross Domestic Product
GFR	General Financial Rules
GHG	Green House Gases
GII	Global Innovation Index
GMP	Good Manufacturing Practices
GoI	Government of India
GOV	Government
GST	Goods and Services Tax
GVA	Gross Value Added
HDFC	Housing Development Finance Corporation Limited
HIMSS	Healthcare Information and Management Systems
HNI	High Net worth Individual
HRD	Human Resource Department

IAN	Indian Angel Network
IBM	International Business Machines
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICICI	Industrial Credit and Investment Corporation of India
ICMR	Indian Council of Medical Research
ICT	Information and Communication Technology
IDMA	Indian Drug Manufacturer's Association
IFCPAR	Indo-French Centre for the Promotion of Advanced Research
IICT	Indian Institute of Chemical Technology
IIM	Indian Institute of Management
IIoT	Industrial Internet of Things
IIPME	Industry Innovation Programme on Medical Electronics
IISER	Indian Institute of Science Education and Research
IIT	Indian Institute of Technology
IND	Industry
INR	Indian Rupees
INT	Intermediary
IoMT	Internet of Medical Things
IoT	Internet of Things
IP	Intellectual Property
IPA	Indian Pharmaceutical Association
IPMA	International Pharmaceutical Manufacturer's Association
IPR	Intellectual Property Rights
IPSSI	Indian Pharmaceutical Sectorial System of Innovation
IRCTC	Indian Railway Catering and Tourism Corporation
IRR	Internal Rate of Return
ISBA	Indian Science and Technology Entrepreneurs Parks and Business Incubator Association
ISID	Institute for Studies in Industrial Development
ISO	International Organisation for Standardization
ISTC	Institution supporting Technical changes
IT	Information Technology
IUSSTF	Indo-U.S. Science and Technology Forum
JEOL	Japan Electron Optics Laboratory Company Ltd.
JSS	Jagadguru Sri Shivarathreeshwara University
KBI	Knowledge-based Institution
K-DISC	Kerala Development Innovation Strategic Council
KGI	Keck Graduate Institute
KMO	Kaiser-Meyer-Olkin
KSM	Key Starting Materials
LAN	Local Area Network
LSSSDC	Life Sciences Sector Skill Development Council
MBP	Market-Based Pricing
MCCI	Madras Chamber of Commerce and Industries
MEAT	Most Economically Advantageous Tender
MEITY	Ministry of Electronics and Information Technology

MIER	Medanta Institute of Education & Research
ML	Machine Learning
MoU	Memorandum of Understanding
MRP	Minimal Retail Price
MSME	Medium Small Micro Enterprises
NAAC	National Assessment and Accreditation Council
NASSCOM	National Association of Software and Service Companies
NBA	National Biodiversity Authority
NBEC	National Bio Entrepreneurship Competition
NCBS	National Centre for Biological Sciences
NCIP	National Conference of Institute of Pharmacy
NCL	National Chemical Laboratory
NEP	National Education Policy
NGO	Non-Government Organisation
NIC	National Industrial Classification
NIPER	National Institute of Pharmaceutical Education & Research
NIPiCON	Nirma Institute of Pharmacy International Conference
NIRF	National Institutional Ranking Framework
NIS	National Innovation System
NIScPR	National Institute of Science Communication and Policy Research
NITI	National Institution for Transforming India
NIV	National Institute of Virology
NLEM	National List of Essential Medicines
NMIS	National Manufacturing Innovation Survey
NPPP	National Pharmaceutical Pricing Policy
NRI	Non-Resident of India
NSDC	National Skill Development Corporation
NSTEDB	National Science & Technology Entrepreneurship Development Board
OBM	Own Brand Manufacturing
OCI	Overseas Citizen of India
OECD	Organisation for Economic Co-operation and Development
OPPI	Organisation of Pharmaceutical Producers of India
PATH	Program for Appropriate Technology in Health
PE	Private Equity
PHDCCI	Progress Harmony and Development Chamber of Commerce and Industry
PIO	Persons of Indian Origin
PLI	Performance Linked Scheme
PMBJK	Pradhan Mantri Bhartiya Jan Aushadhi Kendra
PMTDS	Pharmaceutical & Medical Devices Promotion and Development Scheme
PoC	Point of Contact
PPP	Public-private partnership
PTUAS	Pharmaceutical Technology Up-gradation Assistance Scheme
R&D	Research & Development
RI	Research Institute
RISDC	Research and Information System for Developing Countries

RPA	Robotic Process Automation
SAP	Systems, Applications and Products
SBIRI	Small Business Innovation Research Initiative
SDG	Sustainable Development Goals
SEZ	Special Economic Zone
SI	System of Innovation
SIDBI	Small Industries Development Bank of India
SME	Small and Micro Enterprises
SOP	Standard Operating Procedure
SPI	Strengthening of Pharmaceutical Industry
SSI	Sectorial System of Innovation
STI	Science, Technology and Innovation
STIP	Science, Technology and Innovation Policy
SWOT	Strength, Weakness, Opportunity and Threat
TH	Triple Helix
TIFAC	Technology Information Forecasting and Assessment Council
TNMSC	Tamil Nadu Medical Services Corporation Ltd.
TRIZ	Theory of Inventive Problem Solving
TRL	Technology Readiness Level
TVE	Total Variance Explained
UN	United Nations
UNCITRAL	United Nations Commission on International Trade Law
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organisation
US	United States
USD	United States Dollar
USFDA	United States Food and Drugs Administration
VC	Venture Capitalist
VR	Virtual Reality
WEF	World Economic Forum
WHO	World Health Organisation
ZED	Zero Defect Zero Effect

Conversion factor

1 Crore = 10 millions

1 Lakh = 100,000

Acknowledgements

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The data analysis presented in this report has been performed by Dr. Ritin Koria, Project Specialist for Innovation, UNIDO, Ms. Christi Thomas, Project Associate, UNIDO, and Mr. Pratik Dake, Project Assistant, UNIDO.

Technical chapters of the report have been authored by Dr K Chandra Shekar Consultant Kerala Development Innovation Strategic Council (K-DISC) Government of Kerala; Mr. Ashish Gosain, Centre for Studies in Science Policy, Jawaharlal Nehru University; and Dr. Ritin Koria, Ms. Sirjjan Preet, Ms. Christi Thomas and Ms. Reshmi Vasudevan, UNIDO.

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DST and UNIDO are also incredibly grateful to all the respondents: government policymakers, chief executives of business enterprises, leaders in knowledge-based institutions, directors of financial institutions, venture capital, and knowledge brokering firms for participating in the survey.

Preface

A rethinking of Indian manufacturing and innovation is required if the goal of creating a US$ 5 trillion economy by 2026-27 is to be achieved. India's aspiration to become a global economic powerhouse will be based on the foundation of a robust industrial sector and its innovative performance. In order to deliver rapid but sustained industrial growth, it needs to strategically focus on building a next generation intelligent manufacturing base with domestic manufacturing companies becoming an integral part of global supply chains. India can leverage its strong Information Technology (IT) sector and drive supply chain efficiencies and productivity growth through use of IT deployed at scale. It can harness its soft power advantages to trigger a manufacturing revolution and become a global manufacturing superpower.

Creating an industrial revolution of the scale would require the Indian government to formulate a comprehensive vision for industrial development and execute it through the implementation of coherent and effective industrial policy. The unprecedented disruptions of societies and economies caused by the COVID-19 pandemic have accentuated the need to take immediate action. In recent years, the Government of India (GoI) has launched special initiatives like its Production Linked Incentive (PLI) schemes to underpin India's industrial capabilities and technological innovation in 14 key sectors; They also aim to create and nurture global champions capable of producing for the world. The PLI scheme is a time bound initiative with a clear mandate of focusing on critical sectors such as pharmaceuticals that can attract maximum investments and scale rapidly to provide the maximum returns in terms of higher productivity, employment, and exports. This scheme is also designed to identify and support adoption of the Fourth Industrial Revolution (4IR) technologies that are opening new avenues of opportunity for advancing economic competitiveness, creating shared prosperity, safeguarding the environment, and strengthening knowledge and institutions. More specifically, the Department of Pharmaceuticals' "Pharma Vision 2020" aims to promote end-to-end drug discovery and transform India into a pharmaceutical innovation hub.

Innovation processes are usually the result of interactions and flows of knowledge among people, enterprises and institutions. With knowledge emerging as a critical resource, better management and flow of information is key to the innovative process. A System of Innovation (SI) represents the strength and quality of the systematically organised interactions and linkages between the stakeholders of the ecosystem, namely government, knowledge-based institutions, industry, intermediaries (institutions supporting technical change, industry associations and incubators), and arbitrageurs (venture capital, angel investors, and financial institutions). The mapping and visualisation of the dynamics of an innovation system are crucial to formulating evidence-based policy for the effective use of resources.

Consequently, the growth of the Indian pharmaceutical sector will not only depend on the utilisation of the 4IR technologies and knowledge production, but also on stable pricing, the policy environment and efficient regulatory support for the sector. It needs a clear and targeted policy, enabling the effective allocation of resources in order to make India a global leader in the pharmaceutical sector. UNIDO acknowledges the importance of evidence in optimally deploying policy instruments and targeting available resources (economic incentives and institutions). So that the Indian pharmaceutical sector can achieve a competitive advantage, the development of a well-functioning SI is needed as a driver for long-term socio-economic development.

The "Indian Pharmaceutical Sectorial System of Innovation (IPSSI) Report" maps and analyses the challenges, potential, and opportunities arising from the innovation system. The analysis is based on data gathered as part of the "National Manufacturing Innovation Survey" conducted by UNIDO in 2021-22. The measurement through this survey enables the provision of evidence to guide policy and in supporting the Government of India to elaborate an evidence-based policy that articulates the role of science, technology, and innovation throughout the economy. The mandate of UNIDO – as one of the specialised agencies of the United Nations system – to provide its member states with capacity-building and policy advisory services is manifest in this report.

The chapters in this report are the result of UNIDO's services in capacity-building, policy analysis, and empirical research on the Indian pharmaceutical sector. It aims to enhance the understanding of the role of the core actors, their interactions, and perspectives, thus providing a solid basis for strategic planning, policy, and the management of policy actions to achieve national targets and goals effectively.

Executive Summary

This report, titled the "Indian Pharmaceutical Sectorial System of Innovation (IPSSI) – Measurement, Analysis, and Policy Recommendations" surveys innovation and innovativeness in the pharmaceutical sector in India and maps the functioning of innovation and the associated collaborative processes between innovation stakeholders. The survey and analysis were undertaken within the framework of the "National Manufacturing Innovation Survey 2021-22" (NMIS 2021), co-designed with and funded by the Department of Science and Technology, (GoI).

The report has been compiled for the Government of India (GoI) to inform innovation policy and improve innovation practices within the sector. Furthermore, it aims to facilitate coherent delivery of innovation policy and the establishment of a long-term policy monitoring and management capability for the sector.

Although there are many significant challenges identified, the policy analysis, implications arising from the analyses, and the policy recommendations to address these implications provide an unprecedented menu of evidence-based development priorities and policy choices to address the challenges. The approach outlined in this report is comprehensive and holistic for mapping and measuring the Indian Pharmaceutical Sectorial System of Innovation (IPSSI). It provides an accurate visualisation of the connectivity between the core actors of the IPSSI, the significant barriers to innovation and innovativeness, and the relative success of current policies in overcoming these barriers. After all, it is not the number of assets India has when considering innovation and innovativeness, but rather how well and coherently they are connected and managed and if they are achieving innovative products and business processes and subsequent economic value.

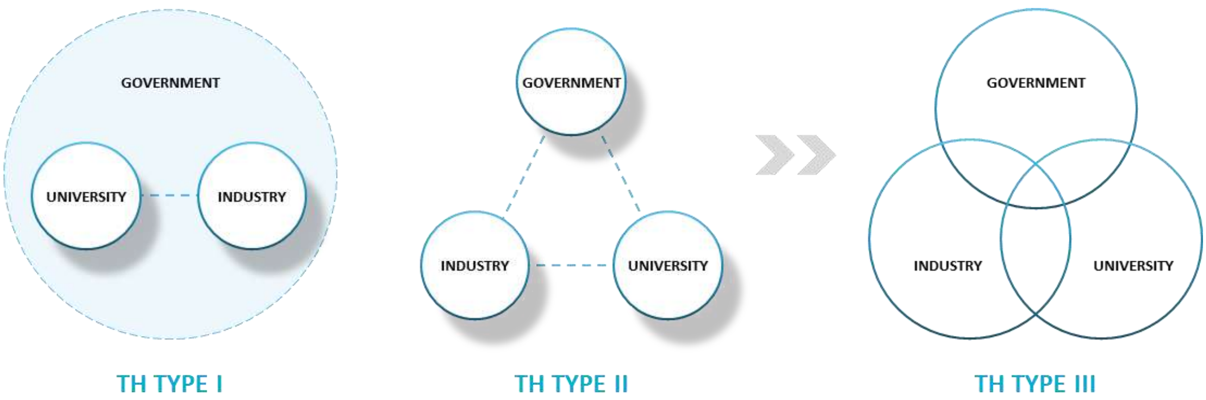
It is imperative that policymakers view the analysis, implications, and recommendations in light of India's economic performance in an emerging economy and in the context of the COVID-19 pandemic, which hit all sectors across the globe.

The analysis of the GoI policy documents; the mapping and measurement of the IPSSI in terms of analysing linkages between (and within) actor groups, barriers to innovation, and the success of policy instruments disclose the significant key policy analysis findings, the major implications from the analysis, and the recommendations that stem from them.

In the specific case of the pharmaceutical sector, our assessment is that the IPSSI falls into the category of a Triple Helix (TH) Type II transitioning to Triple Helix Type III, as per the traditional framing of the TH model. TH-Type I can be considered to be statist, and the three spheres of the actors are strongly institutionally defined, however, work in isolation leading to the local technological knowledge also being kept isolated.

TH Type II refers to mechanisms of communication between the actors that are strongly influenced by the market and technological innovations. In this case, the point of control is at the interfaces and consequently new codes of communication are developed. However, in TH-Type III, the actors assume each other's roles in the institutional spheres as well as the performance of their traditional functions with the formation of a complex network of organizational ties, both formal and informal, among the overlapping spheres of operations. It could be said that the interactions between the actors of the system are more competitive rather than collaborative in nature.

FIGURE 1: Triple Helix types



Consequently, there is the need to foster linkages between crucial actors of the IPSSI, particularly for the use and application of joint research, skills orientation and development, and access to finance.

Based on this observation, the inter- and intra-interactions that need attention are:

- Fostering joint research amongst industry actors with an aim to make the sector more strategically collaborative rather than competitive.
- Bolstering industry-academic interactions for applied research, in particular better participation of public knowledge-based institutions.
- Reducing the rigidity of communication between knowledge-based institutions in order to foster better knowledge exchange and collaboration in the areas of research, particularly with the inclusion of T2 and T3 institutions.
- Support secondments and placements in between the knowledgebase and industry in order to better orient human capital development.
- Strengthen communication channels amongst the knowledgebase and intermediaries, particularly industry associations.
- Increase the channels of funding from venture capital and angel investors to support the process of ideation to market.
- Better knowledge sharing amongst government bodies to promote an 'all of government approach' to innovation thus translating into more coordinated joint research in strategic areas.

Secondly, the analysis highlights that relationships between actors in the IPSSI are imbalanced in that there is an unequal level of exchange between two actors hindering the flow of knowledge and information crucial to the innovation process. This is mainly due to a suboptimal understanding of each actor's role within an effective system of innovation and the terms and conditions unfavourable to meaningful participation. Consequently, 'Industry 4.0' and 'Policy Function', emerge as the main underlying barriers to innovation within the IPSSI.

From the perspective of '**Industry 4.0**', the associated variables are: 'Lack of understanding of I4.0 technologies', 'Lack of access to I4.0 technologies', 'Cost of I4.0 technologies' and 'Lack of infrastructure for I4.0'. Manufacturing in the pharmaceutical sector is rapidly changing, particularly with the adoption of 4IR technologies. This paradigm shift is challenging traditional approaches to manufacturing, with a clear impact on agility, efficiency, flexibility, and consistency in the quality of the industrial production of medicines. In the Indian pharmaceutical sector, a lack of understanding of the value, goals and needs of 4IR technology still exists among many firms. There is the need for robust evaluation mechanisms and decision support tools which can help manufacturing firms understand the impact of 4IR technologies and effectively implement them. In addition, there is the rapid global advancement of personalised medicines and a shift is required within Indian manufacturing to focus on next-generation therapeutics. This requires new and existing therapies to reach the market faster and overall, more effective utilisation of manufacturing capabilities. This also requires manufacturers and raw material suppliers to keep pace with this shift towards 'Biopharma 4.0', where artificial intelligence (AI), big data and smart systems are being leveraged to help transform business models.

With respect to '**Policy Function**', the associated variables are Lack of legal framework', 'Lack of clear national innovation strategy,' 'Restrictive public/ govt regulations', and 'Lack of higher resolution regulations. In the case of the Indian pharmaceutical sector, the main policy bottlenecks include comprehension of legislation, as well as the lack of awareness and knowledge about procedures and regulations. This compounds the fragmented nature of the sector and leads to the creation of specific barriers, particularly for the growth of small and medium pharmaceutical companies.

Finally, with respect to policy success, policy instruments were analysed in terms of supply-side measures (services and financial) and demand-side measures. The study results indicate that in general policy instruments are successful, however the most unsuccessful policy instruments reported by all actors are 'Explicit firm innovation policy support', which is also reflective of the barriers previously reported under the policy function, closely followed by 'Government procurement' 'Explicit firm innovation policy support'. This is reflective of the need to clearly articulate high level goals and visions down to all levels of the system and with respect to industry, to small and medium sized firms, with a reduction in the level of complexity thus better enabling navigation of the sector.

In addition, each actor has a specific view on effective or ineffective policy instruments, which needs to be considered when selecting a policy mix. Policy selection should not be an arbitrary process. It should be based on evidence, reflect the needs of the actors in the system and be in line with India's overall strategic orientation.

The major implications of the analysis outlined in the report are that better externalities need to be generated from the public goods of funding and support. Phrased differently, innovation inputs need to be better translated into innovation outputs.

It is crucial that given the change in the global landscape from generics to biosimilars and cell and gene therapy, knowledge-generation is continually assessed and addressed. This requires strengthening the nexus between the knowledgebase and industry and research institutions. This should be underscored by a focused entrepreneurial and innovation outlook with their respective activities. It is vital that more information percolates from Tier1 institutions to Tier2 and Tier3.

In addition, the remoteness of actors causes them to be relatively independent of the policy-making process, especially in terms of wielding influence in configuring and calibrating policy to exploit knowledge and intermediating the flows of technical know-how. The present public infrastructure needs to be strengthened to create a fabric of vibrant linkages that supports innovation. What is required is a widely accepted conducive environment in which organizational rigidities are overcome.

The IPSSI Report demonstrates the value of comprehensive survey and the critical importance of mapping and measurement to guide the discussion for evidence-based and collaborative policy making, execution, monitoring and impact evaluation. A periodic repeat of systematic mapping and measurement of the IPSSI in two to three years is strongly advised and can help to ascertain the effects of policy choices, implementation, resource application, and hence innovation and innovativeness in the Indian economy.

1. Project Context

Project Context

The "National Manufacturing Innovation Survey (NMIS) 2021-22" is a follow-up to the Department of Science and Technology's (DST) (GoI) first "National Innovation Survey" held in 2011. The 2011 survey results showed that most of the innovations in Indian firms were in the form of introducing new machines, or improvements to existing products and processes (DST, 2014). The study found these firms at par or ahead of their competitors regarding improved ranges of products (better quality and standards), besides improving production capacity and reducing environmental impacts. Such firms were largely privately owned small companies and relied on domestic financial institutions. While these innovative firms struggled with cost factor and availability of skilled manpower, more than 50% did not employ scientists or engineers but reported that access to knowledge and information was a critical barrier.

The decade that followed the 2011 National Innovation Survey saw the launch of key policy initiatives, especially the "Make in India", "Startup India" and the "Aatmanirbhar Bharat Abhiyan", among others, positioned to strengthen and boost the country's manufacturing sector outputs where innovation and entrepreneurship programmes were prioritised. The scope of indigenous innovations and innovation ecosystems thus received greater impetus in this period. In 2019 the DST followed up with the planning of the second nationwide innovation survey and partnered with the United Nations Industrial Development Organization (UNIDO), with greater attention to manufacturing and associated services spread across large, medium, small and micro enterprises. It emphasised the role and separately studied the impact of this ecosystem and its actors on innovations in specific sectors.

1.1 The National Manufacturing Innovation Survey 2021-22

The National Manufacturing Innovation Survey (NMIS) 2021-22 was designed as a 2-pronged survey where the DST-UNIDO collaboration adopted a 360-degree approach to measuring innovation performance at the level of manufacturing firms, and assessing innovation processes, its barriers and support measures at the ecosystem level of industrial sectors. To this end, the survey was designed with two specific components – the Firm-Level Survey and the Sectorial System of Innovation (SSI) Survey.

The objective of the Firm-Level Survey was to capture insights regarding activities impacting innovations in a firm, across a broad spectrum of product and business process innovations and understand the various factors enabling and/or limiting innovation activities. On the other hand, the SSI Survey aimed to measure the innovation system available to specific industrial sectors to examine how manufacturing firms accessed information, knowledge, technologies, practices, and human and financial resources, and what linkages connect the innovating firm to other actors in the innovation system (laboratories, universities, policy departments, regulators, competitors, suppliers, and customers). Thus, with an overarching scope to strengthen, improve and diversify India's manufacturing with targeted and evidence-based innovation policy, the NMIS 2021-22 Survey was launched in February 2021.

TABLE 1: Overview of Firm-level survey and SSI survey

The Firm-Level Survey assessed the following: *(Broad overview)*	The SSI Survey assessed the following: *(Broad overview)*

• Types of innovations in manufacturing firms
  • Product innovation
  • Business process innovations in (e.g., operation, product/business process development, marketing & sales, procurement, distribution & logistics, administration, and management)
• Innovation activities
• Sources of information, collaborations, resources
• Factors hampering innovation activities.
• Impacts of digitalisation, infrastructure, IP
• Impact of COVID-19 pandemic
	• Innovation actors (firms and non-firm actors) for their networks (density, distribution, directionality, symmetry of intra- and inter-linkages of actors)
	• The role and impact of actors and institutions on innovation activities in firms
	• Impact of policy instruments (fiscal, monetary, regulatory, standards and others)
	• Barriers to innovation

With a stratified random sample representing micro, small, medium and large manufacturing companies, the Firm-Level Survey targeted 10,139 firms across 58 manufacturing sectors (as per the national industrial classification 2008[1]) across the 36 states and union territories in the country. The SSI Survey targeted the innovation systems of 5 key manufacturing sectors critical to the Indian economy, prioritised by their gross value-added (GVA) and their presence across the country, impacting state level and national policies and strategies. These 5 sectors are: Food and Beverages, Textiles and Apparel, Automotive, Pharmaceuticals, and Information and Communication Technologies (ICT). A stratified random sample close to 7,851 firms and 1,000 non-firm actors were targeted under the SSI Survey across India. The outcomes of the Firm-Level Survey are separately reported, while this report features the SSI Survey objectives and findings.

1.2 Significance of the Survey of Sectoral Systems of Innovation

The SSI Survey postulates that for a firm to be effective in the innovation process, a conducive environment that consists of an effective support infrastructure of actors is critical. Connectivity between them that is fluid and dynamic will be pivotal in aiding access to the requisite, knowledge, skills, and resources. Hence, the survey aimed to map the innovation capability of manufacturing firms to such actors and institutions of sector-specific systems of innovation and also regional systems of innovation, and national systems of innovations. To this end, the interactions (or linkages) and the density of these linkages to various ecosystem actors were studied to achieve a clear understanding of these relationships in empirical terms to assess the flow of communications and information and assets between knowledge-based institutions, research and development agencies, industry bodies, government agencies, financial institutions, startup incubators, institutions supporting technical change, and arbitrageurs.

The survey particularly took cognisance of the innovation and manufacturing mandate of NITI Aayog, the apex policy advisory body to the GoI[2]. In its strategic recommendation for improving India's manufacturing sector outcomes, NITI Aayog strongly recommended the need for promoting latest technology advancements and predicted a defining role for Industry 4.0 intervention in shaping the sector and achieving an ambitious double-digit growth (NITI Aayog, 2018). Further, the agency has also been assessing the nation's priorities and strategies for consolidating and strengthening science and technology (S&T) initiatives to amplify technology development and commercialisation. Since the 1990s, the Government of India has deployed technology incubators as an important policy tool for S&T entrepreneurship (Surana et al., 2018). The DST has been at the forefront of designing and establishing science and technology entrepreneurship parks, incubation systems, and technology business incubators to build close linkages between universities, academia, R&D institutions and the industry, including MSMEs, and also to generate employment[3]. These initiatives led to strong technology-based entrepreneurship and startups in the country, and set motion to various policy frameworks and initiatives, such that most incubation programmes in the country today leverage support offered under various ministries, who also have a manufacturing stake. The public sector enterprise model for biotechnology-based startups by the Department for Biotechnology (DBT) has been highly successful in converting research into products and attracting investments and has impacted the pharma and life-sciences landscape in the country. Similarly, for strengthening IT and digital startup linkages with markets, the Ministry of Electronics and Information Technology (MEITY) has been offering risk capital and low-cost loans. With their broader mandate, the Ministry of MSME and the Department for Promotion of Industry and Internal Trade (DPIIT) have designed and implemented several startup programmes, and importantly brought SME collaborations to sector-specific incubators, thus offering a stronger market access to entrepreneurs.

India's technology and innovation agenda took a strong leap over the last decade when the Government of India launched a series of high-powered initiatives to amplify and catalyse the pace of innovation and entrepreneurship with greater emphasis on the startup ecosystem. The "Startup India" mission was put in place to tackle the complex, lengthy regulatory processes for startups and introduced tax incentives and high-risk funding to startups[4]. The "Atal Innovation Mission" brought sector-specific attention to the startup agenda for innovation and entrepreneurship incubation infrastructure across the country and widened

[1] National Industrial Classification (NIC) 2008 is an essential statistical standard for developing and maintaining a comparable database according to economic activities: https://www.ncs.gov.in/Documents/NIC_Sector.pdf

[2] About NITI Aayog: https://www.niti.gov.in/objectives-and-features

[3] Science & Technology Entrepreneurship Park (STEP): https://www.nstedb.com/institutional/step.htm

[4] The Startup India initiative (under DPIIT) was launched to improve the innovation ecosystem and handhold, fund and incentivise startups and improve industry-academia partnerships through incubation services: https://www.startupindia.gov.in/content/dam/invest-india/Templates/public/Action%20Plan.pdf

its scope to schools and other academic institutes[5]. Further, the “Invest India” programme was launched to catalyse investments in manufacturing, technologies, incentivising innovations and other areas of trade and commerce[6]. The increased access to risk capital in technologies in this period have played a key role, such that Bain (2022) reports that VC investments in India pegged at US$ 38.5 billion in 2021 and have positioned India as the third largest startup ecosystem in the world[7].

The SSI Survey was positioned to examine how such policy and institutional arrangements (innovation/incubation programmes established in various technology and higher education institutes) across the country have impacted the collaboration of firms with academia, startups and investors for commercialising innovations, thereby addressing various transaction-related problems endemic to lab-to-market journeys. Studies show that traditional R&D institutions in the country, however, continue to prioritise “blue-sky research” over “application-oriented research” and on the other hand, several recent studies have brought attention to the challenges faced by India’s public-funded labs in commercialising their research outputs. While technology interventions have direct impact on productivity, accessing capital in manufacturing technology-based projects continues to be a challenge, owing to the longer gestation period before they yield returns. As Nandagopal et al., (2013) point out, Indian firms continue to be traditionally risk-averse, and are inclined to invest in non-technology-based sectors like retail, banking, infrastructure, entertainment, among others. The SSI Survey made crucial inclusion of the role of arbitrageurs, such as the venture capitalists and knowledge brokers, as these actors have increasingly been decisive in the innovation process in bringing internal and external knowledge and high-risk investments that result in new business models and new types of companies.

1.3 Relevance of the 5 Manufacturing Sectors Prioritised by the SSI Survey

With the goal of significantly increasing the manufacturing sector contribution to the GDP from 16.5%, the “Make in India” mission is a major policy initiative launched in 2014 aimed to make India a high-tech manufacturing hub[8]. The mission now targets 27 manufacturing sectors that have key significance to the economy and the 5 manufacturing sectors identified for the SSI Survey have significant priority in the Make in India mission.

India’s food processing is globally one of the largest, with a significant number of registered factories across the country attributing to the direct employment of 1.9 million people, with 8.9% MVA (food and beverage along with tobacco) (UNIDO IAP, 2023). Despite being a major trader and exporter of agriculture products, India’s export processed food is less than 10% owing to critical impediments across supply chain infrastructure, production and processing, inefficient capacity utilisation, quality and safety challenges, and slow product and technology interventions (RBI, 2020). Similarly, the other large sector in the survey, the textiles and apparel sector, has a prominent manufacturing presence in many states and provides direct employment to more than 45 million people and contributes close to 7% of MVA[9]. In 2021-22 the Indian textiles and apparel industry was valued at US$ 152 billion and accounted for a 4% share of the global textile markets. Yet the highly fragmented sector is also labour and raw material intensive and is mired with productivity challenges that tend to undermine value chains and their backward linkages. For instance, more than 80% of the 50 million spindles and 842,000 rotors deployed by textile mills are found to be outdated or inefficient[10].

The SSI Survey aimed to also gather learnings from actor collaborations, institutional best practices, challenges, technology leapfrogging trajectories and other aspects of systems of innovation in three high performing sectors, such as the automotive, pharmaceutical and ICT sectors. With a 20.1% contribution to the manufacturing GDP, the automotive sector is a top driver of macroeconomic growth and technological development in the country (UNIDO IAP, 2023). With robust performances, the ICT and pharmaceutical sectors are the world’s key players. India’s pharmaceutical sector is the third largest in volume, driven by export markets and the expansion of Indian healthcare that has resulted in innovative products, processes and services, thereby positioning India as the pharmacy of the world[11].

[5] The Atal Innovaiton Mission driven by NITI Aayog established numerous innovation and entrepreneurship centres in schools, universities, research institutions, private and MSME sectors: https://www.aim.gov.in/overview.php

[6] Invest India: Investment Promotion and Facilitation Agency | Invest India

[7] Economic Survey: India becomes third-largest startup ecosystem in the world. Mint: https://www.livemint.com

[8] The Make in India Mission: https://www.pib.gov.in/PressReleasePage.aspx?PRID=1738170

[9] Textile Industry in India - Garment & Apparels Market in India: www.investindia.gov.in/sector/textiles-apparel

[10] India should continue investing in modern, efficient spinning technology to remain globally competitive: https://www.indiantextilemagazine.in/india-should-continue-investing-in-modern-efficient-spinning-technology-to-remain-globally-competitive/

[11] India has become pharmacy of the world: https://www.moneycontrol.com/news/india/india-recognised-as-pharmacy-of-the-world-fm-9759651.html

1.4 SSI Survey to Strengthen Manufacturing Innovation as a GoI Policy Imperative

The Make in India ambitions were further boosted in 2020-21 with the launch of the Production Linked Incentive (PLI) scheme across 14 key manufacturing sectors, to incentivise import substitution by domestic production in strategic growth sectors[12]. Invariably, the domestic manufacturing ecosystem and supply chains are critical to the success of the PLI scheme. Similarly, the "Gati Shakti" programme was launched in 2021 to improve infrastructure and connectivity for faster and more efficient movement of goods and services, and impact manufacturing and business operations at large[13]. Besides technological leapfrogging, world-class innovation capabilities, skills and investments, the Government of India's efforts in improving the investment environment has been critical. The country saw FDI inflow catch great momentum between 2014-22 and by 2019 India was recognised as one of the most attractive emerging markets for investments[14]. However, the FDI share in Indian industries seems to continue to largely benefit non-manufacturing sectors such as software businesses. Nevertheless, the hardware, pharma-biotech and electrical equipment sectors, among others, with strong product sophistication and better production capabilities, attract strong foreign direct investment (FDI) inflow, especially with their digital capabilities in manufacturing and product offerings[15]. The global shifts in advanced digital manufacturing with self-correcting intelligence has been a game changer since the pandemic and has reflected in investment interests as well.

The SSI Survey has attempted to capture the dynamics of communication, stocks and flows of knowledge and organization by introducing the notion of an intersection of exchange relations that feed back into institutional arrangements. The aim has been to understand how co-evolution between the layers of institutional arrangements and evolutionary functions can be conceptualised, in relation to the division of innovative labour among both institutions and functions. This is particularly important when crafting policy for the effective use of resources. Thus, by generating evidence of the barriers and challenges to technological learning, innovation and development, and technological up-gradation of Indian industries the survey findings shall be used for devising policies, programmes, and partnerships to strengthen innovation outcomes and benefits.

The project was supported by the UNIDO Facility for International Cooperation for Inclusive & Sustainable Industrial Development (FIC-ISID), a joint initiative of the DPIIT and UNIDO, with the aim to catalyse inclusivity and sustainability in manufacturing industry development. Five major business membership organizations, respectively the India SME Forum (ISF), the Federation of Telangana Chambers of Commerce and Industry (FTCCI), the Federation of Andhra Pradesh Chambers of Commerce and Industry (FAPCCI), the Madras Chamber of Commerce and Industry (MCCI), and the PHD Chamber of Commerce and Industry (PHDCCI) were key partners in data-collection across India's 28 states and 8 union territories. The survey completed the data collection in early May 2022.

[12] The PLI Scheme: https://www.investindia.gov.in/production-linked-incentives-schemes-india
[13] Gati Shakti: https://dpiit.gov.in/logistics-division
[14] Emerging Markets Private Equity Association 2019 Survey: https://www.globalprivatecapital.org/app/uploads/2019/05/2019-lp-survey-final-web.pdf
[15] FDI in India 2021: https://www.makeinindia.com/policy/foreign-direct-investment

2. Theoretical Framework

Theoretical Framework

Innovation is increasingly viewed as the salient ingredient in the sustainable growth of the modern economy. An economy must continuously absorb new knowledge and develop new skills and capabilities to avoid erosion of competitiveness and facilitate economic growth and diversification. Historically, countries that fostered innovation by developing interconnected innovation systems have proven to be more capable of generating new knowledge and translating it into business opportunities and thus wealth creation (Freeman, 1987; Nelson and Rosenberg, 1993; Lundvall, 1992, 2016; Chaminade et al., 2018). An innovation system refers to a set of institutions that contribute to the development, diffusion and application of scientific and technological knowledge (Dosi, 1988). Studies have shown that well-functioning innovation systems are essential to catch up with advanced economies (Kim, 1992, 1997; Kim and Nelson, 2000; Fagerberg and Srholec, 2008; Malerba and Nelson, 2013; Fagerberg et al., 2017; Shekar, K. C., & Joseph, K. J., 2022).

Innovation systems are framed at different scales, including national, sectoral and local/regional (Chaminade, 2018). The framing of an innovation system involves different types of network and interactions depending on the driving interest, practices, behaviours and the working environment in general. The considerations for building these networks may vary depending on the context and scale of the operations/activities happening among the actors. These networks will evolve based on the behaviour and routine among the actors and their organizational context (Hall, Mytelka, and Oyeyinka 1997; Jacob 2016). However, knowledge and learning remain the central points to the networks (Moschitz et al., 2015). The establishment of such networks for building a system involves breaking barriers and reconstructing channels for knowledge flow. This is done by setting interactive processes, sharing best practices and learning from prior experience, while overcoming failures and filling gaps. The form and the performance of learning approaches may vary from one sector to another, depending on different patterns such as the roles, habits, mode of operation, competencies, demand, among others (Mytelka and Smith, 2002). This suggests a systemic way of establishing a framework that allows interactions among the different groups and contributes to the use of knowledge for the collective/mutual interest of the actors.

Since innovation is a collective action that involves a multitude of actors who co-operate and compete in networks and who are stimulated and constrained by institutional settings in different sectors, the concept of 'Sectorial Innovation Systems' are used. The rationale for using this framework can be further justified on the ground that it encompasses all the relevant aspects that might possibly influence innovation and economic growth and is suitable to analyse the inter-related character of innovation processes. In this backdrop, this chapter presents the theoretical underpinnings for the approach used in mapping and measuring the Indian Pharmaceutical Sectorial System of Innovation (IPSSI). It introduces the concept of the Sectorial System of Innovation (SSI), as well as reviews the elements that constitute its early conceptualisation, through a review of the evolution of seminal literature. Based on this, the chapter outlines the traditional Triple Helix Model of government-university-industry interactions as well as its extension.

2.1 Underpinning Theoretical Framework

The organisation and development of innovation have gained much attention from different perspectives. The traditional notion of innovation as an end provides a narrow view of innovation and the potential it has on societal development in different dimensions. Whereas the consideration of innovation as a process that engages a chain of activities that can lead to different types of innovations that then have diverse socio-economic impacts is more prevalent today. An innovation system considers innovation as a process and considers how the actors interact among themselves to undertake innovation activities. They consider the inputs to innovations and the channels leading to the expected outputs. This does not mean the use of the linear model of input-output that has been used for some time as a way of linking science to innovation. Rather, it considers the complexity of the processes and the interactions among actors involving learning activities and the use and transfer of knowledge (Etzkowitz and Leydesdorff, 2000). The available literature on innovation capabilities in the Indian industrial sector is mostly based on STI indicators that focus more on R&D activities and the creation of access to codified knowledge (Basant, 1997; Basant and Fikkert; 1996; Kartak, 1985; Kumar and Siddharthan, 2013; Shekar, K. C., & Paily, G., 2019). For instance, Basant and Fikkert, (1996) examines the effects of domestic and foreign technology purchases as well as R&D activities in enhancing the productivity of firms in India. The study shows that between 1974-75 and 1981-82, domestic and international R&D spillovers and foreign technology purchases are highly statistically significant as compared to own R&D expenditures. Even though technological strategies greatly contribute to the productivity growth of Indian enterprises it is not directly reflected in export performance, which is also considered as an important indicator of a firm becoming more innovative (Lall and Kumar, 1981). It is highly evident in high technology sectors rather than medium and low technology sectors (Kumar and Siddharthan, 1994). A sector-specific study conducted by Bhaduri and Ray (2004) examines the technological capability of exporting firms in the electrical and electronic equipment industry. Firms in this industry mainly depend on know-how rather than know-why capabilities. In addition to these approaches, innovation systems research focuses on interactive learning, interdependence and non-linearity wherein institutions play the central role (Joseph, K. J, 2009; Shekar, K. C., & Joseph, K. J., 2022). The innovation system perspective has become a widely used analytical tool for academic research, policy formulation and implementation which aim at effective relationships among the agents and increase the innovation efficiency (Dosi et al., 2006). Therefore, the innovation system, which has by now emerged as the most popular approach in innovation studies, involves a more holistic framework to study the inter-related character of innovation processes as it focuses on the interdependencies among the various agents, organizations and institutions while underlining the need for R&D (Freeman, 1987; Dosi et al., 1988; Lundvall, 1992; Nelson, 1993; Edquist, 1997; Shekar, K. C., & Joseph, K. J., 2022).

Since the late 1980s, innovation system concepts have been developed and presented primarily by innovation researchers as a response to the shortcomings of neoclassical attempts to explain innovation and technological progress (Edquist, 1997). According to Christopher Freeman, "…systems of innovation are networks of institutions, public or private, whose activities and interactions initiate, import, modify, and diffuse new technologies" (Freeman, 1987). The innovation system, with a focus on technology and information flows between people, businesses, and institutions, and was created as a tool to understand the innovation process (Lundvall, 1985). Innovation systems help identify how to stimulate innovation and what inhibits its development and have become a viable method for researchers and policymakers to study the innovation process, especially in emerging and developing economies (Weber and Truffer, 2017; Shekar, K. C., & Joseph, K. J., 2022).

Different types of innovation systems have emerged since the identification of the concept of innovation systems such as the National Innovation System (NIS) (Lundvall, 1992; Freeman, 1987; Edquist, 1997; Lundvall, 2007; Nelson, 1993), Regional Innovation System (RIS) (Saxenian 1994; Cooke & Uranga, 1997), Sectoral System of Innovation (SSI) (Malerba, 2002; Breschi and Malerba, 1997) and technological systems (e.g., Carlsson and Stankiewicz, 1991), also known as a technological innovation system (Bergek et al., 2008; Hekkert et al., 2007). The NIS as the common analytical framework for innovation to economic growth. This considers a country as a unit of analysis. It provides the macro indicators in regard to interactions among actors, organization structures, institutions and learning processes as well as the facilitation. It considers interactions among actors as key for innovations. Actors can be firms' organizations and non-firms' organizations (universities, R&D organizations) (Chaminade et al., 2018; Shekar, K. C., & Paily, G., 2019). The categories of organizations may generally be grouped as knowledge producers and knowledge users. Whereas the system is based on these categories and the interactions among them, institutions are very important in the innovation systems. In this context, institutions are considered as a set of routines, behaviour, regulatory tools, and policies (Edquist, 2005; Freeman, 1995). The set of organizations, institutions, knowledge, interactions, and learning make up an innovation system and this system can be analysed at a lower level as a sectorial innovation system. Types of activities, actors, and products; and how these are interconnected determines the sector.

Geographical factors define national and regional innovation systems, whereas sectorial and technological innovation systems are defined by the knowledge base that supports a particular sector or technology (Carlsson, 2016). In the sectoral system of innovation, innovative activities within a particular sector, a set of new and established products and the set of agents involved in the creation, production and sale of those products are examined. SSI surpasses specific technological and geographical boundaries, with sectors being positioned sometimes in small regional clusters, yet sometimes covering global networks, as, for example, within multinational corporations (Stenzel, 2007).

In recent years, advances in innovation theory have gradually moved closer to a fully systemic, dynamic, and non-linear process that involves a range of interacting actors. This process emphasises the significance of knowledge flows between actors; expectations about future technology, market, and policy developments; political and regulatory risk; and the institutional structures that affect incentives and barriers. Thus, while conceptual and methodological specifics vary, these more recent innovation systems emphasise the role of multiple agencies and distributed learning mechanisms in technological change. Rather than all-powerful firms or unidirectional knowledge flows, the focus is on inter-organizational networks and feedback (Winskel and Moran, 2008). The system perspectives still acknowledge the existence of stages of technology development, but they attempt to put these in a broader context.

There are various channels of university-industry interactions that facilitate innovation development. Joseph and Vinoj (2009) provide empirical evidence that in spite of the low level of university-industry interactions in the country, firms that collaborate with universities achieve a high level of innovative activities.

In particular, the role of institutions at all levels in establishing and maintaining the "rules of the game" is a central theme since institutions may constrain choices, driving innovation along certain - possibly suboptimal - paths while often throwing up barriers to more radical change (Foxon, 2003). The importance of feedback between different parts of the system – both positive and negative - is also emphasised, as are the links between technological and institutional change. A well-functioning system vastly improves the chances for a technology to be developed and diffused (Negro et al., 2008; Shekar, K. C., & Paily, G., 2019; Shekar, K. C., & Joseph, K. J., 2022).

Hence, the guiding principle of innovation studies is that if we can discover what activities and contexts foster or hamper innovation (i.e., how innovation systems function) we will be able to intentionally shape the innovation processes (Hekkert et al., 2007).

2.2 Sectorial System of Innovation (SSI) Approach

The notion of sectorial system draws from evolutionary theory, the innovation system approach and the analysis of the dynamics and transformation of industries. According to the SSI approach, a sector is seen as a set of activities which are associated with broad product groups, are addressed to an existing or emerging demand, share a common knowledge base, and are affected by a system of actors and institutions (Malerba, 2002). Malerba (2002) defines SSI as a "set of products and the set of agents carrying out market and non-market interactions for the creation, production, and sale of those products". SSI focuses then on the sector rather than on any geography. A sectorial systems framework focuses on three main dimensions (for a broader discussion see Malerba, 2004 and Malerba and Adams, 2019) that are typically distinguished as: a) knowledge and technological domains; b) actors and networks; and c) institutions (Malerba and Adams, 2019).

a. **Knowledge and technological domains**. A sector is characterised by a specific knowledge base and technologies. Knowledge plays a central role in the sectorial systems approach. Knowledge is highly idiosyncratic at the firm level, does not diffuse automatically and freely among firms (Nelson and Winter, 1982), and must be absorbed by firms through the capabilities which they have accumulated over time (Cohen and Levinthal, 1990). Knowledge - especially technological knowledge- involves varying degrees of specificity, tacitness, complexity, complementarity, and independence (Winter 1987; Cowan, David, Foray 2000; Dosi and Nelson, 2010). From a dynamic perspective, it is essential to understand how knowledge and technology are created, how they are distributed and exchanged between firms, and how such processes can redefine industry boundaries.

b. **Institutions**. The cognitive frameworks, actions and interactions of agents are influenced by institutions, which include norms, common habits, established practices, rules, laws, and standards. Institutions may be binding and more or less formal (such as patent laws or specific regulations versus traditions and conventions). Many institutions have national dimensions (such as patent laws or regulations concerning the environment), while others are specific to sectors (such as standards) and may cut across national boundaries (such as international conventions or established practices).

c. **Actors and networks**. A sector is composed of heterogeneous agents that include firms (e.g., innovating and producing firms, suppliers and users), non-firm organizations (e.g., universities, financial organizations, industry associations) and individuals (e.g., consumers, entrepreneurs, professionals and scientists). These heterogeneous agents are characterised by specific learning processes, competencies, beliefs, objectives and behaviour. They interact through processes of communication, exchange, competition, control, and cooperation. Thus, in a sectorial systems framework, innovation is a process that involves systematic interactions among a wide variety of actors for the generation and exchange of knowledge relevant to innovation and its commercialisation. Actors are individuals and/or organizations that "interact through processes of communication, exchange, cooperation, competition, and governance, and various institutions shape their interactions (norms, common habits, established practices, rules, laws, standards, etc.)" (Malerba, 2002). Under this framework, many actors generate, and exchange knowledge related to innovation and its commercialisation. The sectorial innovation system undergoes changes and transformations through a co-evolution of its various elements (Nevzorova, 2021).

There are several limitations of the SSI approach. Firstly, interactions between various agents in the SSI are shaped by institutions at both sectoral and national levels. Therefore, delineating between national and sectoral boundaries is not easy. Furthermore, distinguishing the characteristics of these institutions (norms, routines, common habits, established practices, rules, laws, standards) at both levels is a challenge. Second, SSIs are also influenced by institutions at a global level. In some cases, the relevant geographical boundaries are global as well as sectoral and in such cases, it is not easy to distinguish the boundary between them. Thirdly, the relationship between national institutions and sectoral systems could differ. That is, the same institution may play different roles in different countries, and thus may affect the same sectoral system differently in different countries. Finally, the nature of relationships and networks differ across sectoral systems and therefore it can be difficult and complex to compare them to each other (Baskaran, and Muchie, 2019).

Notwithstanding this, each of these components of a sectorial system has its own characteristics and its own set of dynamics which are important to disentangle to understand how innovation takes place. But each of these elements is also part of a broader system in which the interaction among the parts drives innovation and change.

Sectorial systems studies also expanded to the analysis of emerging and developing countries, as in Malerba and Mani (2009), Malerba and Nelson (2011), Luz and Salles-Filho (2011) and Muchie and Baskaran (2017), in which the cases of several sectorial systems in Asia, Latin America and Africa are examined. More recently catch-up by emerging and new leading countries in different sectorial systems has been examined by Lee and Malerba (2017 and 2020) and has been associated with opening of windows of opportunities and responses by firms and sectorial systems in catching-up countries and incumbent countries (see in this respect Giachetti and Marchi 2017, Morrison and Rabellotti 2017, Kang and Song 2017 and Lee and Ki 2017). The sectorial systems framework has also been adopted to examine China's catching-up in a variety of "green sectors" (Lema et al., 2020), such as solar photovoltaics (Binz et al., 2020), wind energy (Dai et al., 2020), biomass (Hansen & Hansen, 2020), and hydro energy (Zhou et al., 2020). In these sectors, the windows of opportunity for latecomers are primarily driven by institutional changes that favour clean and renewable energy and by demand conditions (Lema et al., 2020).

The existing literature (e.g., Bhagavan, 1985; Desai, 1985; Prameswaran, 2004) on India's manufacturing sector deal with Science, Technology and Innovation (STI) aspects of innovation strategies such as research and development activities and creating access to explicit codified knowledge, and technical efficiency, etc. The innovation system combining a strong version of the STI mode with a Doing, Using and Interacting (DUI) mode can provide a better picture of innovative behaviour of the firms (Jenson et al., 2007; Shekar, K. C., & Joseph, K. J., 2022).

2.3 System failure

As previously highlighted, the basic conceptual underpinnings of the SI approach are, first, that innovation does not take place in isolation and interaction is central to the process; second, that institutions are crucial to economic behavior and performance (Smith, 1996); and third, that evolutionary processes play an important role, they generate variety, select across that variety, and produce feedback from the selection process to variation creation (Hauknes and Nordgren, 1999).

In all these basic elements, systemic imperfections can occur if the combination of mechanisms is not functioning efficiently. This can translate into various types of system failure:

- Infrastructure failure, where there is a lack of formal institutions/institutional mechanisms as well as soft institutions, social norms, trust, values that hinder innovation.
- Institutional failure, where there is lack of networking/linkages among the different actors in the whole ecosystem.
- Network failure/Capability failure, which underscores the absence of the necessary capabilities of the actors to move up the value chain, adapt to new and changing circumstances etc.
- Directionality failure, where there is a lack of shared vision, collective coordination, regulation, targeted funding regarding the goal and direction of the transformation process.
- Demand articulation failure, caused by improper anticipation and learning about user needs, shaping innovation based on user needs, lack of instruments for supporting user-led and open innovation, novel innovations/solutions not finding enough space in public procurement.

- Policy coordination failure, due to a lack of multi-level policy coordination, horizontal and vertical coordination, across and within different systemic levels; between regional and national or between technological and sectoral systems, etc.
- Reflexivity failure, as a result of an insufficient ability of the system to monitor, anticipate and involve actors in processes of self-governance (Woolthuis, et al., 2005).

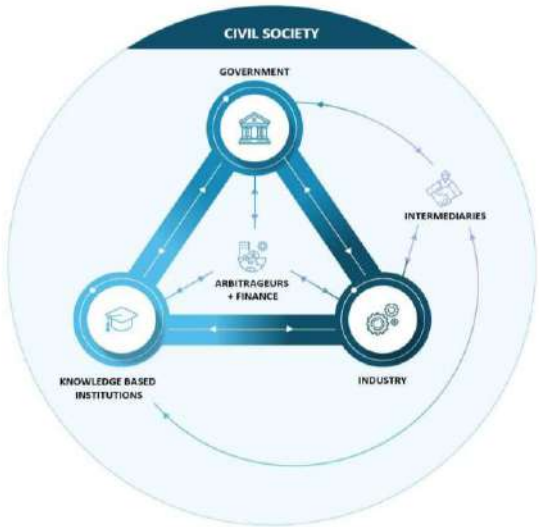
The systemic failures as presented above cannot be addressed directly, or by one actor alone. If policy makers want to use the framework, they will have to address groups of actors to make changes in the innovation system possible. Consequently, as opposed to the market failure approach for driving policy, a systems approach to innovation is seen as more robust (Bergek et al., 2010).

By using the systems framework as a tool for analysis, policy makers can identify: (1) where systemic failures occur; and (2) which actors should be addressed to make change possible. Most problems in the innovation system will not be uni-dimensional but will consist of a complex mixture of causes and effects, and involve several actors. By using the framework, priorities can be given to the most stringent obstacles for innovation and thus also serve as a guideline to implement innovation policy.

2.4 The Triple Helix (TH) Model

Besides the systems approach, there are other tools that have the potential to offer similar facilitation for innovation at the sectorial level. The Triple Helix Model is advocated to be a powerful tool for linking universities to the rest. This can also be seen as a tool for operationalising the IS concept. However, this might require setting-up a proper framework at a low scale to set the foundation for the running of the system, which is expected to be inclusive and socially embedded in the context of developing countries.This interaction between government, universities and firms is addressed in the "Triple Helix" Model proposed by Etzkowitz and Leydesdorff (1997). This model is a descriptive construct of the components, interaction channels and functions or benefits of an effective NIS (Ranga and Etzkowitz, 2013; Santana, 2016).

FIGURE 2: Triple Helix Model extension



Etzkowitz (2002) states that interaction channels are necessary when firms and government are related with universities in knowledge-based economies. From a business perspective, the most important channels of transfer of knowledge are open science, property rights, human resources, projects of collaborative research and development (R&D) and networking among actors (Cohen et al., 2002; Hanel & St.-Pierre, 2006; Arza, 2010; Bekkers & Freitas, 2008; Ruiz, Corrales and Orozco, 2017).

The triple helix is effective in understanding the dynamics of innovation at the sectorial, regional, national or international level, as it provides a well-elaborated framework for understanding central inquiries in innovation processes, including a) What the key actors are and b) What the mechanisms of interactions are (Cai and Amaral, 2021). Traditionally, the literature on the Triple Helix Model has focused on the relationships between universities and knowledge-based institutions (KBIs), firms, governments, and hybrid organizations at the intersection of these three helices (Etzkowitz and Leydesdorff, 1995; Leydesdorff, 2001). Etzkowitz and Leydesdorff developed the Triple Helix Model to explain the dynamic interactions between academia, industry, and government that foster entrepreneurship, innovation, and economic growth in a knowledge-based economy (Etzkowitz & Leydesdorff, 2000).

According to the literature, the scope and intensity of the interactions between the three actors are reflected in varying institutional arrangements, referred to as Triple Helix Type I, II, and III (TH-Type I, II and III) (Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2003, 2008; Ranga and Etzkowitz, 2013).

In the TH- Type I, the three helices are strongly defined, with relatively weak interactions. Institutionally, “the nation state encompasses academia and industry and directs the relations between them” (Etzkowitz and Leydesdorff, 2000: p. 111). New knowledge is produced only within universities and research centres. Hence, TH-Type I is largely viewed as a failed development model with not enough room for ‘bottom up’ initiatives, where “innovation was discouraged rather than encouraged” (Etzkowitz and Leydesdorff, 2000, pg.112). To achieve statist reform “the first step […] is the loosening of top-down control and the creation of civil society where one is lacking” (Etzkowitz, 2003a, pg.304). Otherwise, there is minimal direct connection to the needs of society, which in turn discourages the introduction and diffusion of innovations in the economy (Martin and Etzkowitz, 2000).

Triple Helix Type II is characterised by decreasing direct control of the state on the functions of Type I with a shift of focus on fixing market failures. The mechanisms of communication between the actors are strongly influenced by and deeply grounded in market mechanisms and innovations (Nelson and Winter, 1982; Bartels, et al., 2012). The point of control is at the interfaces (Leydesdorff, 1997) and consequently, new codes of communication are developed (Leydesdorff and Etzkowitz, 1998b). Research is also carried out outside universities and research centres. As research becomes increasingly multidisciplinary and applied, societal needs have a direct influence on it (Etzkowitz and Leydesdorff, 2000; Martin and Etzkowitz, 2000; Ranga and Etzkowitz, 2013).

TH-Type II can be considered a ‘laissez-faire’ model of interaction “in which people are expected to act competitively rather than cooperatively in their relations with each other” (Etzkowitz, 2003, pg.305). To summarise and compare TH-Types I and II, “statist societies emphasise the coordinating role of government while laissez-faire societies focus on the productive force of industry as the prime mover of economic and social development” (Etzkowitz, 2008, pg.13).

Furthermore, in TH-Type III, the three actors assume each other’s roles in the institutional spheres as well as the performance of their traditional functions. With the emergence of TH-Type III, a complex network of organizational ties has developed, both formal and informal, among the overlapping spheres of operations. The transformation of universities is of particular relevance. After having incorporated research as an additional mission beyond teaching, universities recognise their role in the pursuit of economic and social development (Etzkowitz and Leydesdorff, 2000; Webster, 2000; Ranga and Etzkowitz, 2013; Etzkowitz, 2008, 2017). Hence, universities take on entrepreneurial tasks such as marketing knowledge, increased technology transfers and the creation of spin-offs and startups, as a result of both internal and external influences (Etzkowitz, 2017; Etzkowitz and Leydesdorff, 2000; Etzkowitz et al., 2000). These entrepreneurial activities are assumed with regional and national objectives in mind, as well as financial improvements to the university and the faculty (Etzkowitz, et al., 2000). In doing so, universities cease to be ivory towers, disconnected and isolated from society, but interact closely with industry and government (Etzkowitz and Leydesdorff, 2000; Etzkowitz et al., 2000). In addition to the above, “firms develop an academic dimension, sharing knowledge among each other and training employees at ever higher skill levels” (Leydesdorff and Etzkowitz, 1998, pg.98), as well as increasing collaboration with knowledge-based institutions (KBIs). Improved university-industry collaboration is visualised through: i) an increased patenting output, particularly as they are a “repository of information about how the socially organised production of scientific knowledge is interfaced with the economy” (Leydesdorff, 2004); ii) the increase in university revenues from licensing (Perkmann and Walsh, 2007); iii) a greater proportion of industry funds making up university income (Hall, 2004); and iv) the diffusion of technology transfer offices, industry collaboration support offices and science parks (Siegel et al., 2003, in Perkmann and Walsh, 2007, pg. 4). Governments therefore create incentives through “informed trade-offs between investments in industrial policies, S&T policies, and/or delicate and balanced interventions at the structural level” (Leydesdorff, 2005). Phrased differently, there is a shift in the traditional role of policy from the facilitation of basic science to its ‘bridging function’. In a nutshell, the Triple Helix Type III assumes that the three spheres - universities, industry, and government - overlap, and their boundaries become more permeable. A complex network of organizational ties develops individuals and ideas move around the three helices, and synergies are maximised (Etzkowitz, 2002). Actors evolve and assume each other’s roles, with new hybrid organizations emerging at the interfaces, for example incubators, accelerators, science parks, technology transfer offices, venture capital firms, angel networks, and seed capital funds (Etzkowitz, 2000; Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2002; Ranga and Etzkowitz, 2013).

The Triple Helix Model has also been applied to the context of developing economies. Case studies document how innovation and learning processes differ in developing economies, what factors constrain the adoption of more integrated Triple Helix models, and how actors and mechanisms cope with these factors (Sarpong et al., 2017). In this regard, it has been noted that while the components of the triple helix do not change, the intensity and quality of their interactions are often weaker than in developed economies (Dzisah and Etzkowitz, 2008). Generally, in order to address such challenges effectively, through tailored and targeted policy interventions, there is the clear need for system level measurement.

2.5 Towards an Analytical Framework

The framework for analysis of the IPSSI is grounded in the literature, but it extends the traditional model in two main ways and is referred to as Triple Helix (TH-Type IV) Type IV[16, 17]. The TH-Type IV has the additional features of arbitrageurs (banks, financial institutions, venture capital and angel investors) and intermediary organizations (industry associations, institutions supporting technical change and incubators), as well as diffused ICT in the context of the Fourth Industrial Revolution.

Arbitrageurs can be defined as venture capitalists, angel investors/ networks and knowledge brokers. They are essential for the innovation process as it requires internal and external knowledge for the development of new ideas, business models and types of companies. As such, knowledge brokers and venture capitalists fulfil this requirement through the provision of links, knowledge sources and even technical knowledge so that firms can improve their performance, in terms of survival rate, as well as accelerate and increase the effectiveness of their innovation processes (Zook, 2003; Baygan and Freudenberg, 2000). Their resource allocation role is based on the assessment of advantages in information asymmetries (Williamson, 1969, 1971, 1973) (Bartels, et al., 2012, pg.7). However, information asymmetry and uncertainty can lead to transaction problems. "Countries seeking to encourage the emergence and growth of entrepreneurial firms need to devise ways that reduce transaction problems" (Li and Zahra, 2012, pg.95). It can be said that a combination of both formal institutions and (informal) cultural values can provide the proper incentives to reduce transaction problems. Arbitrageurs are therefore of vital importance as the innovation process requires internal and external intermediation (financial, knowledge, transacting and investment), and as such, complement the traditional Triple Helix Model.

Intermediaries are recognised as actors that place themselves in the middle of relationships between other actors, or actors that facilitate the process of interacting in exchange relationships. Four roles of intermediaries include: (a) consultant, providing information and advice in the recognition, acquisition and utilisation of the relevant intellectual property and technological capabilities; (b) broker, brokering a transaction between two or more parties; (c) mediator, acting as an independent third party who assists two organizations achieve a mutually beneficial collaboration and (d) resource provider, acting as an agent who secures access to funding and other material support for the innovation outcomes of such collaborations (Chunhavuthiyanon & Intarakumnerd, 2014; Chappin et al., 2008).

Nakwa et al., (2012) highlight the importance of intermediaries in transforming pre-existing inter-firm networks into more robust, dynamic, and sustainable system-oriented networks. In addition, Nakwa et al., (2012) indicate that "intermediaries play a sponsoring role at the policy level by channeling resources to industry; a brokering role at the strategic level by linking triple helix actors; and a boundary spanning role at the operational level by providing services that facilitate knowledge circulation".

Intermediary organizations are pertinent in facilitating the flow of knowledge, technology, and skills among the actors of the SI. Within this actor group, institutions supporting technical change (ISTC) promote knowledge generation, technology development and commercialisation; facilitators like industry associations establish and reinforce the links between system actors through networking; enablers such as industrial parks and incubators support with infrastructure, framework conditions, capabilities and related resources and funders (Letaba, 2019).

[16] Leydesdorff claims no ex ante or necessary limitation to three helices for the explanation of complex developments, but instead proposes that an N-tuple or an alphabet of (20+) helices can be envisioned. However, in scholarly discourse and for methodological reasons, one may wish to extend models step by step and as needed to gain explanatory power. (Leydesdorff, 2012).

[17] Civil society - comprising the activities of non-state organizations, institutions and movements - has in recent years emerged as the major force for change in the realms of politics, public policy and society both globally and locally. It is also recognized as an actor in the quadruple helix (Roman et al., 2020). Yet, despite the crucial importance of this political phenomenon to the principle and practice of democracy, it eludes definition and systematic understanding (Anheier 2004). The benefits of incorporating civil society within systems measurement, and hence policy craft include: i) the provision of bottom-up insights, particularly as civil society represents demand-side perspectives, such as innovation users and consumers; ii) supports the creation of social innovations, and legitimation and justification for innovations; iii) promotes commitment to and ownership of a development agenda. However, despite the aforementioned benefits civil society comprises a heterogeneous group of actors who must themselves be approached differently and therefore measurement is a challenge. It would be important to note that participation of civil society should be included for the policy selection and implementation process.

Table 2 below shows core actors, arbitrageurs and intermediary organizations by the function they perform in the Indian food and beverages sector. These functions span across the innovation value chain, namely: knowledge generation and transfer; technology development, acquisition, and transfer; product development; testing service; commercialisation; and business development.

TABLE 2: Intermediary organizations by function in the pharmaceuticals sector

Function	Knowledge based institutions	Government	Intermediaries	Arbitrageurs (VCs, Angels, NBFCs)
Technology Development	• NIPER's • CSIR Labs • ICMR, NCL	• BIRAC • Department of Biotechnology (DBT) • Department of Pharmaceuticals (DoP) Ministry of Chemicals and Fertilizers	• IPMA • IDMA • BDMA	
Technology Transfer	• Biotech Parks* • Science Park • University-enterprise joint research centre • University-owned enterprise centre	• BIRAC • Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers • Department of Science and Technology (DST) • Department of Scientific and Industrial Research (DSIR)		
Technology Acquisition	• ICMR • CSIR labs	• Department of Pharmaceuticals, • Ministry of Chemicals and Fertilizers		
R&D		• BIRAC, Department of Biotechnology, • Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers		
Knowledge Transfer		• BIRAC • Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers • Pharmacy Council of India	• BDMA • IPA • IDMA • Ayurvedic Drug Manufacturers Association (ADMA)	
IP Protection	• Science Park	• Patent offices	• IDMA, OPPI, IPMA	
Infrastructure Development		• Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers • Ministry of Education • Ministry of Health	-	
Product Development	• NIPER's • CSIR Labs • ICMR, NCL • Biotech Incubators*	• Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers		
Human Capital Development	• University-enterprise joint research centre, • Pharmaceutical Colleges	• Pharmacy Council of India • Bulk Drug Park of DoP	• LSSSDC - Life Sciences Sector Skill Development Council • IPA • IDMA	
Business Development	• Science Park • Incubator • Industrial Park	-	• Incubator • Industrial Park	
Funding	• University-enterprise joint research centre	• DBT • Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers DSIR • TIFAC	-	
Fund raising		• Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers	-	
Agenda setting		• The Central Drugs Standard Control Organization (CDSCO) • Drug Control Authority of India • Ministry of Environment • DGFT • Ministry of Commerce	• OPPI • IPA • IDMA	
Testing & certification services	• University-enterprise joint research centre	• CDSCO • CSIR - CSIO		

Source: Letaba, Petrus (2019)

Compared to the Triple Helix Type III, our augmented version of the model also gives prominence to the fourth industrial revolution (4IR) and digital transformation through ICTs. Through the spread of digital information and ICT, a new technological wave and a new corresponding mode of development has emerged (Perez, 1983; Freeman and Louça, 2001; Mowery, 2009). Innovation activities shape and use ICTs with lagged but often large effects on productivity and innovation in both developed and developing economies (Paunov and Rollo, 2016; Hjort and Poulsen, 2017). The channels through which ICTs affect firms' productivity and innovation are multiple, and often difficult to disentangle. For example, ICTs can facilitate access to information and knowledge, fostering learning and knowledge flows, or ease communication among firms and SSI actors, thereby promoting collaborative projects. To make the most of these new technologies, countries have put in place several policies. However, often their design does not take full account of the local environment in which actors operate, suggesting a potentially large role for evidence-based policymaking in this area (Koria et al., 2014).

Today, ICTs are at the centre of what many believe to be the Fourth Industrial Revolution (4IR) (World Bank, 2016). Each of the actors in the Triple Helix Type IV has a specific role to play in the context of the 4IR. Using analytics and data, the 4IR allows firms to identify new opportunities, expand their businesses and tap into new markets. 4IR technologies enable firms to increase their productivity, provide better customer experience, and optimise resources.

Universities have a great role to play to make the 4IR a reality, particularly through fostering the development of future skills as well as acting as test beds for new technologies. The role of the government in the context of the 4IR is to facilitate the adoption of emerging technologies through support infrastructure and regulations (Kucirkova, 2019).

The adoption of the 4IR and digital transformation requires investments which could be satisfied with the help of arbitrageurs such as venture capital (Deloitte, 2018a). Innovative technologies are becoming more prevalent and venture capitalists are making even greater investments in them. Venture capital investments in 4IR-focused startups have steadily increased, both in terms of size and number of deals. Globally, venture capital investments in this arena grew from approximately US$ 600 million in 2014 to US$ 2.3 billion in 2016, representing a 40% CAGR (Deloitte, 2018).

However, venture capitalists need to be mindful of conservative and risk-averse investment strategies that fail to consider a broad range of promising investments bias towards companies in specific narrowly defined industries. VCs should not conflate "risk averse" with prudent (Forbes, 2021). Regular communication between arbitrageurs and especially with industry and other actors such as KBIs, government and intermediaries can help VCs understand the dynamics of the sector and invest accordingly.

Due to the rapid changes in technologies linked to digital transformation and the 4IR, firms require the support of intermediaries as knowledge brokers. Intermediaries can ensure that knowledge spillover processes are more inclusive for firms and thereby contribute to developing their absorptive capacities. In addition, intermediaries have a vital role in building efficient technology transfer systems between actors of the system of innovation (Karlsen et al., 2022).

Considering the above, utilising the Triple Helix Type IV for measuring the Indian Pharmaceutical Sectorial System of Innovation (IPSSI) provides an evidence-based framework for identifying barriers and priorities, leading to the articulation of policies and targeted short-, medium-, and long-term interventions.

3. Survey Methodology

Survey Methodology

The Indian Pharmaceutical Sectorial System of Innovation (IPSSI) Survey has been conducted to obtain a holistic view of the SSI as a basis for evidence-based innovation policy for the pharmaceutical sector, one out of the five sectors surveyed under the sectorial system of innovation component of the National Manufacturing Innovation Survey 2021-22.

Essentially, two basic forms of data collection exist, those with and those without an interviewer, or, phrased differently: interviews and self-administered questionnaires (De Leeuw, 2009 in Dillman ed). Interview surveys can either be administered in person or over the telephone. There is a great deal of variation in the use of these methods across countries, due to technical reasons, lack of infrastructure, or cultural norms (Dillman, 1978; Dillman, 1998). Self-administered questionnaires take on many forms and can be used in group or individual settings. A well-known example of a self-administered questionnaire is the mail survey, and its computerized equivalent, the Internet survey, which is the current norm (Raziano, et al., 2001; De Leeuw et al., 2003). Often a combination approach is used, particularly when there is the need to ask sensitive questions. All the taxonomical approaches mentioned are respondent orientated, and the method choice is complex and based on a delicate balance between the quality of the data acquired, time and costs.

The Internet-based approach was chosen in line with the reasoning of Koria, et al., (2012), that i) "… maximising the use of the budget, internet surveys can cover a much larger sample size than the conventional mail survey (Berrens, et al., 2003); ii) the time dimension associated with conducting web-based surveys is much lower in comparison to other forms (Cobanoglu et al., 2001); iii) the quality of retrieved data is higher in terms of non-response and the ability to include conditionality in a discreet manner (Olsen, 2009); iv) a higher reliability of data is achieved due to the reduced need for data entry (Ballantyne, 2004; and Muffo, et al., 2003)." (Koria, et al., 2012., pg.8); and v) the emergence of the COVID-19 pandemic restrictions during the implementation phase of the project which limited face-to face interaction.

3.1 Sample Selection

As per the "Theoretical Framework" chapter, the IPSSI Survey focuses on five core actor groups, namely: government (GOV), knowledge-based institutions (KBI); arbitrageurs (ARB); intermediaries (INT) and industry (IND). The executive policy community, essentially the government (GOV), is represented by high-level officials (national and state level) in the relevant public institutions that are directly or indirectly responsible for innovation in the pharmaceutical sector. Knowledge-based Institutions (KBIs) are represented by the heads of university faculties/ departments from the disciplines of engineering, technology and innovation, think-tanks, as well as both public and private research institutes (RIs). Arbitrageurs (ARB) comprise the venture capital, angel investors, and banks or other financial institutions and are represented by their respective heads or senior management. Intermediaries constitute industry associations and institutions supporting technical change such as regulatory bodies and are represented at the managerial level. The industrial community is represented by the CEOs of firms from the pharmaceutical sector.

Procedure:

Non-firm actors, namely GOV, KBI, ARB and INT were sampled on a convenience basis. A frame was prepared for the pharmaceutical sector with around 200 relevant non-firm actors within GOV (20), KBI (50), ARB (40) and INT (90) which was treated as the universe and the sample. Sampling for firms (IND) were conducted through stratified random sampling across 28 states and 8 union territories, the five sectors, including the pharmaceutical sector from the National Industrial Classification (NIC) 21 (2008) and their respective firm sizes measured through a combination of turnover, investment in plant and machinery or equipment or employment.

The sampling frame for firm actors has been obtained from the "Annual Survey of Industries" (ASI) 2018-19 frame, the Centre for Monitoring Indian Economy's (CMIE) Prowess IQ database (2018-19) and the Department of Science and Technology's (DST) directory (2018-19) with a total of 5,795 firms from the pharmaceutical sector. After sampling, 785 firms were to be surveyed from the pharmaceutical sector.

The target population is broken down into similarly structured subgroups or strata, which are as homogeneous as possible, and form mutually exclusive groups. Appropriate stratification will normally give results with smaller sampling errors than a non-stratified sample of the same size and will make it possible to ensure that there are enough units in the respective domains to produce results of acceptable quality. Wherever possible, turnover and investment in plant and machinery or equipment[18][19], as per the 2020 MSME definition are used to calculate firm size as listed below.

FIGURE: Firm size classification

Turnover					
Turnover	≤ 5 cr	Large	Medium	Small	Micro
Turnover	≤ 50 cr	Large	Medium	Small	Small
Turnover	≤ 250 cr	Large	Medium	Medium	Medium
Turnover	> 250 cr	Large	Large	Large	Large
Firm size classification		> 50 cr	≤ 50 cr	≤ 10 cr	≤ 1 cr
		Investment in plant and machinery or equipment			

The Government of India notification mentions that: If an enterprise crosses the ceiling limits specified for its present category in either of the two criteria of investment or turnover, it will cease to exist in that category and be placed in the next higher category but no enterprise shall be placed in the lower category unless it goes below the ceiling limits specified for its present category in both the criteria of investment as well as turnover.

In some cases, employment data was used as a proxy for firm size and the firms were reclassified post the survey.

- Large – 200 + employees (Kapoor., 2016, p.11)[20]
- Medium – 50 to 199 employees
- Small – 20 to 49 employees
- Micro – 0 to 19 employees (Kapoor., 2018, p.12)

Limitations:

- The data collection was impacted due to the covid crisis as businesses were closed. This affected the survey response rate to some extent with an overall response rate of 48.83%, a firm response rate of 48.28% and non-firm response rate of 51%.
- Absence of a baseline for evaluating the performance of sectorial system of innovations in India as there are no prior surveys conducted along the same lines.
- The classification of firms into large, medium, small and micro is only a rough estimate given the universe is a combination of 3 databases with the absence of similar parameters to measure firm size.

3.2 Data Collection

Due to the technical nature of the data to be collected it is imperative that the quality and integrity of information is ensured. Consequently, the outlined approach was utilised to maintain a level of rigour in the selection of enumerators from the Indian knowledge-based and technical institutions, as compared to standard data collection firms. The merits of the approach are outlined below:

Selection of enumerators and retention

Criteria: Given the highly technical nature of the information collected it is imperative that the selected enumerators were able to:

- Comprehend the specifics of innovation and systems of innovation.
- Effectively communicate innovation constructs to the target respondent.
- Guide the discussion as and when required, based on some degree of understanding and exposure to

[18] The expression "plant and machinery or equipment" of the enterprise, shall have the same meaning as assigned to the plant and machinery in the Income Tax Rules, 1962 framed under the Income Tax Act, 1961 and shall include all tangible assets (other than land and building, furniture and fittings): https://msme.gov.in/sites/default/files/IndianGazzate_0.pdf

[19] Data on turnover and investment in plant and machinery or equipment is inflation-adjusted using CPI with base year 2015. Investment in plant and machinery or equipment values are adjusted for depreciation by taking their net values.

[20] Small firms are defined as those having less than 50 employees, medium firms have 50-199 employees and large firms are defined as those having 200 or more workers.

innovation in the sector, which will also enable them to support data analysis and reporting.

- Demonstrate experience in data collection and therefore be able to extract nuanced information.
- Communicate in the relevant regional language of the focus state; and
- Summarise the findings and participate in further analysis of the data to support the UNIDO team.

Enumerators were trained on systems of innovation, technical aspects related to the pharmaceutical sector and data collection techniques with the Lime Survey®interface. In order to ensure data quality, Lime Survey® enables real time tracking of enumerators to the respondent level through the back end. It also signals when surveys have been partially completed. The fact that an online interface is being used means that there is zero transcription error, that is, once the response to a question is given it is automatically updated to the database. In addition, spot checks from the response data are randomly taken to ensure data quality at the level of each individual enumerator is being maintained.

3.3 The Data Acquisition Survey Instrument (DASI)

The Data Acquisition Survey Instrument (DASI) for the IPSSI Survey was created using an interactive multi-step process, and currently stands at its fourth iteration. The provenance of the earlier iterations of the tool can be found in Ghana, Kenya and Cabo Verde National System of Innovation Survey Reports (Bartels and Koria, 2012, 2015; Koria, 2019). The current iteration, DASI-V4, saw the introduction of new actor-specific questions to support measurement at the sectorial level and to provide better insights at the actor level. This enhancement of the DASI allows for greater accuracy and impact of the policy recommendations in the short-, medium-, and long-term.

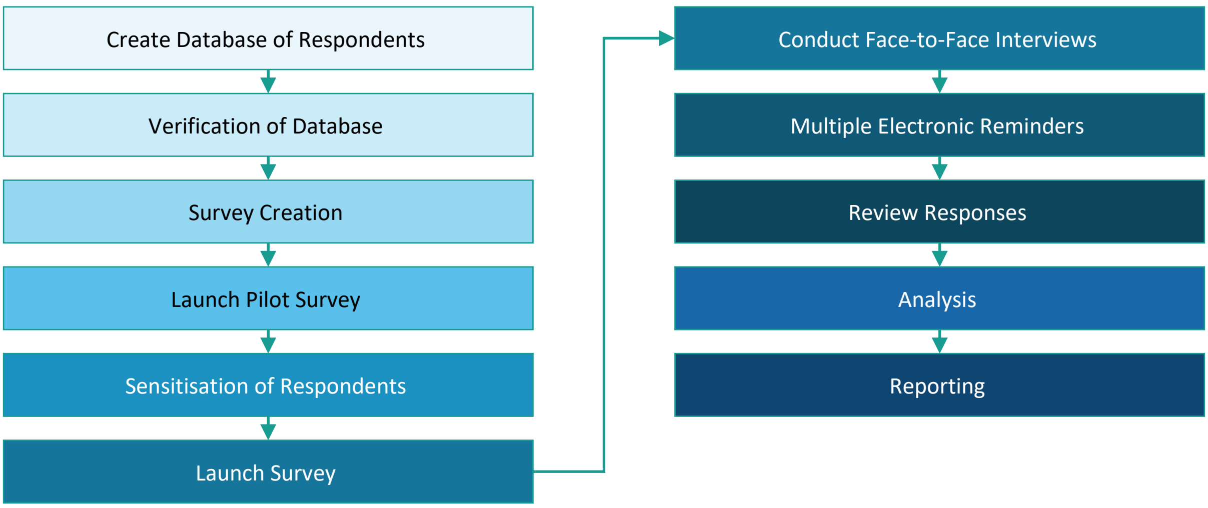
3.4 Survey Operationalisation

The launch of the survey was accomplished by using a combination of both the free open-source software tool Lime Survey® as well as, where possible, face-to-face interviews. The Lime Survey® tool is an advanced online survey system. The outputs from the verification protocol were uploaded into the Lime Survey® system and individual tokens were assigned to each target respondent. This restricted survey access solely to the targeted qualified individual respondent, therefore greatly enhancing the fidelity, reliability and validity of the results obtained.

As previously mentioned, the IPSSI Survey was launched remotely once the initial critical mass of target respondent contacts had been gathered. The survey was remotely and non-intrusively managed via the Lime Survey® interface. Electronic reminders were sent out to the target respondents who had only partially completed or not responded at all. This process was facilitated by the structure of the Lime Survey® back-end, as the system logs the exact date and time at which the survey was accessed and to what degree it was completed.

For those who had not accessed the survey for a long period, a follow up was made telephonically to monitor any potential technical difficulties. Once responses were completed, they were automatically uploaded into the survey response database. On completion of data collection, the survey responses were analysed with the planned statistical analysis in mind. Figure 3 shows the steps associated with the data collection process.

FIGURE 3: Operational Methodology



3.5 Secondary Data Collection

In addition to the primary data collection undertaken, it is crucial to gain a view of what is being presented in the form of secondary sources at the sectorial level, particularly those from the government. The secondary sources that were analysed comprised qualitative material consisting of policy documents, government budget statements, development strategies and action plans at the national and sectorial levels. The purpose of analysing these documents was to gain an understanding of the policy direction that the Government of India is taking with respect to innovation in the pharmaceutical sector. Phrased differently, is there convergence or divergence between what is presented within policy documentation from the actual results obtained? The results of the analysis are presented in the "Results and Analysis" chapter of this report.

3.6 Stakeholder consultation

In order to garner preliminary insights into the results obtained from the survey, a stakeholder consultation was undertaken. Results were presented and discussed with sector experts and practitioners in order to understand whether or not the observations were meaningful. The platform provided an opportunity to orient the report writing through linking the findings to specific case examples as well as highlighting any supporting secondary research that may have been conducted at the national level. The process was important for the identification of any potential outliers in the results.

4. Manufacturing Landscape in the Pharmaceuticals Sector

Manufacturing Landscape in the Pharmaceuticals Sector

4.1 Indian Pharmaceuticals Sector: Structure and Dynamics

The Indian pharmaceutical industry has shown incredible resilience in meeting not only domestic demand but meeting global needs in ensuring the availability of critical medicine. It is the third largest player globally, regarding volume, and is the largest supplier of low-cost generics and vaccines to the world[21].Drugs and pharmaceuticals are the fourth most important export commodity in India's export basket in terms of value. By volume, the country accounts for 20% of the global supply of generic medicines and 60% of the world's vaccine supply. The United States is the key trading partner in this industry. Currently, the sector contributes to 2% of the gross domestic product (GDP) and employs 2.7 million personnel; varying estimates of indirect unrecorded employment place higher figures overall.

The pharmaceutical industry has grown immensely, from US$ 40.8 billion in 2020 to a projected figure of US$ 130 billion by 2030, at a combined aggregate growth rate (CAGR) of 12.3%, with a previous CAGR of 9.43% over the last nine years (IBEF, 2022). Varying estimates of growth predict the market to be US$ 60 billion by 2025 growing by a rate of 11% annually over the next two years (CARE Ratings, 2021). The current size of the domestic pharmaceutical market is US$ 50 billion, up from US$ 42 billion in 2021, which is expected to grow to US$ 65 billion by 2024 (Economic Survey, 2021). Formulations and biologicals continue to account for a major share in total exports at 73.31%, followed by bulk drugs and drug intermediates with exports of US$ 4437.64 million[22] (Figure 4 below).

Due to the increasing importance of biologics, developed upon patent expiry in the United States and the niche upcoming market in new age medical devices, a view of related industries like biotechnology is also necessary. The Indian biotechnology industry comprises biopharmaceuticals, bio-services, bio-agriculture, bio-industry, and bioinformatics. The Indian biotechnology industry was valued at US$ 70.2 billion in 2020 and is expected to reach US$ 150 billion by 2025. The impressive growth in the pharmaceutical industry during the pandemic is attributed to the formulation development capabilities, the trained workforce, and reputation in major international markets like the United States and Europe. India supplies 50% of the global demand for vaccines and 80% of the global demand for anti-retrovirals, as well as 40% and 25% of the of the generic demand in the United States and United Kingdom respectively.

The Indian medical devices industry stood at US$ 10.36 billion in the FY 2020, ranking it 19th in the world. The market is projected to increase at a CAGR of 37% from 2020-25 to reach US$ 50 billion (India Brand Equity Foundation, 2022). The diagnostic imaging market alone is expected to grow at a CAGR of 13.5% between 2020 and 2025 (Singh, 2022). The Commerce ministry data analysed by the Association of Indian Manufacturers of Medical Devices (AiMeD) shows that the imports of medical devices have gone up drastically, by 41 %, to INR 63,200 crore in 2021-22 from 44,708 crore in FY 2020-21, making the level of import dependence around 80% (Mordani, 2022). In this scenario, the development of medical devices is limited to surgical and medical equipment and new categories of digital devices and wearables are primarily based on imported products.

4.2 Overview of India's Export Market in the Pharmaceuticals Industry

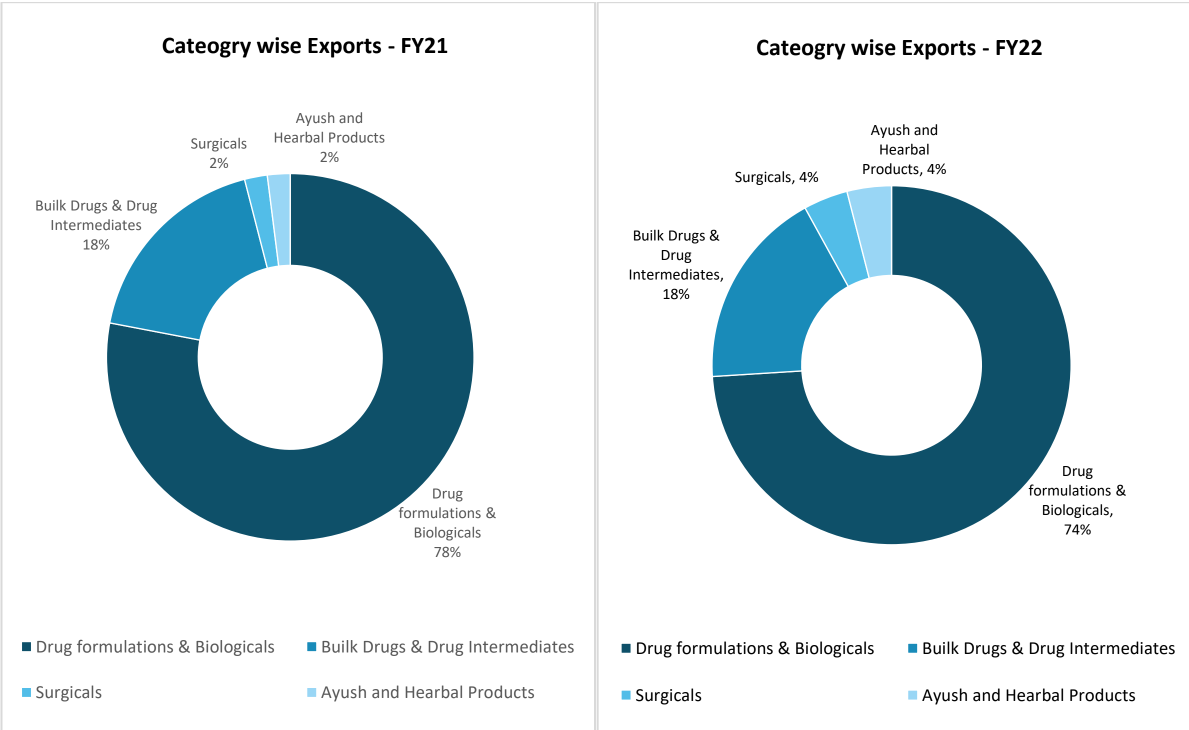
India is the 12th largest exporter of medical goods in the world. It currently exports to 200 countries globally, with the United States being a key export destination. India's drug exports stood at US$ 24.62 billion in 2022 and US$ 24.44 billion in 2021. The major categories of APIs (active pharmaceutical ingredient) under export are anti-infectives, anti-asthmatics and anti-hypertensive and cardiovascular drugs, anti-hypnotics, sedatives, and tranquilisers. Bulk drugs comprise 50% of the domestic market at INR 42,000 crore (US$ 5.10 billion) and 9% of the global market. The Indian API industry is the 3rd largest

[21] Impact of the Pharma Industry on the Indian Economy, KPMG-FICCI Report: https://ficci.in/spdocument/23599/Ficci_Pharma-report.pdf

[22] "India's pharma exports have grown by 103% since 2013-14, pharma exports in 2021-22 sustain a positive growth despite global trade disruptions, pharma trade balance continues to be in India's favour, around 55% of Indian pharma exports cater to highly regulated markets", Press Release no. 1821747, issued by Ministry of Commerce and Industries, Government of India, Press Information Bureau: https://pib.gov.in/PressReleasePage.aspx?PRID=1821747

globally, contributing towards 57% of active pharmaceutical ingredients on the WHO (World Health Organization) pre-qualified list[23]. Figure 4 shows the broad category-wise composition of India's exports in the FY 2020 -21 and FY 20 21-22. India retains an export share of 78% (now 73%) for 'Drug formulations and biologicals' and an export share of 18% in 'Bulk drugs and drug intermediates'. 'Ayush and herbal products' and 'Surgicals' have also both almost doubled their share.

FIGURE 4: Export composition of India's pharmaceuticals industry



Source: Indian Brand Equity Foundation

However, the scenario of import dependence on 53 APIs from China, used in producing medicines for critical illnesses (in some cases an import dependence of up to 90%) (Chaudhuri, 2021) and the resultant delays and cost overruns due to supply chain issues in the pandemic have led to the realisation that a change of trajectory is mandated to sustain the current growth and reduce barriers to export. While the growth of the share of Chinese imports has been reduced over the years to 50% in the case of bulk drugs, the challenge this poses has been the subject of various deliberations[24]. Therefore, the Government of India (GoI) has committed US$ 1.3 billion over the next ten years, as part of a production linked incentive scheme[25] to facilitate import substitution and self-reliance. The short-term target is to reduce import dependence by 25% by the year 2024.

The pharmaceutical industry demonstrated a growth in value-added for pharmaceuticals on a year-on-year basis from 4.9% in 2021 and is projected to grow at a rate of 6.9% in 2023. In contrast, healthcare demonstrated a growth rate in value-added year-on-year of 8.1% in 2021 to a projected growth rate of 4.7% in 2023. Currently (2022) the Indian pharmaceuticals value-added output is growing at 6% annually due to the ongoing rollout of COVID medications, rebound in non-COVID-related medical treatments and a surge in generic medical exports.

[23] For the WHO list of 162 pre-qualified active pharmaceutical ingredients, see: https://extranet.who.int/pqweb/sites/default/files/documents/API_PQ-List_V04_11October2022.xlsx The list of finished pharmaceutical products under assessment is available at: https://extranet.who.int/pqweb/medicines/dossier-status For details on the pre-qualification procedural and other requirements, see: https://extranet.who.int/pqweb/medicines/active-pharmaceutical-ingredients-0

[24] 145th Standing Committee (Gujral Committee) Report on Commerce (2018) titled "Impact of Chinese Goods on Indian Industry", Rajya Sabha Secretariat: http://164.100.47.5/committee_web/ReportFile/13/97/145_2018_7_13.pdf

[25] See Operational Guidelines for the Production Linked Incentive Scheme for Pharmaceuticals: https://pli-pharma.udyamimitra.in/Default/ViewFile/?id=OperationalGuidelinesofPLIschemeforPharmaceuticals.pdf&path=MiscFiles See also, Revised Guidelines for the Production Linked Incentive Scheme for promoting the domestic manufacture of Medical Devices: https://pharmaceuticals.gov.in/sites/default/files/Revised%20Guidelines%20of%20PLI%20Medical%20Devices%20dated%2018.08.2022.pdf

Among the conditions influencing the financing of manufacturing and research and development activities, in terms of structural factors, most including business, financial conditions and a default assessment are favourable in the current scenario of economic instability overall. In Q1 of 2022, drug producers still faced pressures on gross margins due to high commodity and transport costs. However, the balance sheets of these companies remain strong and their ability to generate cash surplus is strong. The firms in the small and medium enterprise sector, however, may not be similarly placed, yet the production linked incentive is targeted at larger firms, which can take the capital-intensive task of API manufacture. Particularly, the scheme provides greater funding to chemical synthesis-based manufacturing plants, in contrast to fermentation-based plants. The latter are used in most APIs in which there is import dependence to a greater extent. [26] In terms of cumulative FDI, the drugs and pharmaceuticals industry ranked 9th with US$ 17, 991 million from 2000-2021[27] (US$ 17,787. 68 million on calendar year basis to December 2020[28]), with an investment inflow of US$ 1,490 million in FY 2020-21 alone[29] (US$ 1,349.9 million for calendar year 2020-21).

India has the maximum, 741, United States Food and Drugs Administration (USFDA) approved manufacturing facilities outside the US (including those for APIs), 2050 WHO-GMP approved plants and 286 EQDM approved plants (European Directorate of Quality Medicine)[30]. Currently, 500 API producers service 8% of global API production. Earlier reports suggest that until 2018, India had the second largest number of USFDA approved manufacturing facilities globally[31]. In FY 2019-20, the number of factories stood at 5,326 units with an invested capital of INR 133,358.9 crore (approx. US$ 16,232.01 million). The number of workers in these factories is 516,095 of a total workforce of 807,279 (Annual Survey of Industries, 2019-20). The domestic network comprises 3000 firms and 10,500 manufacturing units, mostly in the unorganised sector. Of these, 300-400 are recognised as medium to large, organised sector firms with the top 10 manufacturers accounting for 36.5% of the market share. This overall structure arises due to the changes in regulatory definitions of company type contingent upon company size (investment and turnover), regarding small and medium enterprises.[32] For this, we also need to contextualise the current distribution of manufacturing facilities and their implications for the development of healthcare special economic zones, and co-location manufacturing facilities for medical equipment. Figure 5[33] below shows the overall distribution of pharmaceutical facilities clusters across India.

[26] Pharmaceutical Industry Trends India - 2022, Market Monitor: https://atradiuscollections.com/global/reports/pharmaceuticals-industry-trends-india-2022.html

[27] Cumulative FDI Inflows - Sector-wise, Financial Year basis from April 2000-2021. Source: DPIIT, GoI: https://dpiit.gov.in/sites/default/files/Chapter_1.3_A_iv_0.pdf

[28] Cumulative FDI Inflows-Sector-wise, Calendar Year basis from January 2000 till December 2020. Source: DPIIT, GoI: https://dpiit.gov.in/sites/default/files/Chapter_4_3.pdf

[29] Foreign Direct Investment Inflows for FY 2020-21: https://dpiit.gov.in/sites/default/files/Drugs%20%26%20Pharmaceuticals%20%28ix%29-2020.pdf

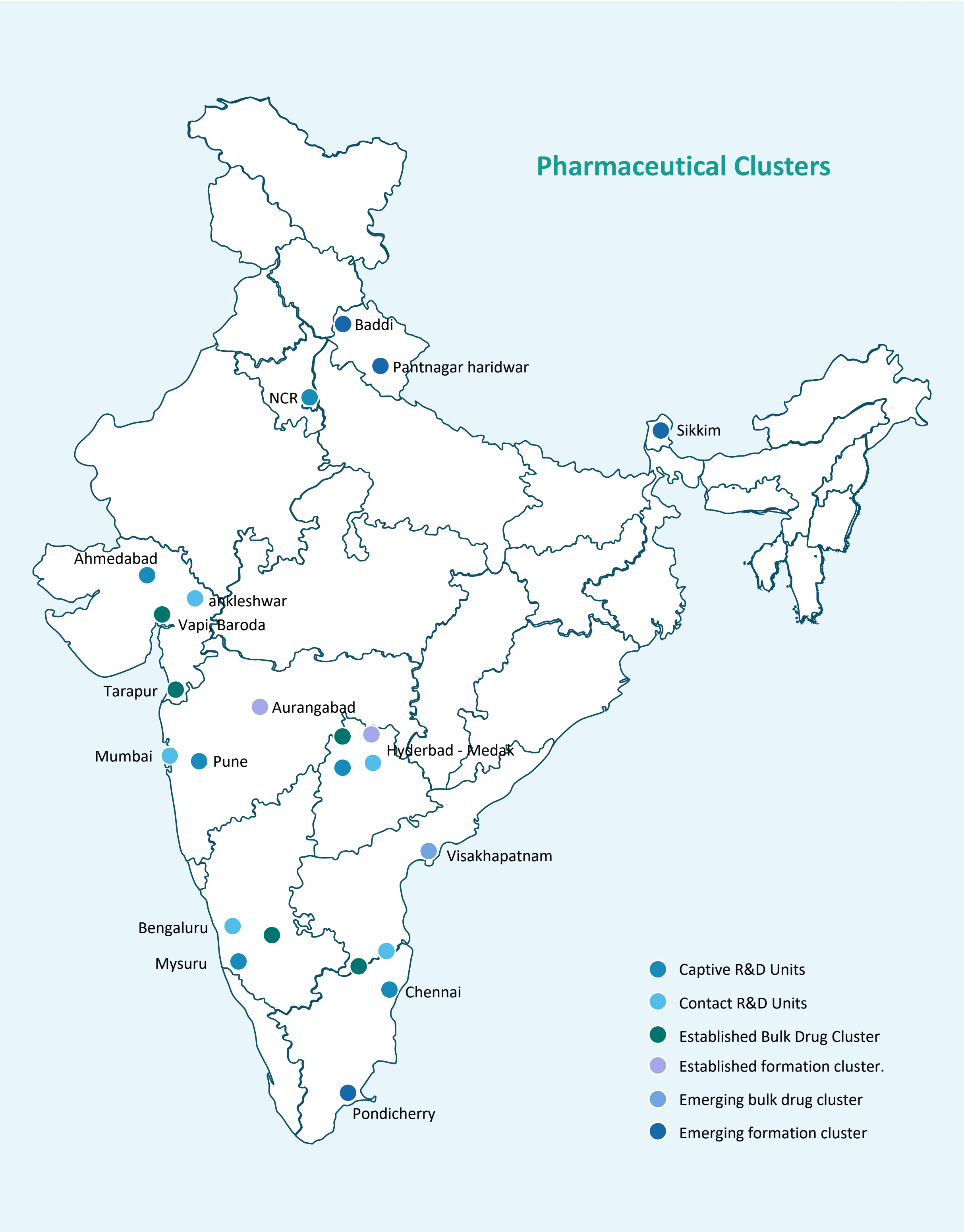
[30] "India: Pharmacy to the World- A Healing Touch with Healthy Profits" (2020), Strategic Research Unit: https://static.investindia.gov.in/2020-08/Invest%20India%20Pharma%20Report_SIRU.pdf

[31] FICCI Report, 2018: https://ficci.in/spdocument/22944/india-pharma-2018-ficci.pdf

[32] Micro, Small and Medium sized Enterprises Development Act, 2006 defines small enterprises as ones having INR 10 crores in investment and up to INR 50 crores in turnover. The limit in respect of medium enterprises was INR 20 crores in investment and up to INR 100 crores in turnover.

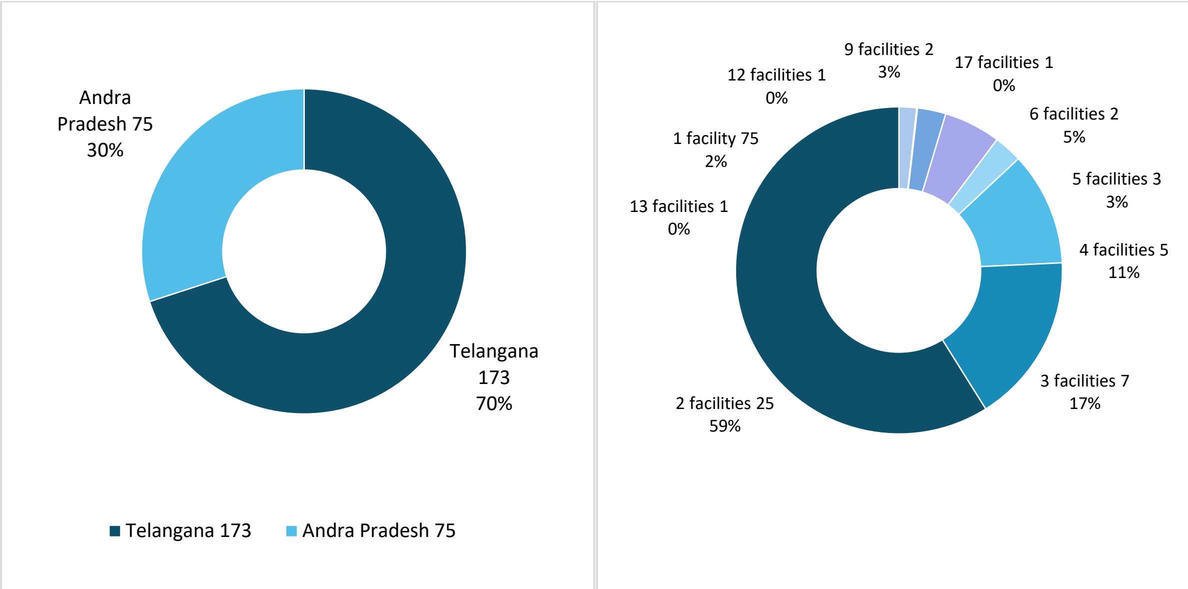
[33] Sourced from: https://marketinsight.in/industry-reports/indian-pharmaceutical-industry-growth-size-segmentation

FIGURE 5: Distribution of types of units and established/ emerging clusters for formulation and bulk drugs



Particularly, Gujarat, Karnataka, Telangana, and Maharashtra have the maximum of these manufacturing facilities in India (See Figure 6 below for distribution of manufacturing facilities overall in the two Indian states and per company in Andhra Pradesh and Telangana).

FIGURE 6: Number of EMA and/or FDA approved pharmaceutical manufacturing facilities in Andhra Pradesh and Telangana



Source: GlobalData: Pharmsource, 2019

4.3 The Technology-Shift in the Indian Pharmaceuticals Manufacturing Industry

The Indian pharmaceutical sector is one of the country's leading science-based industries, having widespread competencies in the complex field of drug manufacturing and technology. The focus on self-reliance through cooperation in existing areas of trade in generics and expanding the development of API manufacturing facilities has made an appearance in the post-pandemic context. There has been a shift in focus towards agile, lean manufacturing practices and the use of intermediaries such as clinical research organizations, contract research and manufacturing services (CRAMS). The penetration of health insurance has been key to the expansion of the market access to healthcare, in addition to disposable incomes to the middle-class household level and the rising costs of healthcare. This is in sharp contrast to the scenario of self-reliance in the post 1991 period of liberalisation (Festa et al., 2022). India's manufacturing and technological trajectory reflect its fragmented nature, in terms of technology adoption and assimilation, and also the conflicts between sustaining volumes, in contrast to profit and economic performance. The former is done through leveraging innovation in upstream activities like research and development, and also the downstream commercialisation of medicines. An unintended consequence has been the failure of incentives to yield outcomes, in terms of innovations in research and development and service delivery mechanisms to provide enhanced access. The country still invests around 0.8% in research and development, while the healthcare allocation overall has increased, due to the impact of the pandemic, including a focus on providing clean drinking water and sanitation facilities, which supports the goals of healthcare and preventive medicine. The current political economy of generating trade surpluses has not lived up to the theoretical promise, due to entry level barriers and market access restrictions. While the GoI allows foreign direct investment (FDI) up to 100% under the automatic route, including green field and brownfield investments in recombinant DNA technology, among a host of new age manufacturing paradigms supporting personalised medicine, the effectiveness of policy measures is nuanced at best. A look at the technology frontier in the global North and South is crucial to develop a contrast on how digital transformation is currently sweeping the pharmaceutical manufacturing landscape in various countries.

4.4 Global and Domestic Technology Frontier: Some Perspectives

Over the past two centuries, medicine underwent an evolution from crude herbal and botanical preparations to more complex manufacturing of sophisticated drugs, products and dosage forms. This evolutionary pathway for medicine has been accompanied by a shift in manufacturing practices from small-scale manual processing with small tools to large-scale production with sophisticated equipment (N. Sarah Arden et al., 2021). To enable significant rapid growth, India's value proposition, must transform itself amidst intense cost pressures and competition, achievable through a major transition from being a generic drug producer to a producer of novel molecules and biosimilars through rigorous research and development activities (Sathya Durga, 2022). In the past decade and a half, the Internet Revolution redefined business to consumer (B2C) industries, such as media, retail, and financial services. In the next ten years it is believed that the Internet of Things will revolutionise manufacturing, energy, agriculture, transportation, and other industrial sectors of the economy, which account for two-thirds of the global GDP (WEF, 2015).

In its latest digital transformation assessment, International Business Machines Inc. (IBM)[34] reports the findings on digital transformation in two-time horizons. Among the immediate priorities, the short-term actions that manufacturers have had to take in response to a highly volatile, unpredictable trading environment. In the face of repeated disruptions, firms have shown an incredible capacity to embrace change quickly. Three interconnected factors have been a priority in this context, namely the human impact, data gathering to support decision-making, and swift and calculated action. The immediate focus has been on increasing operational efficiency and resilience to enhance output with minimum outlay. The heightened need for accurate, real-time information has faced hindrances from outdated hardware and software from multiple vendors within institutional IT environments. Almost all senior executives that participated in the survey noted that manual reporting and data collection are still the mainstay within organizations. It is therefore logical to see the adoption of digital data gathering tools or to fulfil some of the finance or human resources functions. Out of 1200 senior executives, 10% belong to the chemicals and pharmaceuticals domain. An overwhelming 67% of the total respondents have accelerated digital projects in response to COVID-19, with 92% of the total respondents ranking improving operational efficiency as a priority. Other priorities include building resilience, creation of value, etc.

The "UNIDO Industrial Development Report, 2020", outlines that adoption of advanced digital production (ADP) of Industry 4.0 technologies radically alter manufacturing and blurring the lines between physical and digital production systems. Advances in robotics, artificial intelligence, additive manufacturing, and data analytics generate opportunities to accelerate innovation and increase the value-added content of production in manufacturing industries. The report addresses the claims made in relation to these technologies and their labour-displacing effects, coupled with a tendency towards increased back shoring of outsourced jobs and the lack of an inclusive nature, due to a high threshold of capabilities that countries will require to remain competitive. The potential of advanced digital production technologies is emphasised in this context. Technologies can increase the operational efficiency and productivity of industrial production processes, and as evidence suggests, it can also help create new industries. Although many jobs will become vulnerable to automation, it is likely to create job opportunities in more skilled and knowledge-based sectors. The evidence suggests that once the indirect effects across the value chain are considered, the increase in the stock of robots used in manufacturing at the global level will generate employment. Evidence on back-shoring from emerging to industrialised countries shows that the trend is weak. It is counter-balanced by offshoring of production in developing countries, which creates jobs and forward and backward value chain linkages (linkages between industrialised and emerging economies). Policy areas that demand attention in this context are developing framework conditions and digital infrastructure, to embrace new technologies, coupled with fostering demand and leveraging ongoing initiatives using ADP technologies as well as strengthening skills and capabilities. However, the report outlines that many countries have yet to adopt these new breakthrough technologies. Firm level data in five developing countries show that the manufacturing sector is characterised by the existence of "technology islands".

In the UNIDO Industrial Development Report, 2022[35], the authors document the key impacts of the COVID-19 crisis and need for resilience in an environment of vulnerability. A key finding is that industrial capabilities are fundamental to building resilience and enhanced employment potential and income generation. In addition to macroeconomic outcomes, the sector provides access to essential goods and services to populations across the world including food, medical equipment, and pharmaceutical products. Countries with stronger manufacturing capabilities and more diversified industrial sectors withstood the economic and health impact of the pandemic. Findings of the study also allude to the centrality of sustainable development goals (i.e., SDG 9 - building resilient infrastructure, promotion of inclusive and sustainable industrialization and fostering innovation). The uptake of new, advanced digital production technologies helps strengthen resilience. In addition to supporting resilience, manufacturing drives shared prosperity. The innovation and multiplier effects

[34] IBM. 2021 Digital transformation Assessment, CoVID-19: A Catalyst for Change: https://www.ibm.com/downloads/cas/MPQGMEN9
[35] UNIDO. The Future of Industrialisation in a post-pandemic world, United Nations Industrial Development Organization, e ISBN:978-92-1-001150-1: https://www.unido.org/news/future-industrialization-post-pandemic-world-industrial-development-report-2022

and network externalities cause economy-wide effects, as part of integrator function between natural-resource-based industries and services. The uptake of new digital production technologies helps strengthen resilience. There is sound evidence from emerging and developing economies, from Africa, Asia and Latin America that digital technologies have been instrumental in facing the onslaught of the pandemic. The strengthening of digital and manufacturing capabilities is the way forward and requires mutual learning and knowledge sharing. In developing countries, governments, policymakers, and business leaders must strive towards fostering the development of domestic production capabilities to strengthen resilience[36].

Advances in technology are therefore crucial for facilitating India's pharmaceutical manufacturing sector through enabling critical process improvements (process upgrading) including:

- **Virtual product design**, whereby testing, production and assessment of products is done without a physical prototype, reducing lead times. In the case of drug discovery, the actual chemical synthesis of molecules for their pre-clinical validation may implicate a need for a clearer simulation of synthetic and stereochemistry (involving use of molecular structures like isomers, etc.) and pharmacokinetics (movement of molecules within the body, particularly the cells). However, studying the impact on special groups of humans, as is done in randomised clinical trials, may involve very complex algorithms. The manufacturing context, in contrast, involves maintenance of process parameters, including but not limited to formulation manufacture process, pilling, quality testing and control.

- **Robust tracking systems** automatically alter production to reduce logistical failures. The recent regulatory requirement by the GoI under the Drugs and Cosmetics Rules, 1958, to place QR codes on pharmaceutical products is aimed towards greater traceability of batches of manufactured goods.

- **Intelligent sensors and a connected value chain** enable data interchange from design to production and enable supplier/buyer integration. Maintenance of logs, as to conditions of manufacture in real-time, can help identify and support product-recall regulations and quality control.

- **Autonomous robots** enable flexible and adaptive production lines for many models and small customised lots, improving performance. These would comprise a higher degree of digital maturity in terms of digital transformation.

- **Predictive maintenance** links to the cloud for big data and analytics; reducing downtime and improving maintenance (the core of enterprise resource planning). The deployment for data collection comprises a stage of data mastery just above office level automation, which is preliminary to the transition. The capital expenditure component of research and development expenditure is towards maintenance of hardware to support such infrastructure. Within firms, a key finding is that expenditure on information technology-related infrastructure can support the formation of polycentric alliances with competitors, in terms of an antecedent of coopetition (Estrada et al., 2014).

The organizations that are likely to have a competitive advantage in the Indian pharmaceutical manufacturing market are those that continually adopt new technologies; find ways to harness new technology and promote business integration. As part of a 'Technology First' approach, firms are prioritising technology for the maintenance and enhancement of their market position. All new plants must meet the standards set by the "Food and Drug Administration, World Health Organization and Pharmaceutical Inspection Co-Operation Scheme". An increasing number of pharmaceutical manufacturing firms are deploying cloud computing, as well as technologies like artificial intelligence (AI) /machine learning (ML) and robotic process automation (RPA). As a result of the pandemic, firms have learned to adapt to the speed of the global digital transformation and increased supply chain inefficiencies. Information technology firms have been offering varied subscription plans like the 'pay-as-you-use' model. Pharma 4.0 allows firms to leverage the IoT, AI/ML, blockchain and robotic process automation, utilising the digital cloud as the foundation for enhancing distribution and supply chain management by accelerating production and minimising errors. A medium-sized IT firm is currently helping 150 to 200 manufacturing firms upgrade their pharmaceutical manufacturing processes.

The pharmaceutical manufacturing technologies today, continue to evolve as the Internet of Things, artificial

[36] Pharmaceutical Industry Trends India - 2022, Market Monitor: https://atradiuscollections.com/global/reports/pharmaceuticals-industry-trends-india-2022.html. The projected or estimated output loss, in case of India, during the pandemic is very high at 11.7%, higher than Asian Less developed countries, developed countries, and more than double that of sub-Saharan Africa and Europe. The clear negative association with projected output losses and the relative size of the manufacturing sector in 2021 shows that stronger manufacturing sectors are associated with low projected output losses (Figure 3, page 26). Pharmaceuticals is one of the global industries that suffered a relatively small impact of the pandemic, in terms of industrial production index from quarter 2 of 2019 to quarter 2 of 2021 (see Figure 8 on page 31).

intelligence, robotics, and advanced computing (compendiously referred to as Industry 4.0 technologies) challenging the traditional paradigms, practices and business models of pharmaceutical manufacturing evolve (Shah, 2022). Industry 4.0 is characterised by integrated, continuous and autonomous self-organising systems of manufacture. Applied to the pharmaceutical industry, these technologies potentially increase the agility, efficiency, flexibility, and consistency in the quality of medicines. The site of their deployment varies across the lifecycle from data collection to the hallmark digital maturity[37]. Benefits of digital maturity can be reaped by application of seven 'digital pivots' across the enterprise, namely: flexible and secure infrastructure; data mastery; digitally savvy open talent networks; ecosystem management including collaborations and resource interdependencies; intelligent workflows towards high-value production; unified customer experience and business model adaptability (Schatsky and Gurumurthy, 2019). Their operation in concert, as opposed to selectively, is more useful in the context and the greatest benefit comes to those organizations that use them across multiple business functions. Digital pivots are, however, a necessary but insufficient condition for digital maturity, and the presence of soft complementary factors such as strong leadership and a digital mindset[38]. According to a Deloitte report on factors influencing digital transformation, businesses are planning to invest aggressively in digital transformation in the next year and as a result, their budgets will increase by 25%[39]. In a recent survey of US and European business and technology decision-makers, some three quarters had undertaken a digital initiative.

Digital transformation[40] is about more than investment in discrete technologies requiring a broad array of technology-related assets and business capabilities or digital pivots. Implementing foundational pivots focuses on assets such as infrastructure and talent, and then applying a broad range of pivots to one business function to achieve systemic pervasive transformation of that function. Focusing on transformation of back office operational functions at first is less risky, whereas focusing on customer-facing functions may produce market impact more quickly.

In the past decade and a half, the Internet Revolution has redefined business to consumer (B2C) industries, such as media, retail and financial services. Over the next ten years it is believed that the Internet of Things will revolutionise manufacturing, energy, agriculture, transportation and other industrial sectors of the economy which account for two-thirds of the global GDP.

Innovation in the industry is weaker than its potential due to a smaller number of network interactions among actors in the same or different value chain functions and/or steps. Firms' preferences for generic businesses that conduct less research is demonstrative of considerable path dependence. To shift the underlying dynamic, knowledge transfer must be enabled. The advances in information technology have undergone several useful and innovative iterations during the pandemic. The trends in digitalisation have ushered in advances in AI in manufacturing activities like 3-D printing. However, manufacturing as an activity faces considerable scaling and efficiency problems, in terms of addressing resource interdependencies. The development of underlying services used in the production of goods appears as a viable option for expansion of the manufacturing of value-added products and services with an aim to address the social concerns of access and equity.

The discourse on technological trajectories in the developed North is traditionally driven by reducing dependence on labour, as part of the production function and increased internalisation of knowledge inputs by evolutionary increases in absorptive capacity obtained from long-run investments in education and research and development infrastructure. However, in the Indian context, given the scope of employment this sector generates, the key mandate is to extend the efficiency concerns of industrial manufacturing, while at the same time ensuring the employment generating potential of the industry. The cost arbitrage and presence of skilled manpower has run its course and the current need of expansion has skilling dimensions. Table 3 and Figure 7[41] below show the typology of skills required within the industry.

[37] Digital maturity means the extent to which an organization benefits from their digital transformation efforts, distinguished by their cross-functional execution of more digital pivots. More digital maturity is linked to above-average financial performance in terms of net profits and annual revenue growth. The more comprehensive and coordinated an organization's digital transformation efforts are, the more likely it is to be digitally mature.

[38] Pharmaceutical Industry Trends India - 2022, Market Monitor: https://atradiuscollections.com/global/reports/pharmaceuticals-industry-trends-india-2022.html

[39] Ibid.

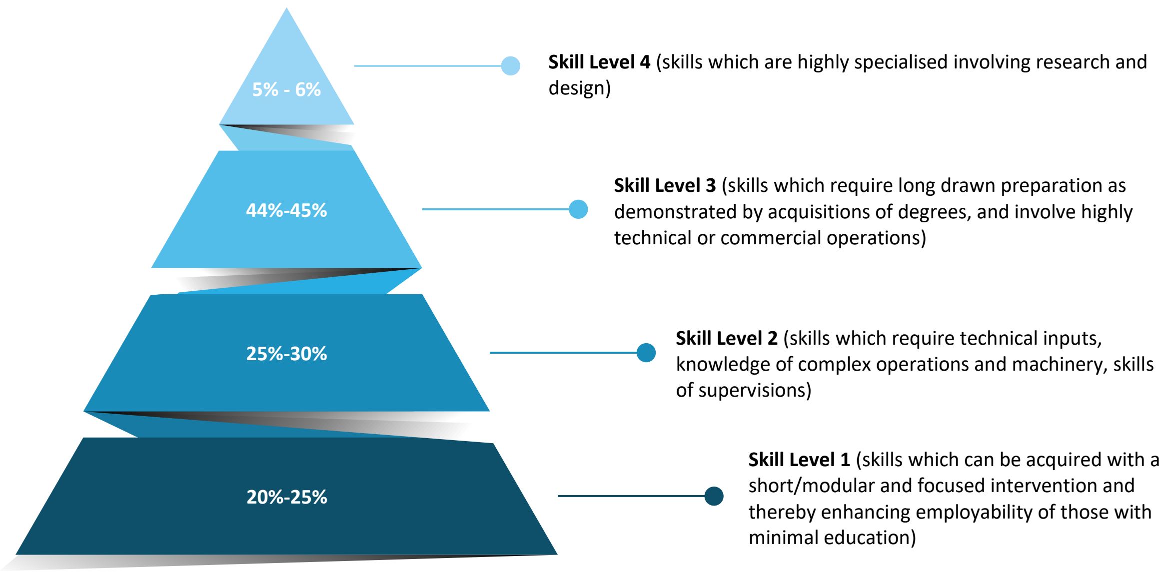
[40] Digital transformation is about the enterprise becoming digital, an organization that uses data and technology to continuously evolve all aspects of its business models-what it offers, how it sells (interacts with customers) and how it delivers, and how it operates.

[41] Sourced from: https://www.nqr.gov.in/sites/default/files/10_NSDC%202022_3.pdf

TABLE 3: Focus area for skill building in the pharmaceutical sector

Personnel for skill building	Indicative coverage areas
Operators	• Knowledge of API and formulation – basic • Cleanliness and hygiene • Operation of equipment • Compliance to cGMP, WHO guidelines • Understanding of SOPs • Understanding of safety, handling of waste, etc.
Sales	• Knowledge of drug and intended use • Conveying benefits of schemes and offerings • Fundamentals of pricing – tax, discounts, etc. • Selling skills and communications skills

FIGURE 7: Skill requirements of Indian pharmaceuticals industry



Particularly noteworthy in the context of this survey is the skills gap at 'Skill Level 2' that has been identified to be key to the growth potential of India's pharmaceutical industry. The direct employment in the sector must address the needs for adopting breakthrough technologies like 3-D printing and artificial intelligence (blockchains, platform technologies, etc.) to facilitate agile manufacturing practices based on the World Health Organization's Good Manufacturing Practices (GMP) through skilled personnel. The bottom of the pyramid, indirect employment, buttresses the overall growth prospects of manufacturing in the Indian pharmaceuticals industry. The introduction of regulatory changes to suit these technologies has been a point of contestation and therefore adequate foresight needs to be developed in this regard.

The traditional advantages of low-cost manufacturing set-up at 40-50% (even 90%) lower costs than the rest of the world are undergoing a state of flux due to supply chain problems, as regards fixed and variable cost components. A key finding in our survey is that the short- to medium-term focus on API manufacturing to reduce import dependence is likely to affect companies, in terms of their willingness and ability to finance research and development, as well as invest in large-scale manufacturing facilities with requisite global regulatory approvals. Among other key weaknesses of the manufacturing segment in the industry, the emphasis is on increasing research and development through novel financing models that assist firms operating under constraints imposed by the context of size and structure of entities, their network interactions and overall absorptive capacity. Aspects like industry-academia collaboration need deeper consideration over traditional approaches of obtaining competitive advantage through competitive dynamics in innovation, without facilitating knowledge transfer in new and emerging areas.

Leveraging information technologies to extend the knowledge transfer process, as well as supporting pragmatic solutions in service delivery mechanisms is key given the informational asymmetries that exist between actors in the ecosystem. The impact of regulatory changes is an ongoing task in progress and initiatives like the enhanced traceability of medicines, quality control, standardisation, and routinisation of GMP through an increased use of digital enabling tools and interfaces are the future steps in expanding the scope and profile of activities in the innovation value chain in the industry.

The Indian pharmaceuticals industry, as demonstrated above, stresses on the generic medicines segment, particularly the formulation drugs segment, where it has a share of 75% of global market supply (IBEF, 2022). Most molecules under development include short chain molecules with relatively short life cycles with an aim to reduce costs of drug development and post drug development timelines. To facilitate any structural shift from incremental innovation to radical innovation, the path dependence on legacy molecules must be balanced with a focus on developing suitable routines like alternative forms of entrepreneurship API manufacture in the short- and medium-term with a view to address import dependence concerns that arose in the pandemic. Clearly, in this scenario, the role of skilling human resources becomes important as well.

In the current post-pandemic scenario, the major pharmaceutical markets are under immense pressure. North America, Europe and Japan comprise 82% of audited and unaudited sales with total sales reaching US$ 773 billion (IMS Health, 2009). Growth in the European Union has slowed down to 5.8%, with sales in the USA increasing sluggishly at 1.4 % and in Japan at 2.1 % in 2022[42]. However, the impending policy changes, promoting the use of generics will put countries like India on the centre stage. With these changes in the marketplace, a fundamental question arises regarding the direction the Indian pharmaceuticals industry needs to take to answer the growing needs and demands of the current and future scenario. High R&D costs, a relatively dry pipeline for drugs, increasing pressure from payers and providers for reducing healthcare costs and a host of other factors are putting pressure on global pharmaceutical companies. The drivers for growth have been understood in terms of a cost arbitrage and productivity uptakes in internal rate of return (IRR), as well as supply-side factors like skilling mandates for manufacturing and research development activities as part of the innovation value chain. The policy interventions include the setting-up of healthcare clusters to allow for the co-location of manufacturing activities with research and development activities. Demand-side factors like the rise of e-pharmacies or online pharmacies, supported by digitalisation of health records through centralised databases during the pandemic and decentralised solutions like apps have generally helped extend the prospects of health care, in informal and formal institutional settings.

Currently, only 30% of Indians are users of modern medicine and there is a vast untapped potential for servicing patient outcomes as part of 'Healthcare 4.0' mandates. The long-standing impact of the pandemic on household incomes is likely to highlight this trend further. Therefore, a focus on enhancing manufacturing capacity needs to be framed, both in terms of increasing self-reliance in respect of APIs, as well as expanding the scope for generic medications. Domestically, only 15% market share is held by multinational companies, whereas globally 70% of the generics supply is met by Indian pharmaceutical companies. Expanding the role of basic science through increased network linkages and polycentric actors is crucial in terms of the knowledgebase for expanding product rollouts. Pharma companies that have started to invest in research and development are actively considering strategies for cooperation through market entry choice to leverage external sources of information through innovation networks to enable downstream commercialisation of innovations, as well as increased product complexity and sophistication.

This is easier said than done. Because of the analysis of the typical drivers of manufacturing and other activities in the industry, the 12th "Five - Year Plan" (2012-17)[43] proposed certain goals based on a SWOT analysis of the sector, highlighting its strengths as:

- A strong low-cost manufacturing sector.
- Significant breadth and depth of product expertise.
- Low cost of growing human resources.

The key weaknesses identified in the context of the industry were:

- High emphasis on generics for both domestic and global markets, where filing of Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs) have left little room for R & D on drug development.
- Inadequate R & D infrastructure.
- Poor industry-academia linkages.
- Lack of required high-end product-development capable human resources.
- Lack of time-driven regulatory infrastructure.
- Poor small and medium enterprise base for high-end manufacture.

[42] Price Water House Coopers. Global Pharma looks to India: Prospects for Growth: https://www.pwc.com/gx/en/pharma-life-sciences/pdf/global-pharma-looks-to-india-final.pdf

[43] See: Twelfth Five Year Plan (2012-2017): https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp12/wg_pharma2902.pdf

The responses to weaknesses include addressing supply-side factors like reform of institutions around labour and skilling; quality standards; production design control and regulation; incentives; skilling of human capital; resource mobilisation (under conditions of interdependency) that private market actors typically resort to; development of innovation system elements in a cohesive and coherent manner, and culminating integration into global innovator and production networks. These are evolutionary processes, which are contingent upon co-location of manufacturing and other value chain activities.

The key opportunities this scenario provides are in terms of expanding the profile of biologics, particularly in low-cost medication for critical and chronic illnesses, as well as new therapeutic segments for rare diseases. The manufacturing capacity enhancement will require enabling informational and infrastructural mechanisms and structures to this end as we discuss in relation to digitalisation, and addressing infrastructural loopholes, etc. The need for upskilling personnel to meet the manpower needs is crucial in the development of the entrepreneurial and innovation ecosystem. This can be done through incorporating a diversity of actors in the quadruple helix of universities-industry-academia-governments, etc., in the conduct of specialised, skill-intensive segments of the innovation value chain, without compromising the social concerns of access and affordability of health care and improved patient outcomes.

5. Policy Landscape

Policy Landscape

Policy has been a key driver of growth for the Indian pharmaceutical sector. Post-independence, India drafted policies with an inward-looking approach to attaining self-sustenance and development. The growth of the Indian pharmaceutical sector and the associated technological change can be attributed to targeted policy interventions and legislative reforms. From 1947 to 1970, India was reeling under high imports, with the highest import dependence in the pharmaceutical sector. Several expert committees were constituted to review laws and make policy recommendations to strengthen the pharmaceutical sector. Various acts and amendments including the Patent Act of 1970 were an outcome of the recommendations of these committees (Chandran and Brahmachari, 2018). As a result, the Indian pharmaceutical industry rose in value from a meagre INR 10 crore in 1947 to INR 289,998 crore in financial year FY 2019-20, making it the world's 14th largest in terms of value and 3rd largest by volume (Department of Pharmaceuticals, 2021). Despite this progress, a lack of stable pricing and policy environment and lack of capabilities in the innovation space are some of the key challenges being faced by the sector. With Industry 4.0 technologies making their way into manufacturing, domestic pharmaceutical firms have to make bold strategic moves into unchartered territory which can be greatly facilitated with improved policy and institutional effectiveness (Sajna T., 2020).

A well-crafted policy decision is a function of the following: understanding of past experiences, acknowledgement of contemporary challenges and perceptions of future potentials for action. Learning is not linear as it does not always flow from science to applied research and development (R&D) to commercialisation, rather knowledge is generated through interactions among actors in the system of innovation. Consequently, the science, technology and innovation policy in a country should focus on building these linkages and networks, stimulating the learning between actors, and enabling entrepreneurship (Schot and Steinmueller, 2018). The sectorial system of innovation of the Indian pharmaceutical industry rests on 3 strong pillars: a proactive policy regime, promising scientific research infrastructure and private sector investment in innovation. Neither the research institutes nor the enterprises have the requisite knowledge and capability to bring a new drug to the market, leaving ample room for robust policy support from the government (Mani, 2006).

Explained below are the core policies of the pharmaceutical sector in India that are addressed in turn, along with the supporting policies that have a bearing on the Indian pharmaceutical sector.

5.1 Core Policies of the Indian Pharmaceutical Sector

National Pharmaceutical Pricing Policy 2012 (NPPP 2012)

The regulatory architecture governing the Indian pharmaceutical industry must fulfil the need to ensure access to essential drugs for the 1.4 billion people without eroding the competitiveness of this vital sector in the global economy (Mondal and Pingali, 2017). The Government of India (GoI) introduced the "National Pharmaceutical Pricing Policy 2012" (NPPP 2012), which replaced the "Drug Policy" of 1994, with the objective of providing a regulatory framework for pricing of drugs to ensure the availability of essential medicines at reasonable prices and also providing enough opportunities for innovation and competition to support the growth of the pharmaceutical sector, thus meeting the goals of employment and shared well-being for all. The regulation of prices under NPPP 2012 is based on three principles; the essentiality of drugs, control of formulations prices and market-based pricing, as explained below:

- **Essentiality of drugs** - NPPP 2012 envisages control of medicine prices based on the essentiality of medicines and not on the market-based principle as in earlier price control regimes that relied heavily on the market dominance or monopoly of pharmaceutical companies. The essentiality of drugs is determined by the medicines specified in the "National List of Essential Medicines" (NLEM) which is revised from time to time based on the country's disease burden, priority health care concerns and affordability concerns. Prices of drugs that form part of the NLEM are kept below a certain threshold so that they remain affordable to the population at large. But public health experts have often accused the government of including obsolete drugs in the NLEM while keeping many of the most-prescribed drugs out of the purview. In February 2022, the Ministry of Health and Family Welfare re-initiated the exercise of reviewing the NLEM in order to address the aforementioned concerns[44].

- **Control of formulation prices only** - Price regulation under the NPPP 2012 is based on regulating the prices of formulations only, which is a departure from the earlier principle of price regulation at two levels; bulk drugs and their formulations. Selvaraj et al., 2012 in their "Pharmaceutical Pricing Policy: A Critique" argued that such provision needs to be scrapped because "companies could misuse this provision by reducing production of single ingredient essential medicines and manufacturing inessential or irrational combinations using essential APIs instead." They feared that it may also lead to a shortage of essential single ingredient medicines in a market that is already flooded with irrational combination drugs that are of no use to patients. Later in September 2018, the GoI banned 328 irrational fixed-dose combination (FDC) drugs and 80 more FDCs the next year, paving the way for improvement in regulatory architecture and patient safety mechanisms (Vendoti, 2018).
- **Market-based pricing (MBP)** – The NPPP 2012 supports an MBP regime as opposed to the cost-based pricing (CBP) under the previous 1994 policy. The policy states that CBP is difficult to administer as it requires manufacturers to provide their manufacturing data in an extremely detailed manner which is usually resisted and may also result in manipulation and time delay. Hence, the MBP approach will result in more transparent and fair pricing. Industry experts argue that given the unique but distorted nature of the Indian pharmaceutical industry, this provision would rather tempt the players in the currently lower-priced segment to drive up prices closer to their higher-priced competitors, legitimising the trend of higher prices (Selvaraj et al., 2012). The MBP mechanism is problematic as it creates an illusion of price control without doing so (Srinivasan and Phadke, 2013).

Thus, the NPPP 2012 falls short of the goal to ensure accessible and affordable medicines for all (Selvaraj et al., 2012). It is important to note that the world average for 'out-of-pocket' health expenditure is 18.2% whereas for India this expenditure stands at 65% (Economic Survey, 2020-21).

Pradhan Mantri Bhartiya Janausadhi Pariyojana (PMBJP 2015)

In September 2015, the Department of Pharmaceuticals launched the "Pradhan Mantri Bhartiya Janausadhi Pariyojana" (PMBJP 2015) scheme with the objective of making quality generic medicines available at an affordable price by the opening Pradhan Mantri Bhartiya Janausadhi Kendras (PMBJKs) across the country. The scheme met the target of FY 2021-22 in just 6 months. As of 31st January 2022, 8675 PMBJK stores were functional, covering all districts across the country. Medicines available under PMBJK are priced 50-90% less than that of branded prices. These stores currently offer a product basket of 1,451 drugs and 240 surgical instruments and have recently added nutraceuticals products for their customers (Ministry of Chemicals and Fertilisers, 2022). Similar schemes in the past that promised subsidised medicines had failed to take off mainly due to poor supply chain management. To address this, the present scheme has also introduced IT-enabled logistics and supply-chain systems for ensuring the real-time distribution of medicines at all PMBJKs. The Bureau of Pharma PSUs of India (BPPI), the implementing agency of PMBJK is tasked with spreading awareness about the salient features of PMBJK through various types of advertisement such as print media, radio advertisements, TV advertisements, cinema advertisements and outdoor publicity like hoardings, bus shelter branding, bus branding, auto wrapping, etc. In addition to this, the BPPI also educates the public about the usage of Jan Aushadhi generic medicines. The GoI has set a target to increase the number of Pradhan Mantri Bhartiya Janaushadhi Kendras to 10,000 by March 2024 (Ministry of Chemicals and Fertilisers, 2021).

Strengthening of Pharmaceutical Industry (SPI) Scheme

The Indian pharmaceutical industry has majorly evolved around the industrial development clusters set-up by state governments but many of these clusters were set-up earlier with antiquated environmental standards compliance potential. This was highlighted in the report prepared by the Working Group on Drugs and Pharmaceuticals constituted by the NITI Aayog in 2011. The report clearly states that the "Department of Pharmaceuticals is expected to play a vital role by providing financial and technical assistance to improve financial sustainability of … and also safeguard the environment from the hazards associated with the unplanned growth of the industry." Against this backdrop, the Department of Pharmaceuticals, GoI, released guidelines for the "Strengthening of Pharmaceutical Industry Scheme" (SPI) which has a total financial outlay of INR 500 crore for the period from FY 2021-22 to FY 2025-26. This scheme addresses the demand and requirement for support for the existing 80

[44] Sourced from: https://www.news18.com/news/india/health-matters-the-curious-case-of-missing-national-list-of-essential-drugs-5-months-after-launch-4793789.html

pharmaceutical clusters and over 10,500 manufacturing facilities across the country to improve productivity, quality and sustainability (Department of Pharmaceuticals, 2022). The scheme has the following three components/sub-schemes:

- "Assistance to Pharmaceutical Industry for Common Facilities" (APICF) – To strengthen the existing clusters by providing financial assistance for the creation of common facilities.
- "Pharmaceutical Technology Upgradation Assistance Scheme" (PTUAS) – to facilitate SMEs to upgrade their plant and machinery in accordance with the World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets.
- "Pharmaceutical & Medical Devices Promotion and Development Scheme" (PMPDS) – To promote the pharmaceutical and medical devices sector through study/survey reports, awareness programmes, the creation of a database, and by bringing industry leaders, academia and policymakers together for an exchange of knowledge and resources for promotion of the industry.

Schemes for Promotion of Bulk Drug Parks and Medical Devices Parks

India is significantly dependent on the import of bulk drugs as they accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19. In March 2020, the GoI announced a special **"Scheme for Promotion of Bulk Drug Parks"** in the country for providing easy access to world-class common infrastructure facilities to bulk drug units located in the parks. The objective is to ensure an uninterrupted supply of quality bulk drugs and significantly bring down the manufacturing cost of bulk drugs thereby increasing the competitiveness in the sector by providing easy access to infrastructure and standard testing facilities. According to the 1st September 2022 official press release, the Department of Pharmaceuticals has conveyed 'in-principle' approval to the proposals of the following three States - Himachal Pradesh, Gujarat and Andhra Pradesh - under the scheme (PIB Release ID: 1856080, 2022).

Similarly, a scheme called **"Promotion of Medical Device Parks"** was approved by the GoI on 20th March 2020. The medical device industry is highly capital intensive and requires both the development and induction of new technologies. These parks will provide common testing and laboratory facilities at one place, reducing the manufacturing cost significantly, and create a robust ecosystem for medical device manufacturing in the country. According to the 24th September 2021 official press release, the State Government of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh have been given 'in-principle' approval under the scheme (PIB Release ID: 1757662, 2021).

National Intellectual Property Rights Policy 2016 (IPR Policy 2016)

Government support is needed for businesses not only to innovate new technologies, but also to safeguard their technological inventions with effective IP protection. In May 2016, the Department for Promotion of Industry and Internal Trade (DPIIT) rolled out the country's first "National Intellectual Property Rights (IPR) Policy 2016" to foster creativity and to implement a strong IP-led innovation model. Prof. Sunil Mani, in his critique on the "New IPR Policy 2016: Not based on evidence" argues that even before the IPR policy, India had a functioning legal regime with individual acts on patents, trademarks, designs and geographical indications, all of which were suitably amended over time to comply with TRIPS (Agreement on Trade-Related Intellectual Property Rights) (Mani, 2014). He contends that "some measures in the IPR policy are laudable but the policy objectives are not evidence-based and are tailor-made to suit the requirements of the western governments." He further argues that the government should rather be spending time and money on improving the performance of patent offices that are understaffed and underfunded leading to major delays in patent approval in the country.

It is evident that India has been taking a decisive stand on patents to the advantage of domestic manufacturers, but it needs more such incentive programmes, with effective and widespread implementation. India has built pockets of knowledge-based growth but has not yet translated this into a broader economic model. Actions to promote knowledge-based economies will require strong, coordinated government policies coupled with investment in ICT (ADB, 2014).

MSME Champions Scheme (2021-22 to 2025-26)

The Development Commissioner of the Ministry of MSME has been implementing the "Credit Linked Capital Subsidy and Technology Upgradation Scheme" (CLCS-TUS) for promoting competitiveness amongst MSMEs by way of wastage reduction through lean manufacturing, design improvement, building awareness on Intellectual Property Rights, the "Zero Defect Zero Effect (ZED) Scheme", digital empowerment of MSMEs and facilitating the adoption of latest technologies in manufacturing through incubation across India. CLCS-TUS was operational until March 2020 and the "MSME Champions Scheme" has been formulated by merging all these components of erstwhile CLCS-TUS for a period of 5 years (2021-22 to 2025-26) in the specified 51 sub-sectors, including the pharmaceutical sector. This new scheme has 3 components: MSME-Sustainable (ZED) Certification, MSME-Competitive (Lean) and MSME-Innovative (for incubation, IPR, Design and Digital MSME).

The main objective of the scheme is to pick up clusters and enterprises and modernise their processes, reduce wastages, sharpen business competitiveness, and facilitate global reach and excellence. However, according to the 2021-22 Annual Report of the Ministry of MSME, the expenditure on all 3 components of the MSME champions scheme remained miniscule with MSME ZED certification component witnessing nil expenditure out of the budget allocated.[45]

Production Linked Incentive (PLI) Schemes

The COVID-19 pandemic uncovered the national security consequences of excessive dependency on foreign supplies, in a vital sector such as pharmaceuticals. It led to the disruption of imports and international supply chains. Many countries are in turmoil to reduce their dependence on foreign supplies, especially for active pharmaceutical ingredients (APIs) which are the most important input in the formulation of medicines. Considering the importance of the health sector, countries are bound to face the challenge to ensure medicines at affordable prices to their people. Countries will prefer sourcing from cheaper options but at the same time, they are looking for diversification of supply sources by exploring a 'China Plus One' approach. India has all the potential to become the centre of this diversification strategy. India exports 3.5% of the total drugs and medicines exported globally (Ministry of Chemical and Fertilizers, 2020). India's pharmaceutical export stood at US$ 16.28 billion in FY 2020. The Indian pharmaceutical sector is expected to grow at a Compound Annual Growth Rate (CAGR) of 22.4% in the near future and the medical device market is expected to grow by US$ 25 billion by 2025. The Indian pharmaceutical sector was valued at US$ 40 billion in 2021 (Department of Pharmaceuticals, 2021). However, the major drawback that the sector faces is its excessive reliance on China for key starting materials (KSM) and APIs which makes it less attractive for other countries as another source of supply. Therefore, it is critical for this sector to become self-reliant and competitive in KSM and APIs for its growth and drug security at the global level. Against this backdrop, the GoI announced the following production-linked incentive schemes that are a cornerstone of the government's push for achieving "AatmaNirbhar Bharat":

- **"Production Linked Incentive (PLI 1.0) Scheme for Promotion of Domestic Manufacturing of Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and APIs"**

  A committee on drug security constituted by the Department of Pharmaceuticals identified 53 APIs for which the country is heavily dependent on imports. To attain the objective of self-reliance and import substitution in critical APIs on 20th March 2020, the Government of India approved the first Production Linked Incentive (PLI 1.0) Scheme for Promotion of Domestic Manufacturing of Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and APIs in India. The intent of the scheme is to attract large investment in this sector by enhancing the domestic manufacturing capacity of KSMs and APIs and thus moving towards import substitution. Financial incentives shall be given based on sales made by selected manufacturers for 41 products, which cover all the identified 53 APIs (Department of Pharmaceuticals, 2020). The tenure of the scheme is from FY 2020-21 to FY 2029-30 with a total financial outlay INR 6,940 crore. PLI 1.0 was followed by a more extensive and broader "PLI 2.0 Scheme for Pharmaceuticals".

- **PLI 2.0 Scheme for Pharmaceuticals**

  Though India accounts for 20% of global exports in generics, much of these exports are low-value generic drugs while a large proportion of the demand for patented drugs is still met through imports. This is because the Indian pharmaceutical sector lacks in value production along with high-risk transformative R&D, which calls on the Indian government to institute policy measures to foster investment in and production of high-value drugs. To this end, the Government of India announced the second production linked incentive scheme (PLI 2.0) on 3rd March 2021. The key objective of this scheme is to boost the manufacturing capabilities of Indian pharmaceutical manufacturing firms via an increase in investment and production and by expanding product diversification to high-value goods in the sector. The goal is to create global champions from India that have the potential to grow and scale using cutting-edge technology and hence penetrate the global value chains.

Pharmaceuticals has been identified as a critical sector under the Department of Science and Technology's **"Draft Science, Technology and Innovation Policy 2020" (Draft STIP 2020)**. The key thrust under Draft STIP 2020 is on developing a cadre of practicing

[45] Sourced from: https://www.financialexpress.com/industry/sme/msme-eodb-msme-ministry-releases-2021-22-annual-report-expenditure-on-multiple-schemes-remains-minuscule/2440274/

scientists and technologists who are dedicated to curating and updating knowledge and its application in a critical sector like pharmaceuticals. It aims to encourage research and innovation in such sectors by giving out prestigious science fellowships to mid-career senior level academics, industry personnel and NGO scientists/technologists who can undertake such challenges (Department of Science & Technology, 2020). Even though the Indian pharmaceutical industry has been a focus of multiple schemes and incentives, the industry is reeling with a complex set of rules and regulations, and amendments made over time to keep up with developments in the sector. It requires a holistic revamp to tackle the same, and to focus on more nuanced issues within the law (Sharma, 2022).

5.2 Industry 4.0 Initiatives

With the adoption of Industry 4.0, the Indian pharmaceutical sector is stimulating the emergence of smart factories. Digital manufacturing is growing and is expected to reach US$ 767.82 billion by 2025 and therefore India considers manufacturing as pivotal to the country's digital transformation. With the development of smart factories there would be change in the job structure, hence, the need for candidates who are better equipped on emerging technologies to lead the digital transformation in the sector (Vijay N, 2022). According to a report by Frost and Sullivan (2016) there is great opportunity for the Indian manufacturing sector, especially in the pharmaceutical, electronic and semiconductors and pharmaceutical & chemical industry. Schemes like "Make in India" will enable the 4IR and develop the foundation for advanced manufacturing in India (Adhikari and Singhal, 2020). The application of Industry 4.0 in pharmaceuticals is termed as "Pharma 4.0" along with the product life cycles through digitisation and automation (Xu et al., 2017, Lu 2017 a, b). The adaptation of Industry 4.0 in pharmaceuticals will enhance the level of transparency and production speed in manufacturing plants. The decision-making process will be faster, enhancing the overall control and security in the given sector. But implementation of Industry 4.0 requires careful integration of expectations, interpretations, and definition alignment with pharmaceutical regulations (Adhikari and Singhal, 2020).

Draft Policy to Catalyse Research & Development and Innovation in the Pharma- MedTech Sector Pharma innovators across the globe are marching towards the application of: telemedicine, artificial intelligence (AI) and machine learning (ML), virtual reality (VR), the Internet of Medical Things (IoMTs), nanotechnology, robotics, 3-D printing, big data and advanced analytics for aided diagnosis, green technology, additive manufacturing, flexible production, mobile applications for chronic disease management, digital therapeutics, precision medicine, and medical records. Several enablers, including a strong local industry, export experience, and depth of technical capabilities can help the pharma and MedTech sectors work towards "Discover in India" and build a strong ecosystem for healthcare innovation (Department of Pharmaceuticals, 2021). In October 2021, the Department of Pharmaceuticals released a **"Draft Policy to Catalyse Research & Development and Innovation in the Pharma-MedTech Sector in India"**. The specific objectives of the proposed policy are:

- To simplify regulatory processes to enable more rapid drug discovery and development and innovation in medical devices.
- To explore mechanisms to incentivise private sector investment in research and evaluate various funding mechanisms – Budgetary support, venture capital funds, corporate social responsibility (CSR) funding, etc., and fiscal incentives to support innovation.
- To identify mechanisms to strengthen the R&D ecosystem through increased collaboration between industry and academia.
- To enable integration of the existing policies and programmes of various departments/ agencies/ institutes in order to develop mechanisms to dovetail research as per the requirements of the industry.

The policy postulates three main focal areas to achieve the above objectives:

- **Strengthening the regulatory framework by streamlining processes/approvals** (the following measures are envisaged to create a regulatory bias in favour of innovation and original research): (a) to reduce process overlapping and time span, for essential approvals all regulators will be assigned to work together; (b) creation of a single end-to-end digital portal is proposed, which will offer a single interface between innovator and regulators; (c) the policy proposes to enhance the capabilities of regulators that would include building in-house expertise in biopharmaceuticals and high-end medical devices; (d) with a view to eradicate inconsistencies and redundancies a review of the multiple legislations that impact R&D in pharmaceuticals and medical devices will be undertaken.
- **Incentivising investments or funding for innovation**
- **Enabling ecosystem for innovation and research:** as the industry and individual institutes involved in Pharma-MedTech research largely work through

informal ad-hoc corporations, they need to be supported with an ecosystem that recognises, facilitates and rewards innovation and research. Countries with such ecosystems are reaping the market and financial benefits. The policy therefore proposes three components for enabling a robust ecosystem: (a) strengthening academic talent and infrastructure (industry-academia linkage), (b) collaborating across institutions and sectors, and (c) creation of dedicated innovation hubs (infrastructure).

Through this draft, a comprehensive national policy framework is proposed to build a robust ecosystem to ensure the holistic development of R&D and innovation while meeting the healthcare needs of the country. The application of Industry 4.0 in the Indian pharmaceutical sector has the ability to enhance efficiency and consistency in the production of quality medicines but how these technologies are deployed will define the next generation of the pharmaceutical manufacturing industry.

5.3 Initiatives for the Future Workforce

Disruptive technologies are fast changing the face of global manufacturing. If India aims to become a central part of the global manufacturing supply chain, it has to close the demand-supply gap for the skilled workforce through well-designed policies and initiatives. The size and nature of the population determine the range and depth of human resource initiatives in a country. The UNDP-Planning Commission (now NITI Aayog) 2010 "Report on Human Development in India" acknowledges that human resource development is not limited to the national level but is characterised by state and district level human development analysis, driven by state and local governments. The report further states that "the attempt to "operationalise" human development is another distinctive feature of India's journey on human development. The emphasis on linking planning to human development reporting is unique and this ensures that the human development reports do not merely remain books on the shelf but are actually integrated into planning processes of the government at a decentralised level."

India has been the first country in the Asia Pacific region to reconstitute its Ministry of Education as the Ministry of Human Resource Development (Rao, 2004). But disruptive innovation and mega trends in technology together with globalisation and increased competition are transforming the job market landscape and changing the way of doing business. There is an urgent need to address the dynamic needs of business, especially in a vital sector like pharmaceuticals.

The adoption and use of novel tools and technologies by human resources could represent a competitive advantage for the pharmaceutical sector in India. Indian healthcare has been one of the major stakeholders in global demand and supply and in research and development (Rakshit and Sharma, 2020). In order to acquire a leadership position in drug discovery and development and to continue to excel in the formulations, the GoI recognised the need for developing human resources by promoting quality and excellence in pharmaceutical education and research. To this end, the first National Institute of Pharmaceutical Education & Research (NIPER) was set-up at SAS Nagar Mohali in 1998 and was declared an Institute of National Importance. During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of a mentor institute. The NIPERs host several research facilities, foster vigorous institute-industry collaborations, interdisciplinary research collaborations and industrial training opportunities to help develop a skilled workforce for the sector. The Indian pharmaceutical sector needs support in understanding the global regulatory landscape, which can be facilitated through creation of 'Regulatory Cells' in the NIPERs and other institutes, as these will play a key role across the functionalities of process support, capacity building and infrastructure support (Department of Pharmaceuticals, 2015).

To address the need for adequate and trained human resources for health research across the country, the Department of Health Research under the Ministry of Health & Family Welfare launched the **"Human Resource Development (HRD) Scheme for Health Research"**. The scheme was first approved in 2013 and underwent three extensions with the most recent one being for the period of 5 years starting from 2020-21 to 2025-26. Though India has the largest number of medical colleges in the world, much of the biomedical research in the country is carried out in only a handful of institutes. There is also a disparity in the distribution of education institutions offering pharmaceutical education with the majority concentrated in western and southern parts of the country. This scheme intends to create a pool of talented health research personnel across India by upgrading the skills of medical colleges (faculty), institutes, scientists and medical students by providing specialised training in priority areas of health research. It is critical to encourage and support high-risk high-reward research in pharmaceutical science and technology as incremental advances alone might jeopardise India's long-term ability to compete in the global pharmaceutical market. This scheme also encourages and supports the trainees to develop and undertake research projects for addressing critical national and local health problems and provides financial assistance to institutions for upgradation of infrastructure to enable them to provide training with state-of-the-art technologies. The development and implementation of online web-based courses in health research is also an important component of the scheme (Department of Health Research, 2021).

Workforce diversities can be beneficial for organizations and especially the pharmaceutical sector tends to serve all irrespective of their origins (Saji, 2004). The scheme also promotes workforce diversity by focusing on the training of women scientists who have had a break in their career and encouraging non-resident Indians (NRIs), persons of Indian origin (PIO), overseas citizen of India (OCI) serving abroad in health research activities, to come back to India and undertake research in identified areas.

Pharmaceutical education in India suffers from serious backdrops. These include but are not limited to: outdated curricula and teaching styles, entry of unqualified and non-meritorious students in the course, a lack of skilled teachers and uncompetitive salaries offered to teachers, lack of industrial and clinical exposure, and disparity in laboratory infrastructure across states. (Jishnu V. et al., 2011). At the same time, pharmaceutical education comes under professional education which is a key focus area under the **"National Education Policy 2020" (NEP 2020)**. To improve the present situation, the NEP 2020 emphasises the preparation of professionals involving critical and interdisciplinary thinking, discussion, debate, research, and innovation. It discerns that professional education should not take place in the isolation of one's speciality; rather it should become an integral part of the overall higher education system. This will require closer collaborations between industry and higher education institutions to drive innovation and research; Academia will also be required to introduce specialisations at the graduation level for professional expertise and excellence (Jishnu V. et al., 2011). Rapid technological advancements and globalisation are eroding the silos between pharmaceutical education and other disciplines. Therefore, the NEP 2020 advocates a renewed focus on opportunities to deeply engage with other disciplines. The policy document explicitly states that "India must also take the lead in preparing professionals in cutting-edge areas that are fast gaining prominence, such as artificial intelligence (AI), 3-D machining, big data analysis, and machine learning (ML), in addition to genomic studies, biotechnology, nanotechnology, neuroscience, with important applications to health, environment, and sustainable living that will be woven into undergraduate education for enhancing the employability of the youth".

The National Skill Development Corporation (NSDC), which is a not-for-profit public limited company set-up by the Ministry of Finance with a public-private partnership model, is a nodal agency that facilitates skill development and entrepreneurship by fostering private sector initiatives in skill development programmes and provides funding in sectors where market mechanisms are insufficient or missing. The NSDC, in its study of the "Human Resource And Skill Requirements in the Pharmaceuticals Sector" (2013-17, 2017-22), reported a major skill deficit in human resources for the Indian pharmaceutical industry. As per the report, the higher spectrum of R&D organizations in the sector require candidates who have a doctorate or post-doctorate degree but PhD/ M.Tech/ M.Sc account for only 5–8% of the workforce in the chemicals and pharmaceuticals segment; a majority of the people employed in the sector have an educational background of 12th grade or below. The report identified the following key HRD challenges and recommendations for stakeholders in the sector:

Challenges	Recommendations
Pharmacy courses and industry needs are totally divorced.	Strong industry-academia linkages to figure out industry needs and teach/train accordingly.
Reluctance of students to work in community pharmacy and low awareness of emerging streams in pharmaceutical education.	Spreading awareness about emerging job roles and customisation of curriculum accordingly.
Lack of practical training.	Upgradation of infrastructure to impart industry-relevant training.
Lack of coordination among regulatory bodies leading to stagnation of curriculum.	Strengthen coordination between various accrediting bodies. Taking inputs from industry, academia and government bodies for holistic development of curriculum.
Quality of teachers is not up to mark.	Incentivise and bring quality instructors into the pharmaceutical sector.
Sub-standard level of R&D.	Promoting and investing in R&D.

The Government of India (GoI) needs to improve the outreach of its training facilities and skill development initiatives to those who are not in the education stream and to those working in the unorganised sector both in terms of infrastructure and diversification of courses to suit their needs (Sanghi, 2012). There is also a need to strengthen linkages between policy actions and programmatic interventions. This can only be done by synergising efforts of different ministries and departments and mobilising private sector participation in the skill field.

Experts have argued that the Department of Pharmaceuticals should be brought under the Ministry of Health and Family Welfare to ensure better coordination of various functions in the drugs and medicines sector (Selvaraj et al., 2012). It has also been suggested that an effort should be directed towards continuously collecting and disseminating pharmaceutical market data (e.g., market share, consumption patterns, prices, etc.) as it is done by private agencies like IMS health. The cost of obtaining this data from a private agency is too expensive, making an independent evaluation by health and public interest an impossible task. Therefore, these data should be available in the public domain and should be under government control.

In conclusion, the dynamics of policy, knowledge and market are clearly more complex today in comparison to the mid-1990s, and policy drivers have become more international. With the continuous change in technological capacities and legislation, Indian firms are pushed towards searching for novel research methods that not only enhance productivity in domestic firms but also prepare them for competing with foreign firms in the open market. This rapid pace of change has compelled the system actors to function in sync with each other. Collaboration is a requirement for success, and it is the only way to promote new scientific discoveries and technologies in the sector and hasten the translation of new discoveries into new drugs. The scope and style of collaborative efforts can be explored but government support for such partnerships can be a game changer for the future of the Indian pharmaceutical sector.

6. Results and Analysis

Results and Analysis

This chapter sets out to analyse the results of the IPSSI Survey. It uses a combination of univariate and multivariate analysis which provides a strong empirical foundation. The frame of analysis can be divided into the following sections. Firstly, the characteristics of the survey are described in terms of the composition of the sample and its respondents. This is followed by a comprehensive analysis of the relationships/linkages between the actors of the system. This then leads to the elucidation of the barriers that exist within the pharmaceutical system of innovation, and those that are most predominant for each actor group.

This is also linked to the question of how successful existing policies are at highlighting either the convergence or divergence between the results and what is articulated in government policy. With this in mind, this chapter aims to highlight the avenues that need attention within the IPSSI.

6.1 Descriptives

The composition of the actors in the IPSSI Survey has been detailed in the "Survey Methodology" section. Table 4 below shows the actor distribution and response rate.

TABLE 4: Indian Pharmaceutical SSI - Convenient sample, data collected and response rates

Firm			Non-firm				Total Number of Non-Firm Actor			Total
Industry			Government	Knowledge based institution	Intermediary	Arbitrageur				
Sample	Data collected	Response rate	Data collected				Sample	Data collected	Response rate	
785	**379**	**48.28%**	**7**	**24**	**63**	**8**	**200**	**102**	**51.00%**	**481**

The overall response rate of the IPSSI Survey is 49%. As shown in Table 4 above, the response rate for industry is 48%, for non-firm actors 51%, out of which intermediaries alone account for 62% of data collected in the non-firm category; this is followed by KBIs at 23% while arbitrageurs and government each account for 8% and 7%, respectively.

Figure 8 below summarises the distribution of respondents by actor group, with the clear majority belonging to 'Industry' at 79%, followed by 'Intermediary' (13%), 'KBI' (5%), 'Arbitrageurs' (2%) and 'Government' (1%).

FIGURE 8: Actor distribution of respondents

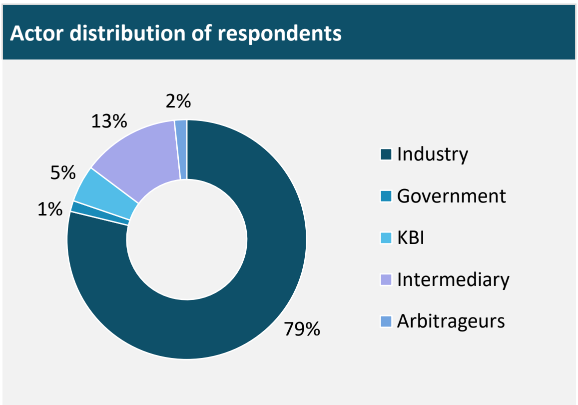


Figure 9 below shows the ownership structure of the firms surveyed. Out of 379 firms surveyed, 376 are domestically owned and only 3 are foreign-owned firms.

FIGURE 9: Ownership structure of firms

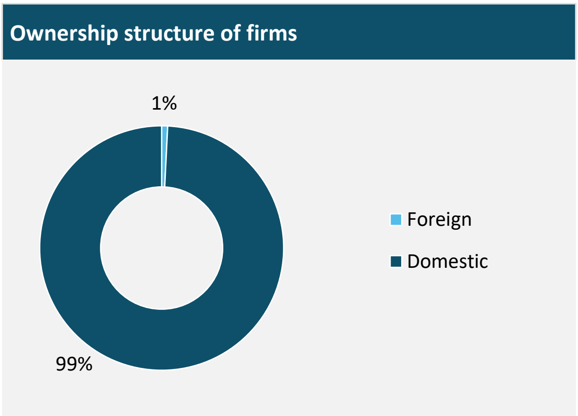
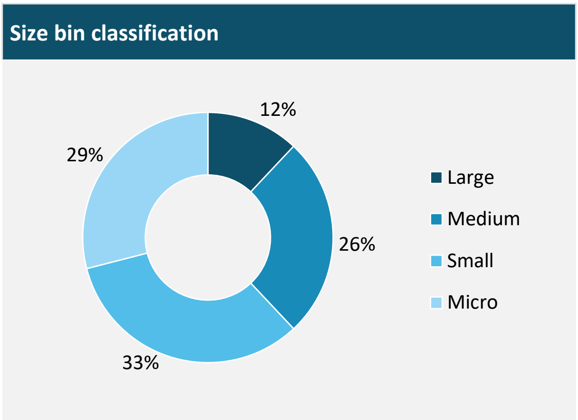


Figure 10 below shows the size classification of firms surveyed. It is important to know the size of firms that participated in the survey as it can determine the level of innovation, internationalisation, and adoption of emerging technologies. It can be seen from Figure 10 that the majority of firms surveyed belonged to the 'Micro' size category (32%), closely followed by 'Small' (30%) and

'Medium' size firms (23%). The 'Large' size firms constitute the smallest percentage (15%) of the total firms surveyed.

FIGURE 10: Size classification



The following figures depict the distribution of respondents by affiliation for each actor group. Figure 11 shows that the industry actor group is made up of 354 'Firm' (93%) and 25 'Firm OBM' (7%). Figure 12 depicts KBI affiliation comprising universities, public research institutes and private research institutes, the majority being 'University' at 79%. Subsequently, Figure 13 shows that intermediaries are majorly represented by the group 'Academic Incubator' at 41%, followed by 'Industry Association' at 26%, public institution supporting technical change or 'Public ISTC' at 21%, 'Corporate/Private Incubator' and 'Government Incubator' at 6% each. Arbitrageurs are equally composed of banks and venture capital while the government comprises both central and state governments, with majority representation from central government agencies. This is outlined in Figure 14 and 15, respectively.

FIGURE 11: Industry – Affiliation

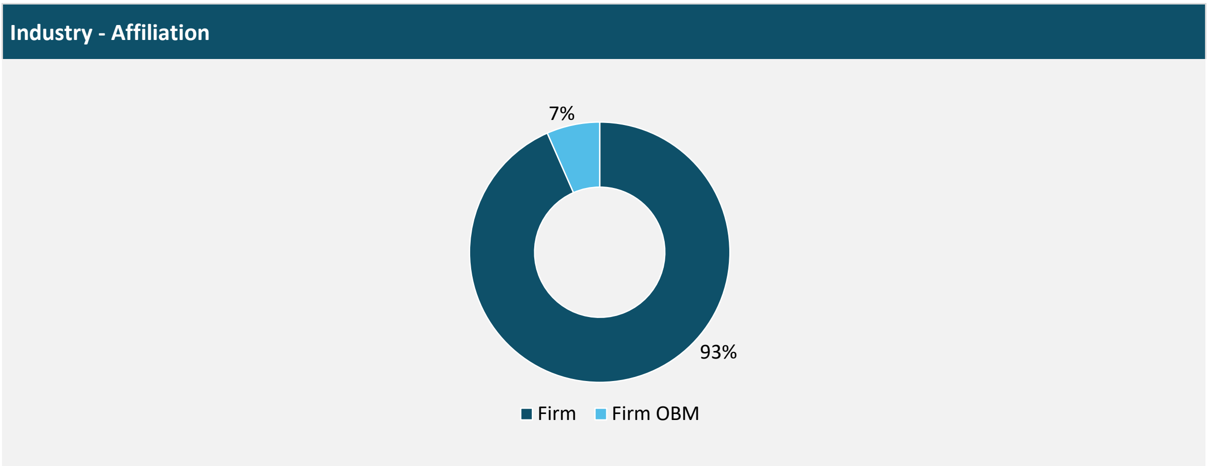


FIGURE 12: KBI – Affiliation

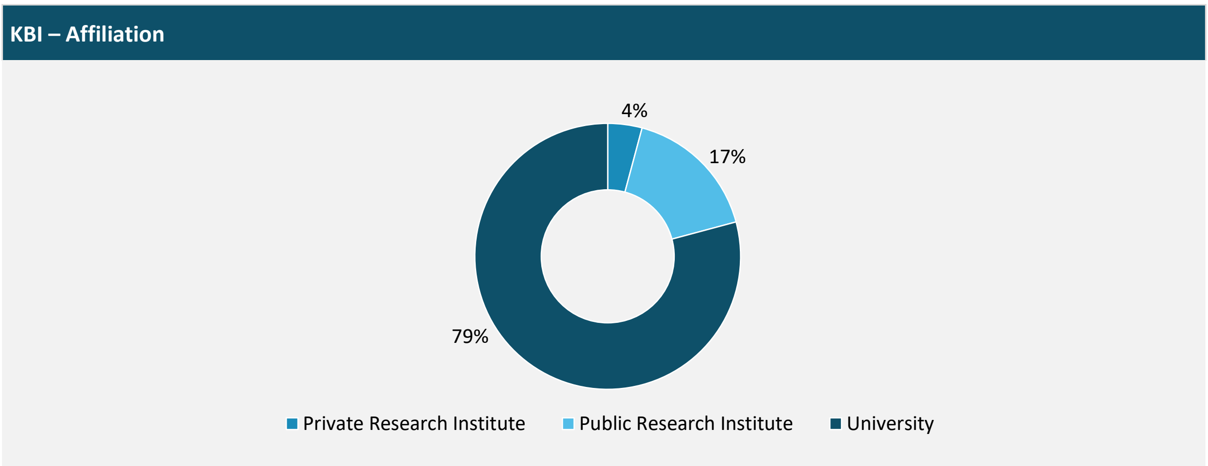


FIGURE 13: Intermediary – Affiliation

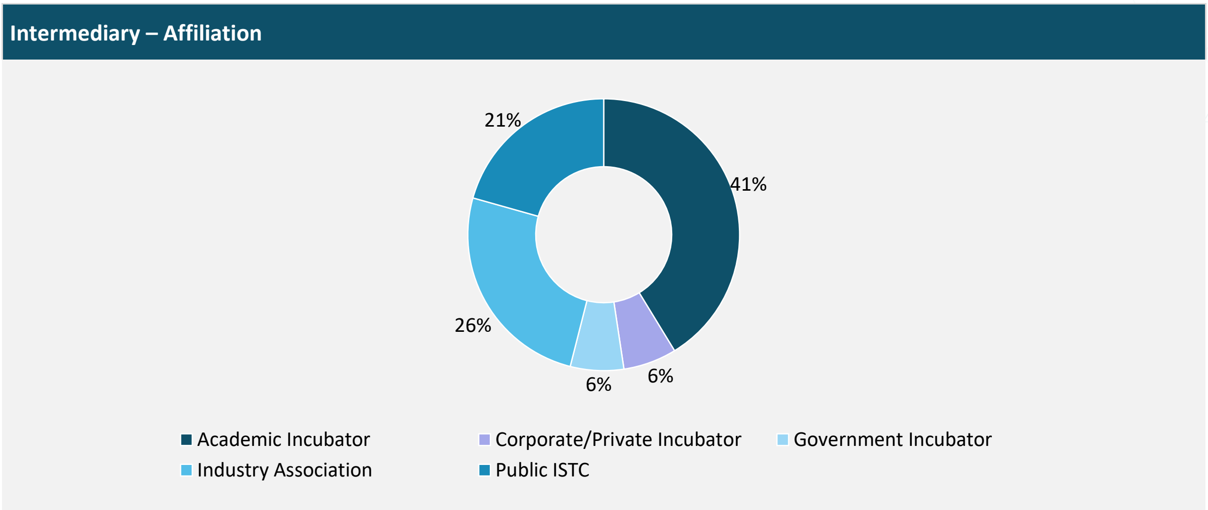


FIGURE 14: Arbitrageur – Affiliation

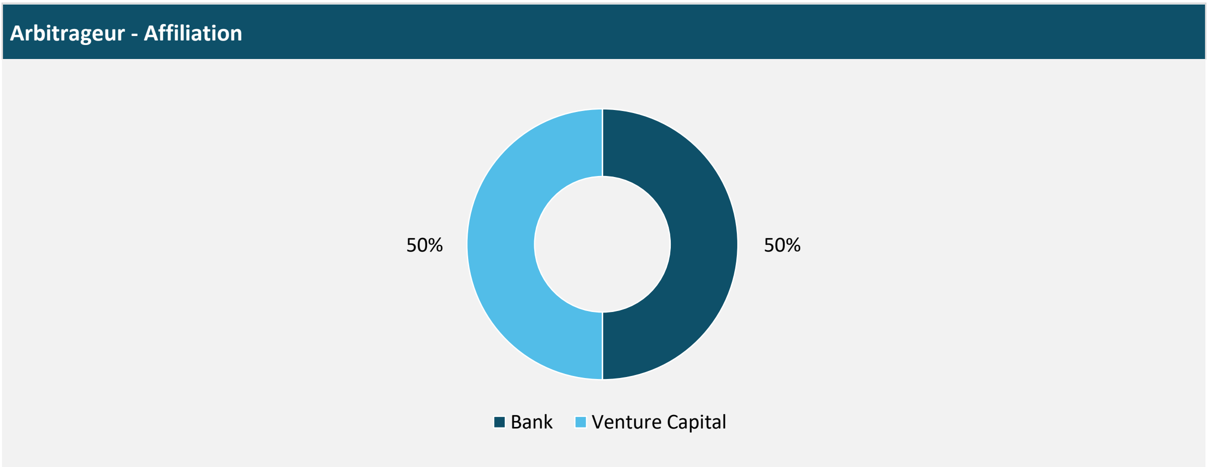
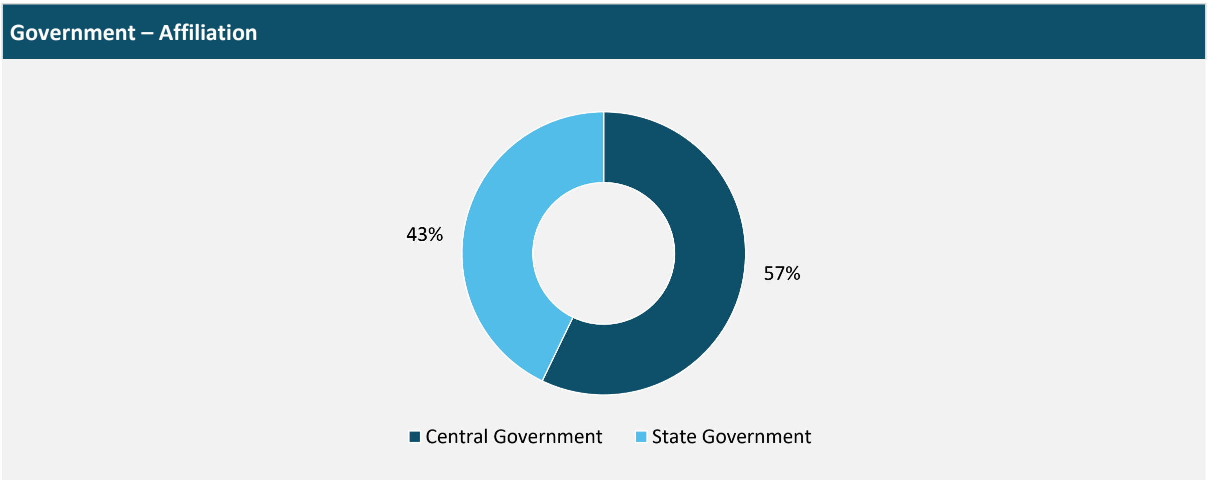
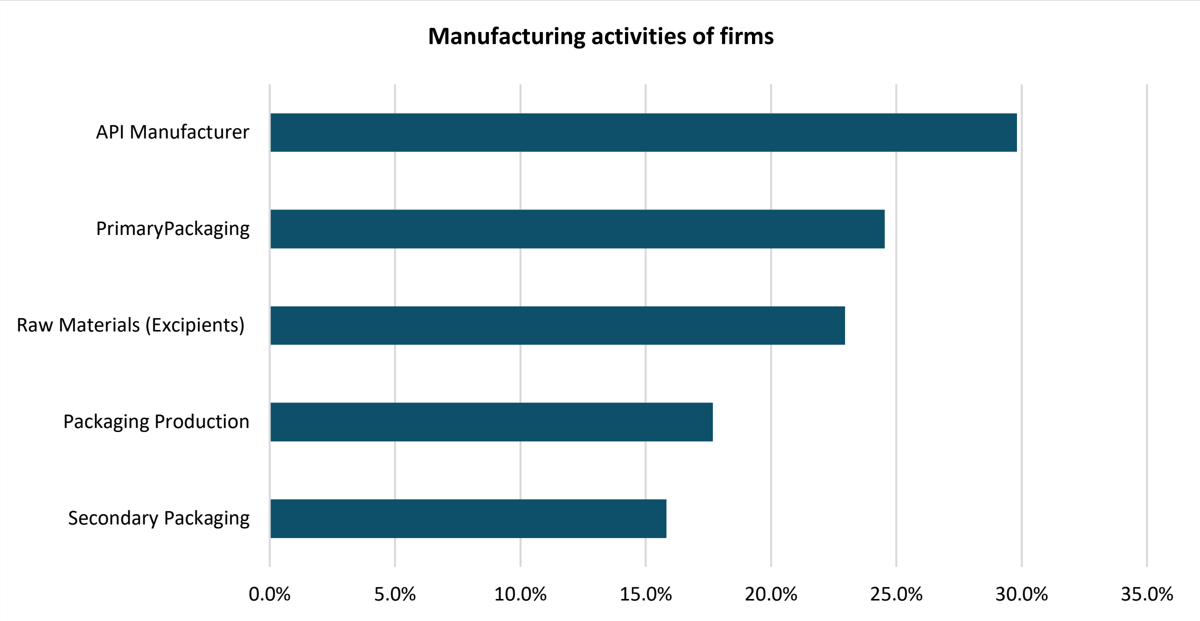


FIGURE 15: Government – Affiliation



It is important to get further clarity with respect to the industry actors in order to better elucidate the data in this report, particularly as the majority of innovation takes place at the firm level. Figure 16 below depicts the types of manufacturing activities of the firms surveyed.

FIGURE 16: Manufacturing activities of firms



About 30% of the firms surveyed are involved in the manufacturing of active pharmaceutical ingredients (API), 25% are involved in primary packaging activities, 23% produce raw materials, 18% do 'Packaging Production' and 16% manufacture 'Secondary Packaging'.

6.2 Linkages

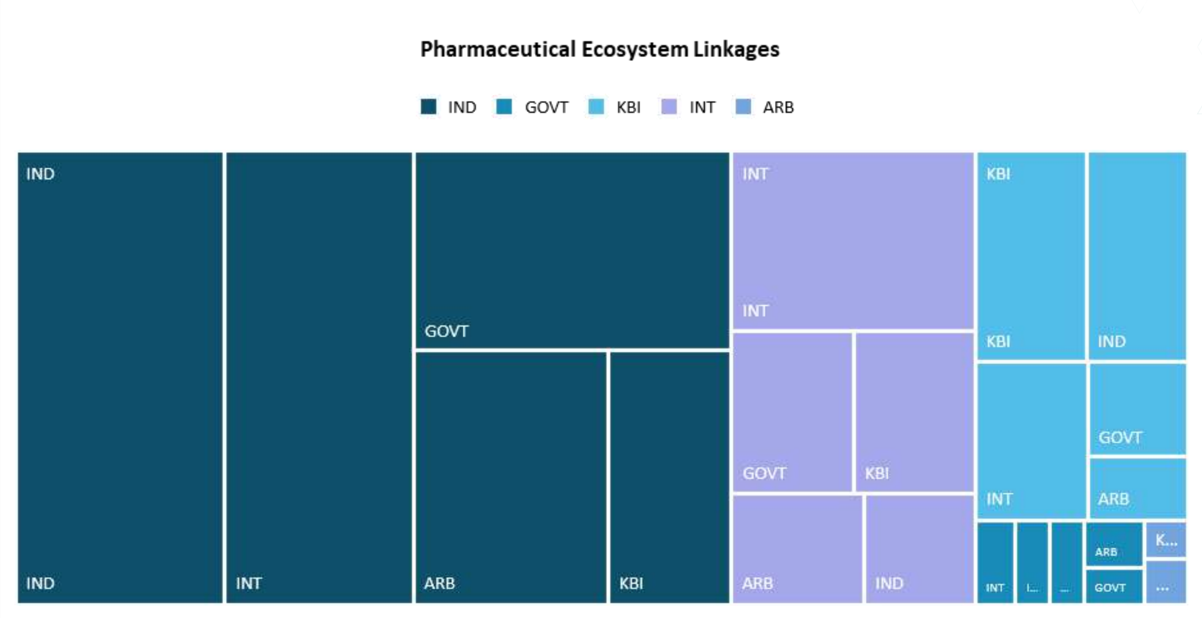
Before the issue of the linkages between the actors in the IPSSI is brought to the fore, it is important to reiterate the importance of linkages from the perspective of the SSI. For instance, in their critique of the linear approach to innovation, Edquist and Hommen (1999) stress the importance of interactive learning and innovation networks, for which linkages between actors are crucial (Oyelaran-Oyeyinka, 2005). Cavalcante (2011) articulates that interaction between agents through formal and informal linkages can take the form of: joint research and publications, personnel exchanges, patents and licenses, the purchase of equipment, or the transfer of technologies or methods. In this light, the analysis conducted is twofold: an understanding of the type of relationships that are present and who initiates them.

Types of Linkage

The next point of analysis is to determine which type of engagement occurs when an actor interacts with players in the system. This can be broken down in terms of intra- and inter-relationships. Each respondent was asked to list other actors (industry, government institutions, KBIs, intermediaries and arbitrageurs) their organization engaged with and the respective type of engagement. The types of linkages indicated include. 'Contract buyer', 'Contract supplier', 'Joint patents', 'Non-disclosure agreements', 'Trademarking', 'Joint research', 'Co-publishing', 'Secondments', 'Licensing agreements', 'Procurement contracts', 'Formal meetings', 'Informal meetings', 'Seminars/Training', 'Recipients of funding', 'Recruitment/Placement' and 'Joint ventures'. This chapter highlights both the major and minor intra- and inter-relationships as well as the strategic interactions that are crucial to driving innovation in the SSI. Finally, those interactions that are truncated or missing are highlighted in order to better understand and articulate interventions that need to be undertaken to bolster the SSI.

In general, it can be seen from Figure 17 that the majority of relationships are in proportional terms between the actors in the sectorial system of innovation. Firstly, in order of magnitude, the number of respondents the actors who participated interacted with are industry, intermediary, knowledge-based institutions, followed by government and arbitrageurs and financial institutions. Industry actors have the lion's share of interaction with intermediaries, namely industry associations. Knowledge-based institutions primarily interact with industry. Intermediaries mostly interact with themselves, whereas the government interacts with intermediaries. Finally, financial institutions and arbitrageurs primarily interact with the knowledgebase.

FIGURE 17: Ecosystem relationships



Sankey diagrams (refer to Figures 18, 19, 20, 21 and 22 below) have been used to display the types of relationships (intra- and inter-linkages) between the system actors, from the perspective of each actor. The diagram is composed of two distinct sections. The left-hand side of the diagram shows the specific system actors being engaged from the perspective of a selected actor, as well as the number of interactions. This provides an indication of who is connected to whom.

From the right-hand side of the diagram, we can see the various types of interactions, as well as the total cumulative number for all actors engaging in these types of interactions. However, the specific number of interactions for each actor are not represented in this visualisation.

Overall, the Sankey diagram offers valuable insights into the complex network of relationships and linkages that exist within a particular sector. It can help identify knowledge and resource flows between actors, thus making it a useful tool for understanding the dynamics of the sector.

6.2.1 Industry

Figure 18 highlights the industry intra- and inter-linkages.

Intra-relationships

The major intra-relationships are user-producer relationships in the form of contract buyer and contract supplier. Given the size representation of the firms surveyed and that the Indian pharmaceutical sector largely focuses on generic drug manufacturing, these relationships would generally present themselves as the supply of raw materials (pharmaceutical intermediates and ingredients) and secondary packaging materials.

Additionally, the next prominent type of interaction is communication between firms in the form of formal meetings and informal meetings. This indicates that there is a level of knowledge and information flow between firms and indicates that they do not function in isolation. Formal meetings contribute to the process of sharing information, exchanging and developing ideas, as well as expressing disagreement, and managing conflict (Shasitall, 2022), however this mechanism indicates there is a structured approach with a focused agenda. Whereas informal communication is more flexible and seen to be crucial for idea generation and the sharing of timely information (McAlpine, 2017). The combination of formal and informal channels of communication greatly boosts innovation (Grimpe and Hussinger, 2008).

There is a clear understanding that the Indian pharmaceutical value chain is complex. Only through the reduction of this complexity, through the consolidation and optimisation of the network as a whole, can the benefits be unleashed. Larger manufacturers are aiming to support seamless communication across suppliers, manufacturers, distributors, and customers through the removal of redundancies in order to improve supply chain efficiency and release 'sunk' capacity; consolidate capacities to align assets with capabilities and strategies, leading to top-line improvement (ATKearney, 2019). Examples of such activities include large manufacturers providing information and training on SAP/ERP systems for suppliers. A specific example is the case of Cipla who initiated a long-term capacity augmentation programme that included supply-and-demand mapping and rationalisation across all sites. As a result, it now has a good grip on complexity to help achieve its desired profitability and operational efficiency levels.

The emergent minor linkages reported are in the form of procurement contracts, non-disclosure agreements, as recipients of funding, joint research, and joint ventures. Little innovation outputs are emerging from the interaction and this highlights the fact that despite the information flow between firms in the pharmaceutical sector they are generally competitive rather than collaborative in nature. The lower level of knowledge protection activities and innovation outputs may be indicative of this.

Inter-relationships

When examining the collective inter-relationships with other actors of the system, the most prominent interactions are in terms of formal and informal meetings, seminars and trainings, joint research, recruitments and placements, licensing agreements and as the recipients of funding.

Formal communications with the government generally focus on issues of regulation, compliance, and trade. With respect to knowledge-based institutions there are channels of communication that result in the transmission of tacit and codified knowledge. An example being the “Supply Chain Initiative”, which is an annual in-person conference which acts as an opportunity to enable suppliers to informally interact with member companies and expert organizations in the areas of: human rights and labour, ethics, health & safety, and environment and management systems. The conference explores the challenges facing the industry, recognises contributions that partners are already making and aims to further develop expertise. This is particularly important given the knowledge-intensive nature of the pharmaceutical sector.

In the case of industry interaction with intermediaries, both formal and informal communications are commonplace and can be seen as meetings of manufacturers with their member industry associations. An example includes the Indian Drugs Manufacturers’ Association (IDMA) which was established in 1961 and is the country’s largest and most widely recognised pharmaceutical industry association with over 1000 plus members manufacturing formulations, APIs, etc.

A crucial function of industry associations is dissemination as is exemplified by platforms such as the Global Pharmaceutical Quality Summit, an annual conference organised by the Indian Pharmaceutical Association (IPA). Other intermediaries such as standards bodies for example the Central Drugs Standard Control Organization (CDSCO) regularly provide trainings on GMP certification and quality issues.

Other mechanisms of knowledge dissemination include the Biocon Academy which was founded by Biocon[46] in 2013 as a CSR initiative, designed to be a Centre of Excellence for advanced learning in applied biosciences. The academy endeavours to transform raw talent in India into skillful industry professionals and bridge the gap between industry and academia. This skill development objective is achieved by offering short-term certificate programmes focused on imparting industrial training. Within a span of 7 years, 700 students were trained in the life sciences sector and successfully placed in 40+ biotech industries across India. Biocon Academy's flagship programme, the “Biocon KGI Certificate Program in Biosciences” in partnership with Keck Graduate Institute, California, is the best-in-class programme that aims at transforming graduate and post graduate students into professionals ready to take on the evolving challenges of the biotech industry. Biocon Academy has partnered with the JSS Academy of Higher Education and Research (formerly JSS University), to deliver a first-of-its-kind “Certificate Program in Global Regulatory Affairs”.

As for joint research, Indian pharmaceutical companies have been slow to grow in the innovation space (e.g., new molecular entities, complex generics), due to a limited government-supported research ecosystem. There is scope to improve collaboration between government institutes and industry on innovation-focused research initiatives. For example, clinical trial approvals in India are subject to stringent regulatory norms and pharmaceutical companies often face challenges in securing the participation of government institutes in clinical trials (IPA 2019).

The link between industry and KBIs highlights how some large firms in the high-technology sectors have sought to break away from the limitations of internal R&D by engaging in external collaborative projects in order to gain access to the open knowledge networks from the knowledgebase. Thus, seeking to forge close institutional ties with their university partners and develop network career structures in order to engage academic scientists in joint knowledge production (Lam 2007). Another mechanism that was driven by policy is the “Small Business Innovation Research Initiative” (SBIRI) scheme of the Department of Biotechnology, Ministry of Science & Technology, which was the first-of-its-kind, early-stage

[46] Sourced from: https://www.bioconacademy.com

innovation-focused PPP initiative in the area of biotechnology fostering academia and enterprise linkages.

The high level of recruitment/placements indicates that KBIs are seen as a source of skilled human capital. Successful platforms that reflect this are the "Employer Facilitation Program for Apprenticeships" from the Life Sciences Sector Skill Development Council (LSSSDC), the aim of which is to mitigate challenges faced by employers in the life sciences sector.

A successful example of licensing agreements is that of Sun Pharma with the CSIR Indian Institute of Chemical Technology, Hyderabad (CSIR-IICT), for patents related to certain compounds with potential therapeutic activity. The objective of which was to bring innovations from Indian research institutes to the market to address the unmet needs of patients globally.

Most relationships between industry and arbitrageurs and financial institutions are as recipients of funding; the majority of which comes from banks rather than venture capital or angel investors. With respect to the innovation process, an example is the "Pharmaceutical Technology Up-gradation Assistance Scheme" (PTUAS), implemented by the Small Industries Development Bank of India (SIDBI) agency on behalf of the GoI. Funding flows can also be explained by schemes such as the PLI scheme (INR 15,000 crore) announced by the central government which aims to enhance India's manufacturing capabilities by increasing investment and production in the sector and contribute to product diversification of high-value goods in the pharmaceutical sector. The scheme has three categories of companies – Category A (FY20 global manufacturing revenue of pharma goods is more than equal to INR 5,000 crore), Category B (between INR 500 crore to INR 5,000 crore) and Category C (revenue less than INR 500 crore). The quantum of incentives vary for the three groups – INR 11,000 crore (Group A), INR 2,250 crore (Group B) and INR 1,750 crore (Group C). To date, 55 drug manufacturers have been selected under the PLI scheme (Business Standard Online, 2022).

BOX 1: Pfizer IIT Delhi Joint Innovation and IP Program (IND - KBI linkage).

Objective

To catalyse a healthcare innovation ecosystem through technology institutes for strong market access linkages.

Approach

In 2015, the international drug manufacturer Pfizer partnered with IIT Delhi to launch the "Pfizer IIT Delhi Innovation and IP Program" to provide comprehensive support to Indian startups for creating healthcare innovations in the country.[47]

The initial phase of the programme, launched in 2015, offered innovators residential incubation at IIT Delhi and a capital investment of INR 50 lakh each, besides mentoring support from IIT Delhi's faculty, access to infrastructure and prototyping laboratories, IP search and filing services, guidance from Pfizer's global experts, and access to VC and other industry linkages. For startups with ready PoCs, up to INR 3 lakh each was given to access IP attorneys and services and cover the patent fee[48]. The collaboration resulted in the establishment of the Foundation for Innovation and Technology Transfer (FITT) at IIT-Delhi which successfully incubated nine healthcare innovations and 19 IP filings to date. The success of the initiative broadened the FITT mandate such that in 2022 Pfizer launched the "Pfizer Innovation Program" in collaboration with a broader group of stakeholders that includes, the "Atal Innovation Mission" (AIM), NITI Aayog, "Invest India", and Social Alpha [49].

Under FITT's oversight, and with IIT Delhi as the principal incubation partner, customised incubation support is provided through various technology incubation centres at other IITs, major technology institutes and the incubation network of Atal Innovation Mission across India. Social Alpha is partnered to support the startups through their lab-to-market journey. Grants up to INR 65 lakh are offered for healthcare product trials, pilot studies, and product market launches to accelerate the lab-to-market journey of their innovation.

Outcomes

The Pfizer initiative has evolved to anchor innovations from lab to markets and importantly, is leveraging, connecting, and strengthening the healthcare stakeholder linkages via tech innovations. Besides technology institutes and incubation centres, Pfizer CSR initiatives are now channelled to support the innovation programmes with the collaboration of a host of non-profits working across a wide array of healthcare issues. These partners include the UN Health Innovation Exchange, "Program for Appropriate Technology in Health" (PATH), Association of Healthcare Providers (India), and Marico Innovation Foundation, leading research centres and hospitals such as St Johns Research Institute, HCG Hospitals, Cytecare Hospitals and broader innovation initiatives such as Google for Start-ups, Design Alpha, Healthcare Information and Management Systems (HIMSS), and international innovation ecosystem providers like the TenX250.

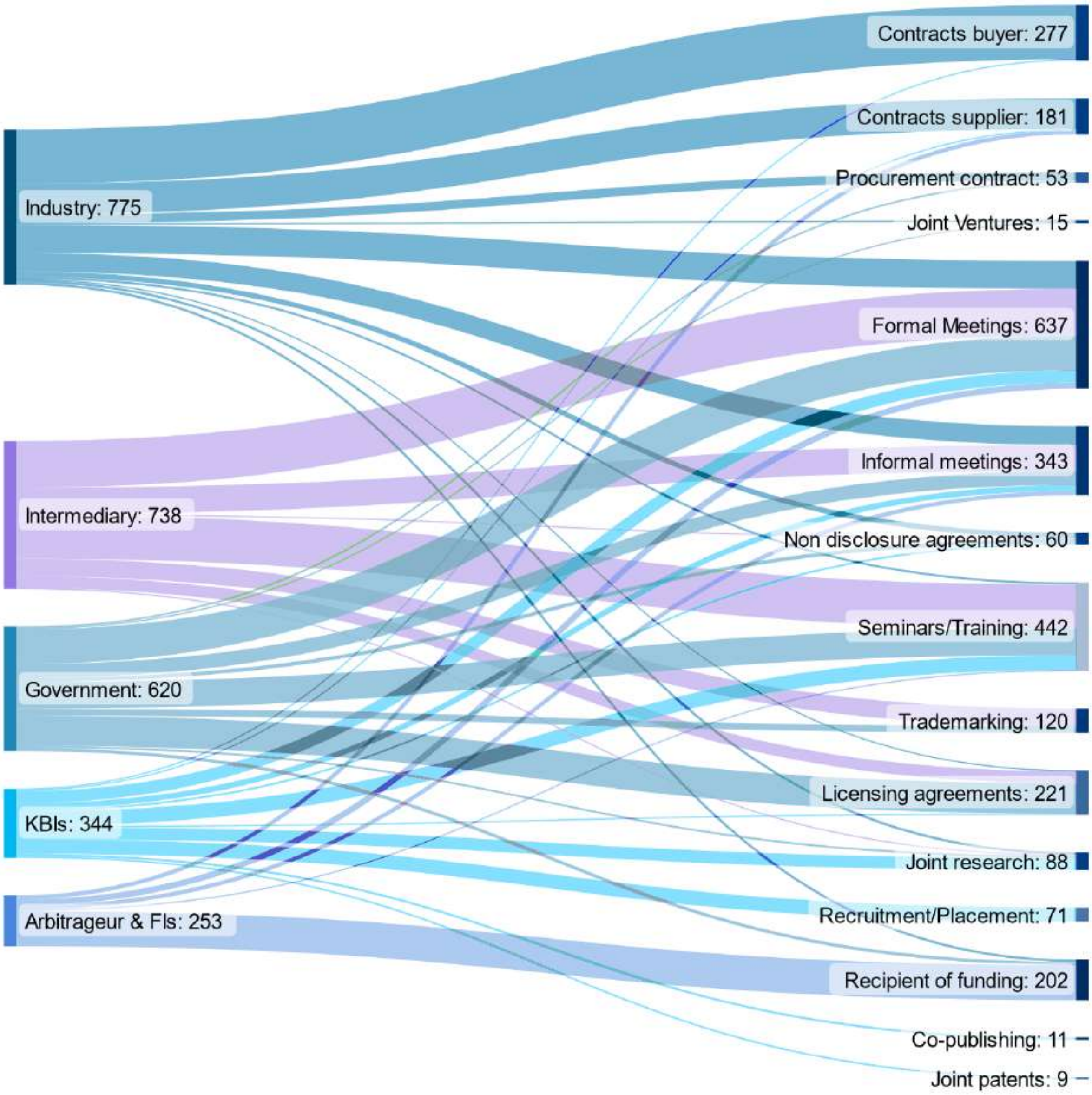
[47] Sourced from: https://www.thehansindia.com/posts/index/Education-and-Careers/2015-11-24/Pfizer-IIT-D-launch-healthcare-innovation-and-IP-programme/188648

[48] Sourced from: http://www.pharmabiz.com/NewsDetails.aspx?aid=97755&sid=2

[49] Sourced from: https://inc42.com/buzz/pfizer-to-back-oncology-healthtech-startups/

[50] Sourced from: https://www.pfizer.co.in/our-community-efforts/csr-initiatives/indovation-healthcare-innovations-made-in-india

FIGURE 18: Industry relationships



6.2.2 Knowledge-Based Institutions

Figure 19 highlights knowledge-based institution intra- and inter-linkages.

Intra-relationships

The majority of intra-linkages reported by KBIs are in the form of seminars/training, formal and informal meetings, joint research, and co-publishing which highlights there is some degree of collaboration between KBIs in the pharmaceutical sector.

An example of knowledge diffusion through seminars and training is the Nirma Institute of Pharmacy International Conference (NIPiCON) and National Conference of Institute of Pharmacy (NCIP), which are organised every other year. These fora aim to offer a knowledge-sharing experience in various areas of pharmaceutical sciences with emerging trends and innovative approaches. Areas of focus include: the drug discovery process, nutraceuticals, medical devices along with pharmaceutics, biopharmaceutics, and novel drug delivery systems, phytopharmaceuticals and natural products, medicinal chemistry and chemical biology, molecular pharmacology, regulatory affairs and intellectual property rights. In addition to these conferences, many national seminars, like “Recent Advances in Drug Discovery” and “Interpretation of Spectral Data” are also organised. The advisory committee for both conferences are composed from leading institutions across India. It is crucial that given the change in the global landscape from generics to biosimilars and cell and gene therapy, it is imperative that pedagogical topics are continually assessed and addressed. In addition, there needs to be more information percolating from Tier1 institutions to Tier2 and Tier3.

As was previously highlighted, a combination of formal and informal communication drives the innovation process. In the case of knowledge-based institutions there is more formal than informal communication, which indicates a level of rigidity to the exchange.

Examples of successful joint research includes Stanford-India Bio design, which was launched in 2007 as a first-of-its-kind collaboration between Stanford University, the All India Institute of Medical Sciences (AIIMS), and the Indian Institute of Technology (IIT) Delhi. The goal of the partnership was to identify and train a first generation of local innovation leaders in medical technology who, in turn, would help stimulate India's nascent MedTech industry. A more recent example includes IIT Delhi and AIIMS New Delhi, the two leading institutions in the country, have jointly set-up the Centre for Advanced Research and Excellence in Disability & Assistive Technology (CARE-DAT), a Centre of Excellence (CoE) created under the aegis of the Indian Council of Medical Research (ICMR) (Ref, 2021).

Additionally, the Indo-French Centre for the Promotion of Advanced Research (IFCPAR/CEFIPRA)[51] is a model for international collaborative research in advanced areas of science and technology. The funding is provided for KBI-KBI and industry-KBI from India and France.

The Indo-German Max Planck Centres in Bangalore and New Delhi serve as fine examples of KBI-KBI linkage in the international arena. The Max Planck Centre was established on the initiative of the Max Planck Institute of Molecular Cell Biology and Genetics in Dresden, the Max Planck Institute for Infection Biology in Berlin, the Max Planck Institute of Colloids and Interfaces in Potsdam, the National Centre for Biological Sciences (NCBS) in Bangalore and the Institute of Life Sciences in Bhubaneswar, all of which are involved in the research work of the Max Planck Centre. Scientists at the Indo-German Max Planck Centre for Research on Lipids are primarily intending to conduct a comprehensive survey of lipids in various cells and organisms. The aim is to develop tools that will utilise the individual fat components for the biological system analysis and by doing so make it easier to research and treat diseases.

A point of note is the general cost associated with R&D in the pharma sector and whether or not this translates at the level of Tier2 and Tier3 institutions, which are more resource constrained.

There is also the externalisation of knowledge with respect to co-publishing which may very well be associated with National Assessment and Accreditation Council (NAAC) accreditation under the pillar of research innovation and extension, or the National Institutional Ranking Framework (NIRF) under the pillar of research and professional practice.

Inter-relationships

Among the collective inter-relationships with other actors of the system, the most prominent interactions are formal and informal meetings, seminars and training, recruitments and placements, and as recipients of funding.

As was previously highlighted, combining formal and informal communication has a positive effect on innovation (Grimpe and Hussinger, 2008). From the perspective of KBIs, this combination enables the dissolution of organizational rigidities and better exchange of ideas, to some extent, which may then be formalised in terms of formal transfer mechanisms like licensing and the acquisition of patents (Jensen and Thursby, 2001; Thursby and Kemp, 2002), joint research (Cockburn and Henderson, 1998) or consulting (Thursby et al., 2007).

Within the innovation process, intermediaries are important organizations in mitigating systemic failures (Sutthijakra and Intarakumnerd, 2015). Major KBI interactions with intermediaries take the form of formal meetings, informal meetings and seminars/training. This reflects tacit knowledge transfer between industry associations and KBIs. In the pharmaceutical sector this is exemplified by collaborative initiatives such as the jointly hosted Student Congress by the Indian Pharmaceutical association (IPA) and National Institute of Pharmaceutical Education & Research (NIPERs). The objective of which is to participate in pharmacy policy development in a proactive way and serve as a platform for students to give exposure to international pharmacy scenarios.

Communication between knowledge-based institutions and arbitrageurs can be explained through the process of ideation to market. Given that, arbitrageurs are the dominant source of commercialising risky new ideas and technologies (Lerner and Nanda, 2020). This process requires a degree of formal and informal communication during the process of risk assessment before the eventual funds are committed. An example of funding is C-CAMP and Japanese venture capital firm, Beyond Next Ventures (BNV)

[51] Sourced from: http://www.cefipra.org/Industry_Academia_Project.aspx

setting-up an innovation hub to fund and foster early-stage innovations in India[52].

Another example for KBI-industry-arbitrageur engagement is C-CAMP, Bangalore. This incubator organises the "National Bio Entrepreneurship Competition" (NBEC)[53], a nationwide competition to attract, identify, and nurture bio-entrepreneurs working on novel and scalable business ideas with significant societal impact. Applicants compete for attractive cash prizes and investment opportunities. First launched in 2017, the NBEC has emerged as a flagship platform for bio-entrepreneurs and innovators in India to showcase their deep science-driven ideas and has had a great impact. It has brought to the forefront 63 exceptionally promising young entrepreneurs as winners who grabbed the attention of investors, were featured in national and global media, and went on to win many other accolades. Industries like Biocon, Anthem Bio, Aurigene, Syngene, Novozymes, Biocon Biologics, L'oreal, Bug works are some of the industries who offer prizes to the innovators. In addition, arbitrageurs like Sangam VC, Kotak Private Equity, Indian Angel Network (IAN), Social Alpha, and Enzia Ventures offer investments.

One of the finest examples for Government-KBI engagement to promote innovation is the "Bio-NEST" (Bioincubators Nurturing Entrepreneurship for Scaling Technologies) scheme to create globally competent bioincubation facilities across the country. Bio-NEST bioincubators are mandated to provide incubation space to entrepreneurs and startups along with shared access to high-end infrastructure, specialised and advanced equipment, business mentorship, IP, legal and regulatory guidance, and networking opportunities. Through the Bio-NEST scheme, BIRAC has supported 60 bioincubators placed either within academic/research Institutes, medical hospitals, biotech clusters or as stand-alone incubators that are supported through private, central or state governments.[54]

With respect to seminars and training, the knowledgebase is seen as a source of technical knowledge. In addition, the inclusion of industry actors ensures relevance based on real world problems, as well as continuous learning between industry and the knowledgebase (Kaklauskaset al., 2017). Practical examples of this include the Institute of Good Manufacturing Practices India under the Department for Promotion of Industry and Internal Trade (DPIIT) imparting training programmes to provide training to industry in the areas of pharmaceutical and healthcare manufacturing. There are international initiatives such as the "Sakura Exchange Programme" where the knowledgebase brings government stakeholders up-to-date on the latest technical issues relating to the sector.

One of the most popular incubators in India is Venture Center, Pune, founded in 2007 as an initiative of CSIR's National Chemical Laboratory. Venture Center was incorporated as an entrepreneurship development center under Section 25 of the Companies Act, 1956 (now Section 8 under the Companies Act, 2013). Venture Center is an approved incubator of the National Science and Technology Entrepreneurship Development Board of the Department of Science and Technology, Government of India (DST-NSTEDB).[55]

Another example of Government-Arbitrageur-KBI engagement is IKP Knowledge Park which is a 200-acre premier science park and incubator in Hyderabad and Bangalore. It is set-up with the mission to create a world-class ecosystem for fostering leading-edge innovation in the country. IKP promotes the advancement of technology-based innovators, entrepreneurs and small and large companies through customised space, shared equipment, incubation, mentorship, and funding. IKP has so far supported over 430 companies from seven countries, 90% of which are startups. IKP Knowledge Park launched its "Grants Management Programme" in 2011 and conducts Grand Challenges and other innovation scouting programmes in partnership with international development agencies and state and central government departments.[56]

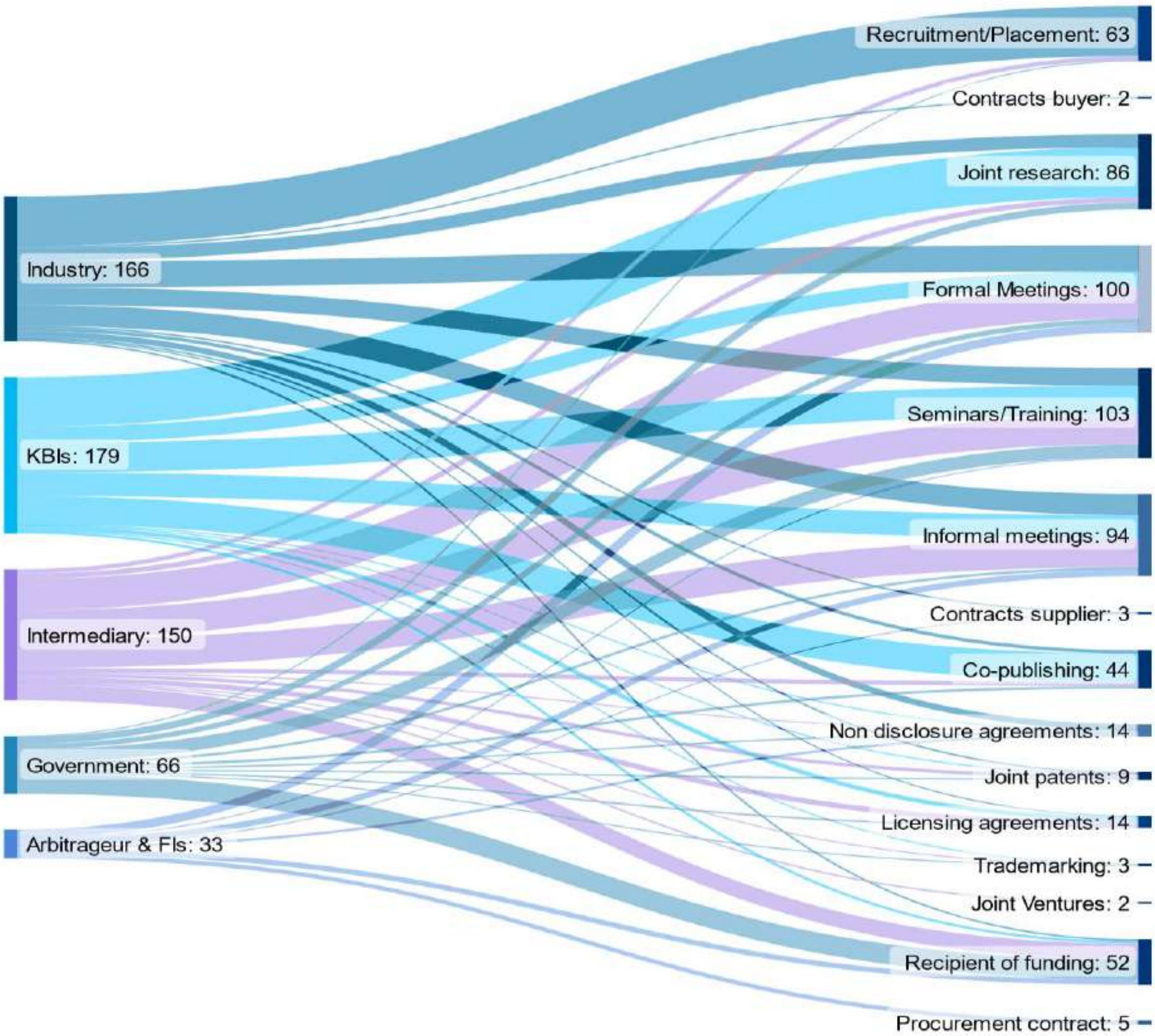
Recruitments and placements offer clear benefits to the actors involved. Industrial placement schemes can facilitate student learning, from the theoretical to practical, and make them more 'industry ready´ (Wandahl & Faber, 2016). In addition, the benefits of fostering such industry-KBI interaction include the ability to guide and improve curricula development (Arlett et al., 2010, Wandahl et al., 2011). The talent pool with advanced skills is limited in India with only 2,000 PhD students enrolled in pharmacy institutes (compared to over 15,000 PhD students enrolled in the US). There is also a gap between the college curricula and industry's requirements. However, this is part of Life Sciences Sector Skill Development Council's (LSSSDC) agenda, along with the introduction of apprenticeships (IPA, 2019). However, in the case of many Indian institutions, relationships of academia with industry, rather than that of the institution, are strong drivers in the success

[52] Sourced from: https://www.ccamp.res.in/seed-funding-CBIH
[53] Sourced from: https://www.nationalbioentrepreneurship.in/
[54] Sourced from: https://birac.nic.in/bionest.php
[55] Sourced from: https://venturecenter.co.in
[56] Sourced from: https://www.ikpknowledgepark.com/

of the placement process[57]. The indication being that formal mechanisms need to be bolstered. An example being the "Employer Facilitation Program for Apprenticeships" from the LSSSDC.

Flow of funds can be explained in terms of the traditional relationships of funding education (Government of Karnataka, 2018), as well as the provision of research grants. Examples of successful research grants for the pharmaceutical sector include R&D projects sponsored by the Department of Science and Technology (DST) and Department of Scientific and Industrial Research (DSIR) to the National Institute of Pharmaceutical Education & Research (NIPERs).

FIGURE 19: Knowledge-based institution relationships



6.2.3 Government

Figure 20 highlights the government intra- and inter-linkages.

Intra-relationships

The main intra-linkages reported are contract suppliers, seminars and training, formal and informal meetings, joint research, co-publishing, and licensing agreements.

Supplier contracts between government bodies emerge as central public undertakings or state public undertakings supplying to the state government, for example Tamil Nadu Medical Services Corporation Ltd. (TNMSC) supplying the Government of Tamil Nadu. An example of joint research and co-publishing has been how the Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV) were key institutions for conducting advanced research, publishing, and disseminating

[57] First, academic engagement is practiced primarily by scientifically productive individuals, suggesting it is complementary to, or even instrumental for, academic research activities. Second, relatedly, academic engagement is positively correlated with mobilising research funding and resources. Third, academic engagement appears, as compared to commercialisation activities, to be more driven by autonomous individual motivations and characteristics and less influenced by embedded university characteristics.Perkman et al., 2021: https://www.sciencedirect.com/science/article/pii/S004873332030189X

information relating to COVID-19. Licensing agreements generally exist for such technologies and materials.

Due to the complexity of policy making, the division of labour between government agencies makes it almost impossible for one agency to dominate the process. Joint efforts involving different agencies are essential as is highlighted by formal and informal communication. Therefore, communication, coordination, and mutual adjustment between these stakeholders and between the stakeholders and the environment against which policy is made is required (Flanagan et al., 2011). With respect to the pharmaceutical sector this was exemplified during the COVID-19 crisis by the engagement of the Ministry of External Affairs - Department of Pharmaceuticals (under Ministry of Chemicals & Fertilizers) - Directorate General of Health Services for vaccine production and supply.

Another example of how communication occurs amongst different parts of the government is the "Industry Innovation Programme on Medical Electronics" (IIPME), a collaborative project between the Ministry of Electronics and Information Technology (MEITY) and Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Government of India. The project goal is to fund a portfolio of India-led pilot projects targeting innovations in multidisciplinary areas comprising electronics, engineering, medical devices, healthcare, software, algorithms and information technology, to help medical electronics fraternity and to bring in fast-paced research and development in this area. The idea is to provide funding support to applicants for testing their bold ideas, mentorship from various subject matter experts, networking platforms and an opportunity to scale-up their technology. Under this project support will be provided at the seed, early transition, and transitions to scale stages.

On an international level, the Indo-U.S. Science and Technology Forum (IUSSTF)58 established under an agreement between the GoI and the US in March 2000, is an autonomous bilateral organization jointly funded by both governments. It promotes science, technology, engineering, and innovation through substantive interaction among government, academia and industry. The Department of Science and Technology, Government of India and the U.S. Department of State are the respective nodal departments.

With respect to minor relationships, the overall number of respondents is low and the relationships that emerge are generally balanced in nature.

Inter-relationships

On review of the inter-relationships between government and other actors, the most prominent type of interactions are formal and informal meetings, seminars and training, joint research, licensing agreements and trademarking/standards.

Critical issues facing the Indian pharmaceutical sector have emerged from frequent and unexpected changes to the domestic pricing policy, in particular, an uncertain environment for investments and innovation. The government and stakeholders would need to constructively engage to develop a framework that ensures the availability and accessibility of affordable drugs for citizens, while providing a workable pricing structure for pharmaceutical companies (IPA, 2019). In this sense, the openness of both formal and informal channels of communication is key to finding feasible solutions.

Bio Angels is a unique partnership between BIRAC, an enterprise of the Department of Biotechnology, and the Indian Angels Network (IAN), India's single largest horizontal platform for seed and early-stage investing in BioTech, MedTech, HealthTech, pharma, AgriTech and CleanTech startups supported by angel investors who bring deep domain expertise. It has strategic operations in the areas of investment opportunities, mentorship, market access, overseas partnerships and R&D facilities. Key to their success is tacit knowledge transfer in terms of formal and informal communication.

Dissemination of information is highlighted by intermediaries such as the IDMA along with the Department of Pharmaceuticals (DoP), Government of India (GoI), organising various webinars and workshops on GMP, GST, the Government of Orisha´s Sugam Portal across India.

Recent example in terms of joint research as of the CSIR-Central Drug Research Institute, Lucknow (CSIR-CDRI) and NIPER Guwahati, Assam (NIPER-G) engaging in collaborative R&D projects for scientific upliftment of North-East India. Knowledge dissemination and transfer is exemplified by initiatives such as the Technology Information Forecasting and Assessment Council (TIFAC – NIPER Guwahati) joint workshop on the techno-commercial assessment of the Technology Readiness Level (TRL) 6 and above technologies developed in India by academia, research labs and industries.

The "Contract Research Scheme" (CRS) aims at validation of a process or prototype (developed by academia) by the industrial partner. This serves as an example for KBI-

[58] Sourced from: https://iusstf.org/home

industry linkage funded by a government body (BIRAC). Examples of each are addressed in turn.

In the case of trademarking/standards, the Drugs Controller General of India - CDSCO under Directorate General of Health Services - issues WHO-GMP Certificates/Certificate of Pharmaceutical Products (CoPP). In terms of licensing agreements, during the COVID-19 pandemic, the Indian Council of Medical Research (ICMR) developed Covaxin and provided Bharat Biotech with the sole license to manufacture.

BOX 2: The BioAngel Program (GOVT - ARB linkage).

Objective

To drive seed funding and early-stage investing in BioTech startups through a public-private partnership association of the Biotechnology Industry Research Assistance Council (BIRAC), under the GoI Department of Biotechnology, and the Indian Angels Network (IAN).[59]

Approach

Founded in 2019, the BioAngel platform is India's largest horizontal platform for seed and early-stage investments in technology-led BioTech ventures across verticals such as MedTech, HealthTech, pharma, AgriTech and CleanTech. Besides funding, the platform offers mentoring, and an enabling ecosystem for the startups for taking their research-backed innovations to the market.

Over the last decade BIRAC has built a pipeline of 500 startups and enterprises who received support for strategic research and innovations to meet India's product development needs[60]. To commercialise these products and solutions, the IAN mobilises investments through a consortium of angel investors, high net-worth individuals (HNIs), early-stage VCs, family offices and corporates. Investors work with domain experts from BIRAC and the scientific communities to understand the science behind the application of the science and the entrepreneurial propositions by the startups. Patient capital to the tune of INR 2.5 – 100 lakh crore is made available to the startups.

The platform works with startups to help them articulate their business objectives. Investors are able to assess the customer needs being addressed, the science behind it and the growth ambitions of the startup and its team. This includes assessing the size of the targeted accessible market, the current competition and the delivery model of the company, and also strengthening its operational focus, frameworks, processes, and governance.

Outcomes

The BioAngel platform is raising INR 350 crore for investing in 130 startups engaged in innovative research[61]. To take innovation excellence quickly to market, the platform is specialised in providing nuanced services to bio-tech companies. For instance, startups founded by scientists and technical experts building IP make them valuable investments. The platform identifies the right investment mode - in this case the exit option for the investor would largely be enabled when the company is acquired[62]. The revenue-earning startups with shorter gestation tend to have a mix of scientists and business experts. Such startups are making great strides in innovative precision medicines for preventive and curative medicines by convening the expertise of scientists, data analysts, and business experts. The IAN have also built an app, called the "BIO App" for mapping investors, scientists, domain experts, and industry leaders for collaborative support to startups.

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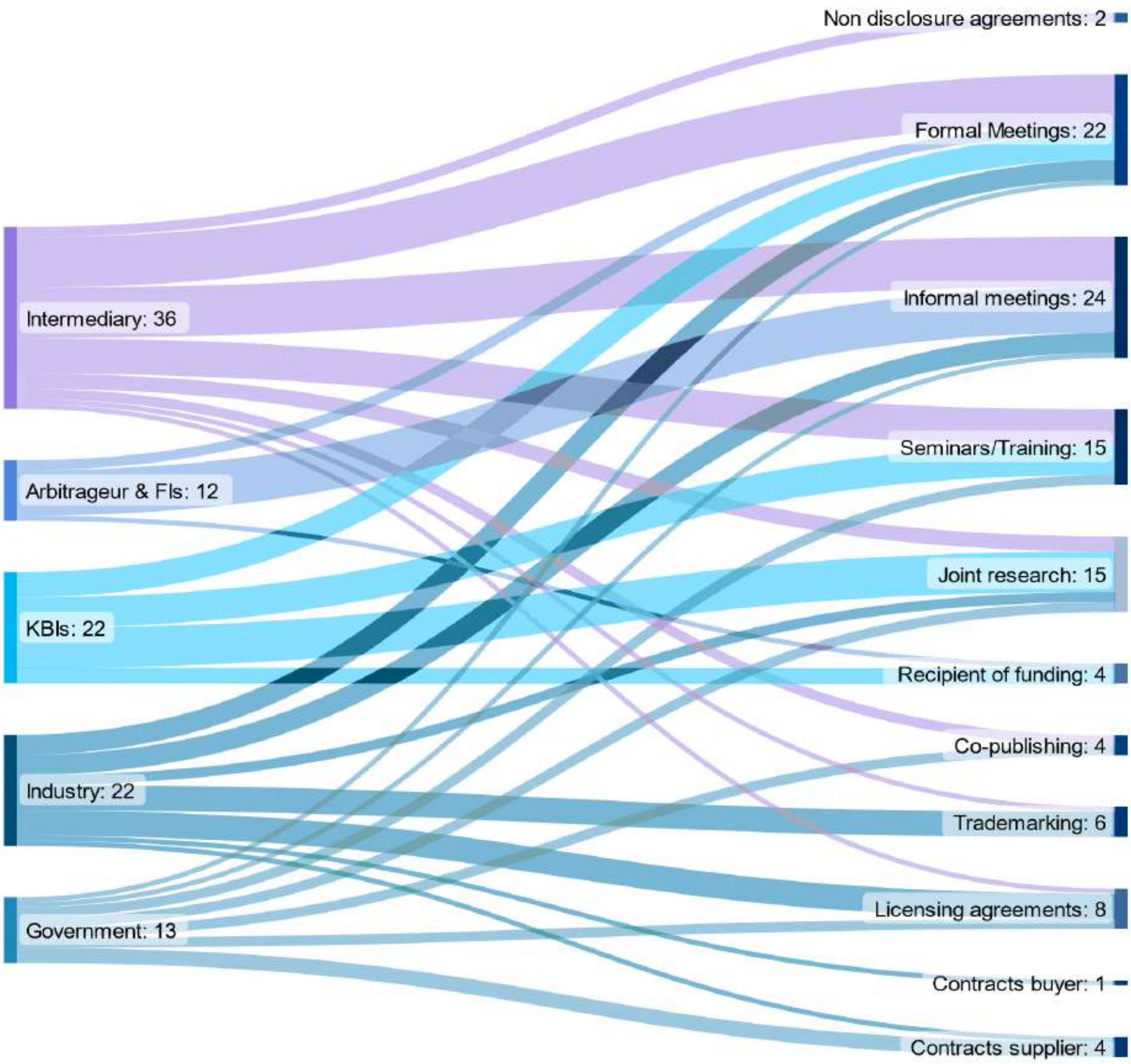
[59] Sourced from: https://bioangels.vc/

[60] Sourced from: IAN Signs MOU with BIRAC to Bring Bio Technology Startups Closer to Angel Investors - BW Disrupt (businessworld.in)

[61] Sourced from: https://bioangels.vc/2022/05/11/ian-birac-to-launch-bioangels-to-raise-rs-350-cr-for-startups/

[62] Sourced from: The science behind the healthtech startup must be understood well - Express Healthcare

FIGURE 20: Government relationships



BOX 3: Sakura Exchange Programme in Science for Indian Researchers/Administrators (GOVT – KBI linkage)

The "Sakura Exchange programme in Science for Indian Researchers/Administrators" was supported by Japan Science and Technology Agency from January 20th to Jan 26th, 2019, in Tokyo, Japan[63]. An Indian delegation of 42 members, comprising 2 officers from the Department of Biotechnology, 3 officers from the Ministry of Human Resources Development, 2 officers from the Department of Science and Technology, 3 Officers from the Department of Scientific and Industrial Research, 1 post doctorate from the International Centre for Genetic Engineering and Biotechnology (ICGEB), and 21 young scientists from the Indian Institute of Technology (IITs) and the Indian Institute of Science Education and Research (IISERs) attended the programme

The focus of the exchange programme was artificial intelligence and deep machine learning. The programme enabled the young researchers from the IITs and IISERs to exchange their ideas with Senior Professors from 16 Japanese universities with an aim to establish strong Indo-Japanese collaborations in science and technology. The Indian delegation also made visits to key universities partnering in the programme including, the University of Tokyo, Tokyo Institute of Technology, University of Tsukuba, National Institute of Advanced Industrial Science and Technology, Riken Center for Advanced Intelligence Project, and Japan Electron Optics Laboratory Company (JEOL), Ltd

[63] Sourced from: https://dbtindia.gov.in/sites/default/files/Monthly_Cabinet_Summary_January-2019.pdf

6.2.4 Intermediary

Figure 21 highlights intermediaries intra- and inter-linkages.

Intra-relationships

The main intra-linkages reported are formal and informal meetings along with seminars and training. This indicates high tacit knowledge transfer between intermediaries. Close and regular formal and informal communication can be seen between the Indian Drugs Manufacturers' Association (IDMA) and Indian Pharmaceuticals Association (IPA) who historically have a sibling-like relationship. There is also regular engagement between national and regional offices of industry associations. From the view of incubators in order to facilitate knowledge transfer, the Indian STEPs & Business Incubators Association (ISBA) is a common platform for networking between incubators across the country. With respect to knowledge dissemination through seminars and trainings, the Indian Drugs Manufacturers' Association (IDMA) and Kerala Indian Pharmaceuticals Association (IPA) regularly conduct joint training programmes like the "Orientation to Pharma Industry" for pharmacy graduates.

Amongst intermediaries, the minor interactions reported are in terms of licensing agreements, trademarks and joint ventures.

Inter-relationships

With respect to inter-relationships the most prominent are formal and informal meetings, seminars and training, joint research and as recipients of funding.

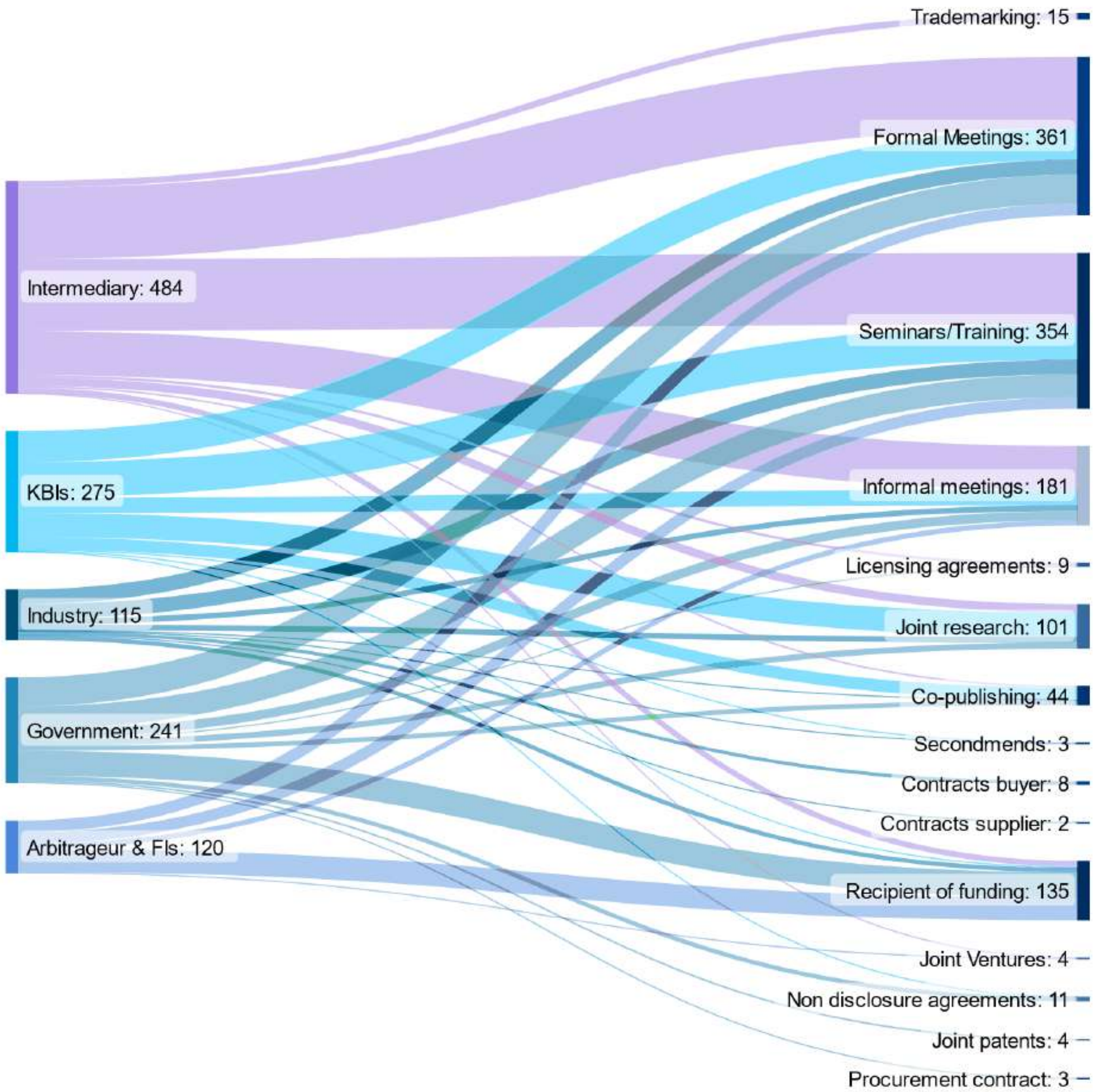
Communication channels between industry and intermediaries are clear and evident primarily due to the firms being members of industry associations.

The representation of formal and informal communication between intermediaries and government highlights the role of industry associations as facilitators between industry and government. Other examples include the "Bio-NEST" initiative BIRAC's support of 59 bio-incubators. Their engagement with KBIs such as the Medanta Institute of Education & Research (MIER) for mentorship, networking and training is a clear example of both tacit knowledge transfer in the form of seminars and training as well as formal meetings.

In terms of joint research, the "Refreshing Research Initiative" of the industry association the Organization of Pharmaceutical Producers of India (OPPI) is a hackathon type approach to promote the development of novel solutions and innovations in the pharmaceutical sector. It targets youth and has a focus on the areas of: women's health, mental health, public health, anti-microbial resistance and vaccines, supply chain management, and sustainability in the pharmaceutical industry. The results of which are regularly disseminated online.

Funds flow can be between intermediaries and arbitrageurs. Platforms such as the "Atal Innovation Mission" of the NITI Aayog, are an example of intermediary interaction with arbitrageurs for facilitating the flow of funding, providing INR 10 crore grants to establish incubation centres. Tacit knowledge exchange between the two actors is in the form of formal meetings, informal meetings and seminars/training. It is important to highlight the relationship between the Enterprise Incubation Centre (EIC) of premier B-school IIM Lucknow's Noida campus and the HDFC Bank, who signed an MoU to help startups with mentoring, training, product acceleration, and banking services.

FIGURE 21: Intermediary relationships



6.2.5 Arbitrageurs and Financial Institutions

Figure 22 highlights arbitrageur and financial institution intra- and inter-linkages.

Intra-relationships

The main intra-linkages reported are formal and informal meetings which indicates high tacit knowledge transfer between arbitrageurs (banks and VCs). In order for arbitrageurs and financial institutions to effectively stay on track with the market and assess risk, information flow is crucial. Hosting the Investor Conclave for assessing regulatory scenarios and high-end networking among the PE/ VC investors by the Indian Venture Capital Association provides one such platform. Other sector-specific initiatives are the Indian Venture Capital Association and Ernst & Young spotlight series Pharma Talk. In the case of arbitrageurs and financial institutions, there are no minor relationships that emerge.

Inter-relationships

With respect to inter-relationships, once again formal and informal channels of communication are prominent, followed by knowledge dissemination activities in the form of seminars and training, followed by non-disclosure agreements.

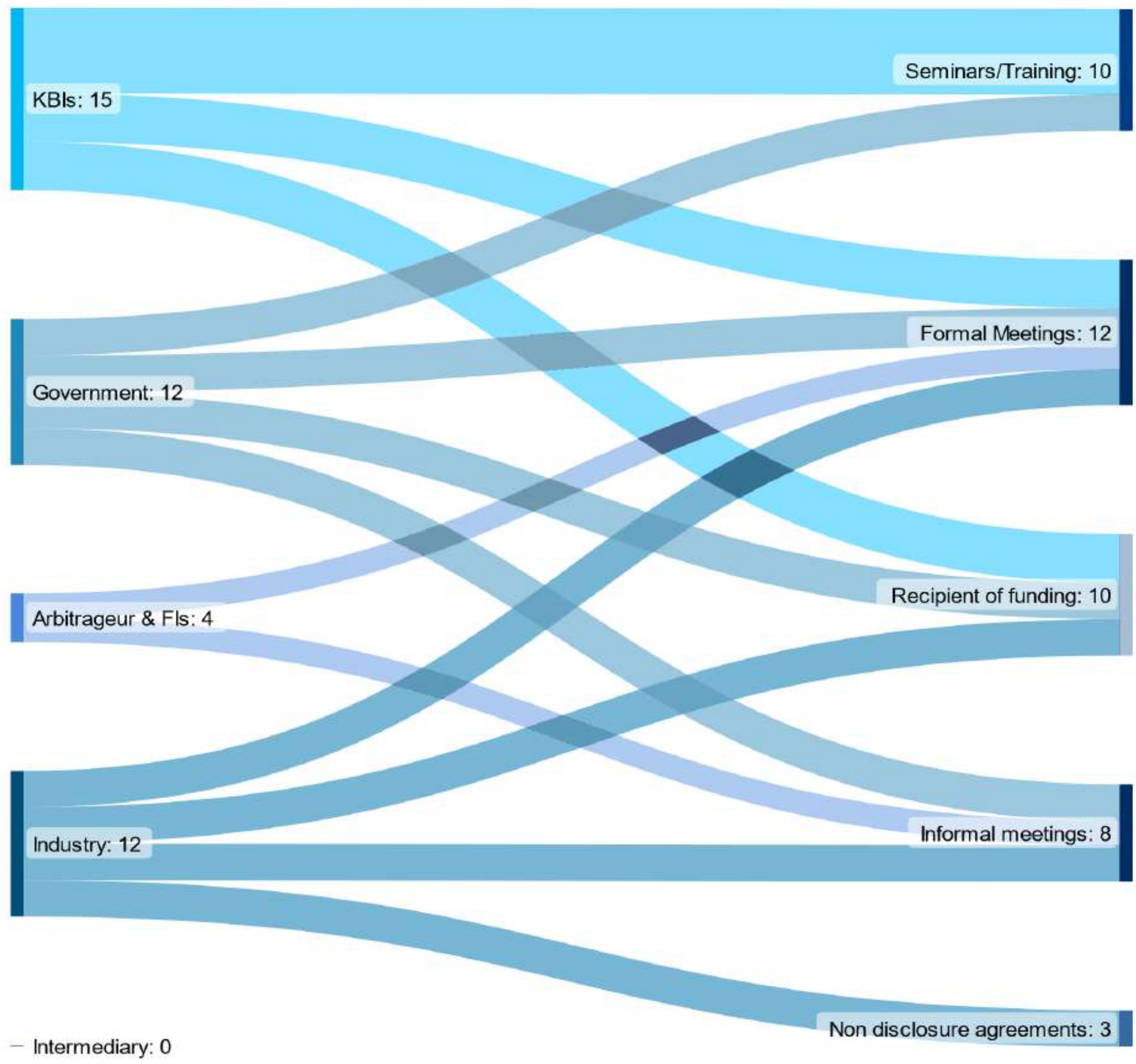
Formal and informal communication between arbitrageurs and financial institutions and government generally orient around investment policies. An example is the 4th "Roundtable with Global Venture Capital Fund", organised by the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, to explore new sectors for investing, promote and protect the intellectual property created by the young Indian entrepreneurs, provide expertise to scale-up and explore greater capital infusion including risk capital. The interaction also reports funding aspects between arbitrageurs and government such as the "BioAngels1 Program", a unique partnership between the BIRAC, an enterprise of the Department of Biotechnology and the Indian Angel Network (IAN). In addition, the IAN – BIRAC partnership (arbitrageur-government) in the biotechnology industry will allow new innovative startups to gain a foothold in this high-cost, high-risk sector. While the BIRAC has been at the forefront in leading the bioeconomy at large, it is imperative to support and unleash the true potential of innovative new businesses operating in this space with private angel investments.

Other funding initiatives include the ICICI Bank tie up with 22 educational institutions across India to fund ideas of the students, where the bank will own the intellectual property rights (IPR) of startups for three years.

Non-disclosure agreements indicate the confidentiality policy of banks for determination of materiality and disclosure of events/information with the industry or startups, as is exemplified by the SIDBI's disclosure policy for MSMEs.

What is important to note is that there were no linkages reported between arbitrageurs and financial institutions and intermediaries, indicating their relative isolation from each other in the pharmaceutical landscape. This highlights the need to strengthen the presence of angel investors and venture capital in pharmaceutical-oriented incubators. In addition, there is the need to bring financial institutions closer to industry players through industry associations. This is particularly crucial in facilitating acquisition of new technologies, particularly at the level of MSMEs.

FIGURE 22: Arbitrageur and financial institution relationships



To summarise, the main type of interaction is innovation inputs with little translating into innovation outputs. In the relationships presented above, there are some interactions which are robust, however what emerges is the need to bolster certain truncated relationships in order to facilitate knowledge and resource flows within and between the actors, hence fostering innovation. According to the literature, the scope and intensity of these interactions between the actors are reflected in varying institutional arrangements, referred to as Triple Helix Type I, II, and III (TH-Type I, II and III) (Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2003b, 2008; Ranga and Etzkowitz, 2013). In the specific case of the pharmaceutical sector, TH Type II transitioning to TH Type III is observed. TH Type II refers to mechanisms of communication between the actors that are strongly influenced by the market and technological innovations. In this case, the point of control is at the interfaces and consequently new codes of communication are developed. The role of the government is primarily to limit cases of market failure. It can be considered a 'laissez-faire' model of interaction "in which people are expected to act competitively rather than cooperatively in their relations with each other". However, in TH-Type III, the actors assume each other's roles in the institutional spheres as well as the performance of their traditional functions. With the emergence of TH Type III, a complex network of organizational ties has developed, both formal and informal, among the overlapping spheres of operations. Hence, universities take on entrepreneurial tasks such as marketing knowledge and creating companies as a result of both internal and external influences.

Hence, the inter- and intra-interactions that need attention are:

- Fostering joint research amongst industry actors with an aim to make the sector more strategically collaborative rather than competitive.
- Bolstering industry-academic interactions for applied research, in particular better participation of public knowledge-based institutions.
- Reducing the rigidity of communication between knowledge-based institutions in order to foster better knowledge exchange and collaboration in the areas of research, particularly with the inclusion of T2 and T3 institutions.
- Support secondments and placements in between the knowledgebase and industry in order to better orient human capital development.
- Strengthen communication channels amongst the knowledgebase and intermediaries, particularly industry associations.
- Increase the channels of funding from venture capital and angel investors to support the process of ideation to market.
- Better knowledge sharing amongst government bodies to promote an 'all of government approach' to innovation, thus translating into more coordinated joint research in strategic areas.

6.3 Barriers to Innovations

This section sets out to analyse the results of the IPSSI Survey using a multivariate analysis approach which provides a strong empirical foundation. The focus of this chapter is the elucidation of the barriers that exist within the pharmaceutical system of innovation. It is crucial to understand which barriers to innovation are significant for the pharmaceutical sector in order to critically understand where resources need to be applied to bolster the system of innovation and boost innovation for the sector. To this end, factor analysis is used to indicate the underlying factors that significantly influence barriers to innovation, enabling evidence-based policy design to be targeted specifically and accurately to overcome the highest barriers to innovation in prioritised sequencing. Factor analysis condenses observed variables into factors in a pattern matrix (clusters of inter-correlated variables) with 'mutual interdependence' (Gaur, 1997). The factors represent the underlying structure that is responsible for the variation of variables in the data and thus the population (Kim Jae-On and Mueller 1978). The next section aims to articulate this both from the system perspective, as well as from the level of each individual actor.

Description of Table Structure

The column 'Factor Number' indicates the descending rank order (by importance) of the factor, which influences the sets of barriers to innovation variables. The column 'Factor Name' provides a description for the grouped variables influenced by the factor and enables meaningful policy discussion of the barriers to innovation. The factor names are assigned based on the factor loading of the variables taking the higher loading variables into consideration as well as the judicious use of empirical evidence and theory in the literature of SI. The naming of factors therefore reflects the variables that are most influenced by the underlying factor. Furthermore, the column 'Factor Loading' indicates the correlation between factors and variables, i.e., the extent to which the factor influences the variable. The column 'Cronbach's Alpha' indicates the internal consistency and reliability of the factor, and hence the cohesion of variables as a group. The dominant heuristic, or commonly accepted rule of thumb for describing internal consistency and reliability using

Cronbach's Alpha, is indicated in Table 5 (George and Mallery, 2003; Kline, 1999; Cortina, 1993).

For the purpose of policy analysis, factors influencing groups of variables with Cronbach's Alpha below 0.7 are deemed inconsistent and unreliable and are rejected for policy purposes. The factors enable economy-wide policy prescriptions, as well as actor (sector) specific policy prescriptions to be carefully and accurately designed.

The column 'Total Variance Explained' (TVE) indicates the amount of variance (variation) of the groups of variables in the data sample and population, which is accounted for by the factor. It is an indication of the extent or power of the influence of the factor. The column 'Kaiser-Meyer-Olkin' (KMO) is a measure of sampling adequacy. It indicates the robustness of the sample in terms of the distinct and reliable factors extracted (Kim Jae-On and Mueller, 1978). The Bartlett's Test of Sphericity (BTS) indicates the significant confidence level regarding the coherence of factors, reproducibility and generalisability of the results (Kaiser, 1974; Dziuban and Shirkey, 1974, p.359; Kim and Mueller 1978, p.54; Rummel, 1970) (see Table 6). It should be noted that there are only representations provided for all actors as there are more variables than observations, and it also represents the system as a whole. For the individual actors, barriers to innovation are represented as a frequency analysis.

TABLE 5: Internal consistency of factor

Cronbach's Alpha	Internal Consistency/ Reliability
a ≥ 0.9	Excellent
0.9 > a ≥ 0.8	Good
0.8 > a ≥ 0.7	Acceptable
0.7 > a ≥ 0.6	Questionable
0.6 > a ≥ 0.5	Poor
a < 0.5	Unacceptable

TABLE 6: Kaiser-Meyer-Olkin (KMO)

Internal consistency of factor	
KMO = 1	Perfect
KMO > 0.9	Marvellous
0.9 > KMO > 0.8	Meritorious
0.8 > KMO > 0.7	Middling
0.7 > KMO > 0.6	Mediocre
0.6 > KMO > 0.5	Miserable
KMO < 0.5	Unacceptable

Source: Kim Jae-On and Mueller, 1978

From the analysis of all actors (see Table 7) four factors emerge which account for 52.967% of the total variance explained (TVE), namely, '**Industry 4.0**', '**Policy & Function**', '**ICT**' and '**Market Dynamics**'.

Factor 1- '**Industry 4.0**' is the most significant factor barrier to innovation and accounts for 27.696% of the TVE within the sample, hence the population. When examining the factor loading, in order to understand the relationship of each variable to Factor 1, 'Lack of understanding of I4.0 technologies', 'Lack of access to I4.0 technologies', 'Cost of I4.0 technologies' and 'Lack of infrastructure for I4.0' are deemed to be 'Excellent' (Tabachnick and Fidell, 2007).

The 4IR consists of a set of complex, interrelated and advanced digital production (ADP) technologies that have changed the face of global manufacturing. The key technology pillars of 4IR include: the Internet of Things (IoT), big data, artificial intelligence, robotics, additive manufacturing, cloud computing, augmented reality, virtual reality, cyber-physical systems, system integration and simulation. The complexity of 4IR technologies demands high interdependency of competences and technological complementarity (Dalenogare et al., 2018; Reischauer, 2018; Rübmann et al., 2015).

Implementation of 4IR technologies at a broader organizational level is required for a measurable impact of digital transformation. Transforming factories from being manual and labour-intensive to being automated and highly digitised requires enhanced capabilities, not limited to investment in technologies. Firms require a vast set of capabilities to digitally transform their entire operating model using 4IR technologies (Boer et. al, 2021). Such capabilities are hard to find in a single technology provider, especially in the case of small and micro enterprises (SMEs) (APO, 2019).

Manufacturing in the pharmaceutical sector is rapidly changing, particularly with the adoption of 4IR technologies. This paradigm shift is challenging traditional approaches to manufacturing, with a clear impact on agility, efficiency, flexibility, and consistency in the quality of the industrial production of medicines. Industry 4.0 promises advancements of entire manufacturing systems and infrastructures (Shah, 2022). In such an environment, performance data can be analysed by algorithms and used for critical real-time business and operational decisions that directly impact production outputs. This is crucial, particularly in an industry that is highly regulated and a large proportion of time is spent on documentation (product dossiers, machine logs, batch records, etc.).

In the case of the Indian pharmaceutical sector, examples of best practices of 4IR adoption are those of Dr Reddys and Cipla. Dr. Reddy's embarked on an ambitious programme to 'digitise its core'. This involved an upgrade of infrastructure and digitisation of processes for robust and comprehensive data capture. Real-time data and insights laid the foundation for "Project OpsNext" which was initiated two years ago to transform the plant into an Industry 4.0-driven 'lighthouse' factory as defined by the WEF. The site saw the deployment of six of the eight 4IR technologies – Advanced Analytics, Digital Twins, Robotic Process Automation, Augmented/Virtual/Mixed Reality, Digital Performance Management and the Industrial Internet of Things (IIoT). The site deployed more than 40 4IR use cases by operating in garage mode, leveraging the IIoT and a democratised platform for advanced analytics. As a result, it improved manufacturing costs by 43% while proactively enhancing quality and reducing energy by 41%.

Additionally, Cipla deployed digital, automation and analytics solutions to 22 Indian sites to preserve global access to high-quality affordable drugs while facing an increase in material and labour costs. The company's Oral Solid Dosage facility in Indore led this journey by implementing 30 4IR use cases, thereby improving total cost by 26% and enhancing quality by 300%, while reducing greenhouse gas (GHG) emissions by 28% (WEF, 2022).

The first step towards 4IR implementation is a clear understanding of I4.0 technologies. A lack of understanding of the value, goals and needs of 4IR technology still exists among many firms (Bai et al., 2020). Robust evaluation mechanisms and decision support tools can help manufacturing firms understand the impact of 4IR technologies and effectively implement them. A clear understanding of 4IR technologies, their benefits and impacts can help firms develop an organization-wide 4IR strategy and set implementation targets. Educating the workforce on 4IR technologies and up-skilling them is key to its effective implementation. A well-functioning innovation ecosystem can allow collaborations between system actors for knowledge sharing and awareness building. It will enable firms to integrate resources and co-create 4IR solutions (Grant Thornton & CII, 2017).

Due to the rapid global advancement of personalised medicines, a shift is required within Indian manufacturing focusing on next-generation therapeutics. There is a need for new and existing therapies to reach the market faster and overall more effective utilisation of manufacturing capabilities. As the transformation of biopharmaceutical manufacturing continues, manufacturers and raw material suppliers are entering the frontier of 'Biopharma 4.0' where artificial intelligence (AI), big data and smart systems are being leveraged to help transform business models (Vijay, 2022).

The role of automation has been enhanced particularly to the positive impact of the COVID-19 pandemic, leading to an understanding of the potential to transform processes and enhance overall performance, resulting in faster and more cost-efficient operations (Vijay, 2022). However, while there is a rapid level of deployment of I4.0-based technologies in the global North, in India modernisation of pharmaceutical manufacturing is still in its infancy. Companies are finding use cases in many commercial operations primarily amongst the larger players. Nevertheless, as the labour costs in India are lower than in other countries, cost sensitivity must be considered a prime factor. Pharmaceutical companies are beginning to use AI and ML, but it's still in the proof-of-concept stage. India is only starting to utilise blockchain for transparent data sharing between contractors and suppliers. While skill and labour aren't a significant issue in India, unstable prices and policies impede sector expansion (Durga, 2022).

Factor 2 – '**Policy & Function**' which are a key foundation to an effective system of innovation (Reiljan and Paltser, 2015), accounts for 9.97% of the TVE with 'Lack of legal framework', 'Lack of clear national innovation strategy,' 'Restrictive public/ govt regulations', and 'Lack of higher resolution regulations' loading on it. The association between the variables in Cronbach's Alpha is 'Acceptable'.

It is generally recognised that the public sector has an important role in promoting innovation – its task is to support the development, diffusion and implementation of innovations (Edquist 2006, p.182) through the creation of effective incentives and disincentives. Public sector intervention in the economy is usually justified by the need to overcome market and system failures. With the support from national regulations (laws, standards and norms) and public sector institutions, the task of policy is to integrate both formal and informal institutions (social, political, economic, educational, scientific, etc.) of the society in order to create and develop a conducive environment which guides economic agents to innovate and increase their competitive performance. The government sector directly guides the innovation processes through various political support activities (public procurement, tax breaks, subsidies, etc.). The activities and effectiveness of economic units in their innovation processes is largely dependent on the smooth functioning of the innovation system, including the effectiveness and coordination of innovation policy measures (Reiljan and Paltser, 2015).

In the case of the Indian pharmaceutical sector, policy bottlenecks can be seen in the incomprehension of legislation. For example, India's Biodiversity Act is a mystery to most biologists and startups. Unfortunately, there aren't any awareness programmes to help researchers and entrepreneurs understand the implications of the act. Take for instance Section 3 of the act that requires all foreign nationals to obtain an approval from the National Biodiversity Authority (NBA) before using any biological resource. If you are a company using a biological resource — plants, microbes, animals or bio-products derived from it— this clause implies that you need to think twice before allowing any foreign investment or participation in your company. Any individual who has citizenship to another country or is a Non-Resident Indian (NRI) is considered a foreigner under the act and is not allowed to either fund or be part of the senior management without prior approval. Foreigners are not allowed to handle biological material, so they can't even do lab work that directly deals with a biological resource (Manupriya, 2017). This has a clear impact on innovation.

India's biodiversity law does warrant a review, but the process is complex as proposed changes cannot solely focus on realising India's international commitments or responding to the concerns of industry. For positive change, the amendment exercise would need to address the most fundamental challenges in implementation at the local level, that of maintaining the fine balance between bio trade on the one hand, and sustainable use and bio sovereignty on the other (Bhutani and Khili, 2022).

Additional policy challenges include drugs price control and minimal retail price (MRP) based on GST which burdens companies with higher tax.

Small and medium pharma companies have a crucial role in the growth trajectory of the Indian pharmaceutical industry. However, the fragmented nature of the sector leads to the creation of specific barriers, particularly for the growth of small and medium pharma companies. One such factor is the lack of awareness and knowledge about procedures and regulations.

Any international collaboration or research based on bio resources is covered by the Biodiversity Act which is deemed to be restrictive in nature, therefore having an impact on the innovation potential of the sector. The Patent Act of 2005 has also hindered the pharmaceutical sector with indications being made that there should be policy amendment on 'ever-greening' of patents. In addition, section 3(d) of the Indian Patent Act restricts grant of patent for 'incremental innovations' in many drugs unless it provides significant therapeutic advantages to existing molecules. Overall, this is compounded by there being a trust deficiency in the sector as enforcement of NDA's, material transfer agreements, trade secrets are not robust in the Indian context.

Factor 3- '**ICT**' accounts for 8.41% of the TVE in the sample, hence the population. The variables that load on the factor are: ´ICT capacity´, and ´Rate of access to ICT´ and are deemed to be 'Good' in terms of the Cronbach's Alpha. Increased ICT adoption reduces information asymmetry (Mushtaq et al., 2022) and information flows are vital for the innovation process (Allen 1977; Katz and Tushman 1981; Tushman and Scanlan 1981; De Meyer 1985; Macdonald and Williams 1993; Assimakopoulos and Yan 2006; Allen, James et al., 2007; Doak and Assimakopoulos 2007). In general the pharmaceutical industry has been resistant to digitalisation, mainly due to fair experience and complexity of the entailed development and manufacture processes (Hole et al., 2021). However, based on the expert stakeholder discussion, this result is thought to be an outlier. This reflection is also supported by the Government of India´s Department of Pharmaceuticals' "Annual Report 2020-20" which lists a series of successful ICT-based initiatives being undertaken for the sector. Namely: Local Area Networks (LAN) which are IPv6 compliant, E-publishing of tenders, and development of software grants for the sector, etc. (Government of India, 2021).

Factor 4- '**Market Dynamics**' shows the importance of markets in driving innovation through demanding customers and innovative customers, as well as distinct 'rules of the game' articulated through higher resolution regulations. The TVE, amounting to 6.89%, and the relationship of the variables 'Lack of demanding customers', 'Lack of innovative customers' and 'Lack of competition' with respect to internal consistency can be seen to be 'Questionable'. Market dynamism can be described by rapid changes in technologies, changes in market structure, the instability of market demand, intense fluctuations in the supply of materials, and the probability of market shocks (Nguyen & Harrison 2019; Jansen, Van Den Bosch and Volberda 2006; Sirmon, Hitt and Ireland RD, 2007). Volatility and unpredictability characterises market dynamism (Miller and Friesen, 1983), therefore a high level of market dynamics restricts the ability to distinguish the market boundaries, develop clear successful business models, and identify market participants such as competitors, customers, and suppliers and their respective needs (Eisenhardt and Martin, 2000).

Consequently, this leads to external uncertainty thus making it more difficult to predict future market situations, plan and organise their resources, and respond with their own knowledge and related processes. Therefore, firms are required to improve and modify their products and services with innovation continuously to meet customers' needs. Less dynamic markets, in contrast to highly dynamic markets, present less frequent changes that market players can usually anticipate or regular changes that occur periodically and are hence predictable. In less dynamic market environments, there is better clarity on market boundaries, the market participants (e.g., firms, customers and suppliers) know each other well and customer demand is relatively stable. Hence, firms do not feel the need to innovate or modify their products or business processes (Eisenhardt and Martin, 2000; Schilke, 2014).

In light of the above, in order to promote innovation, a dynamic market is required. "Regulations which encourage market dynamism, innovation and competitiveness improve economic performance. The aim of regulatory reform is to increase efficiency and effectiveness and to have a better balance in delivering social and economic policies over time" (OECD, 2011 p.4). Poorly designed or weakly applied regulations can hamper business responsiveness, divert resources away from productive investments, hinder entry into markets, reduce job creation and generally discourage entrepreneurship. Hence, there is the need for administrative simplification (OECD, 2009) with the provision of clear, consistent and coherent rules for dynamic markets to function well. Long-term planning is an important consideration in this process.

A direct example of such a barrier can be seen in the case of a startup that was involved in development of a recombinant enzyme for green manufacturing of API intermediates. The enzyme was originally developed against conversion of Intermediate A to Intermediate B. Though the cost benefits were high, the unwillingness of customers to implement the solution was a big challenge. Typically, Intermediate A was imported from China and later the Chinese stopped supplying Intermediate A and only Intermediate B was supplied to India. The failure was attributed to lack of early adopters and market dynamism.

In the case of certain products like protein hydrolysate or value-added products made from rice bran, the consumer acceptance is very low. The idea of nutritional products being made from waste was not well received. In DeepTech, innovations like conversion of methane to protein using gas fermentation may also face similar challenges in terms of acceptance for human food. However, the innovator was leveraging the protein for the animal feed market to address the challenge.

Factors 2, 3 and 4 are significant but collectively only account for 19.77% of the TVE. Factor 1 ranks as the most important factor as it contributes close to 27.69% of the TVE and should be the main focus of system-oriented policies. Once again this expounds the importance of Industry 4.0 technologies as a driver for innovation particularly for the pharmaceutical sector.

The overall implications for policy emerging from the analysis of barriers to innovation is that resources should be used on two levels. Firstly, at the level of the system through more overarching interventions, and secondly at the individual actor level in order to address their specific needs. Each of these will be articulated in the "Recommendations" chapter. A structured dialogue between stakeholders is required to orient which policies can be most effectively used to address barriers and challenges. Policies and their targets should not be unattainable or 'out of reach' but issues need to be addressed from a realistic perspective.

TABLE 7: System-wide barriers to innovation

Barriers to innovation faced by all actors in the pharmaceutical sector (N = 481)									
Factor Number	Name of Factor	Variables	Factor loading	Cronbach's Alpha	Total Variance Explained (TVE)	KMO	Bartlett's Test of Sphericity		
							Chi squared	Df	Sig.
1	Industry 4.0	Cost of I4.0 Technologies	0.857	0.909	27.70%	0.834	4412.811	231	0
		Lack of understanding of I4.0 technologies	0.852						
		Lack of access to I4.0 technologies	0.845						
		Lack of infrastructure for I4.0	0.813						
2	Policy & Function	Lack of legal framework	0.82	0.758	9.97%				
		Lack of clear national innovation strategy	0.75						
		Restrictive public / governmental regulations	0.678						
		Lack of higher resolution regulations	0.562						
3	ICT	ICT Capacity	0.849	0.846	8.41%				
		Rate of access to ICT	0.844						
4	Market Function	Lack of Demanding Customers	0.812	0.696	6.89%				
		Lack of Innovative Customers	0.7						
		Lack of Competition	0.642						
Cumulative Total Variance Explained						52.97%			

The determinant of the R matrix should be greater than 0.00001; if it is less than this value, look through the correlation matrix for variables that correlate very highly (R > .8) and consider eliminating one of the variables (or more depending on the extent of the problem) before proceeding[64]

6.4 Success of Policy Instruments

Having understood the barriers to innovation, both at the actor and system level, it is important to ascertain how actors perceive various policies, and consequently, an understanding of whether or not they are effectively calibrated and configured to reach their intended target's needs. To begin with, it is important to understand what public policy instruments are, they can be defined as "a set of techniques by which governmental authorities wield their power in attempting to ensure, support and effect (or prevent) social change" (Borras and Edquist, 2013., pg.1515). Unsurprisingly, the objectives of innovation policy have to do with the different national traditions and forms of state-market-society relations, not to mention the orientation of governmental ideology.

Generally speaking, there are three main categories of policy instruments: i) Regulatory frameworks[65]; ii) Economic and financial instruments (also referred to as market-based instruments)[66]; and iii) Soft instruments (also known as behavioural instruments.[67] Phrased differently, these can be considered as "sticks", "carrots" and "sermons". In this vein, the respective perceived success or failure of national policies is reviewed grouping them as per the aforementioned classifications.

[64] Sourced from: http://users.sussex.ac.uk/~andyf/factor.pdf

[65] "The first type, regulatory instruments, use legal tools for the regulation of social and market interactions. The logic behind this type of instrument is the willingness from the government to define the frameworks of the interactions taking place in society and in the economy. Naturally there are many different types, but common for them all is that these regulatory instruments (laws, rules, directives, etc.) are obligatory in nature, meaning that actors are obliged to act within some clearly defined boundaries of what is allowed and what is not allowed. Obligatory measures are typically backed by threats of sanctions in cases of non-compliance. These sanctions can be very different in nature (fines and other economic sanctions, or temporary withdrawal of rights), depending on the content of the regulation and the definition of legal responsibility. Some authors believe that sanctioning is the most crucial property of regulatory instruments (focusing on the imposition and hierarchical side of regulation). Others see the normative authority of governments as the most important feature of these instruments (hence focusing on the normative-positive side of obligatory regulation). From the point of view of innovation policy, regulatory instruments are often used for the definition of market conditions for innovative products and processes" Borras and Edquist, 2013., pg.1516.

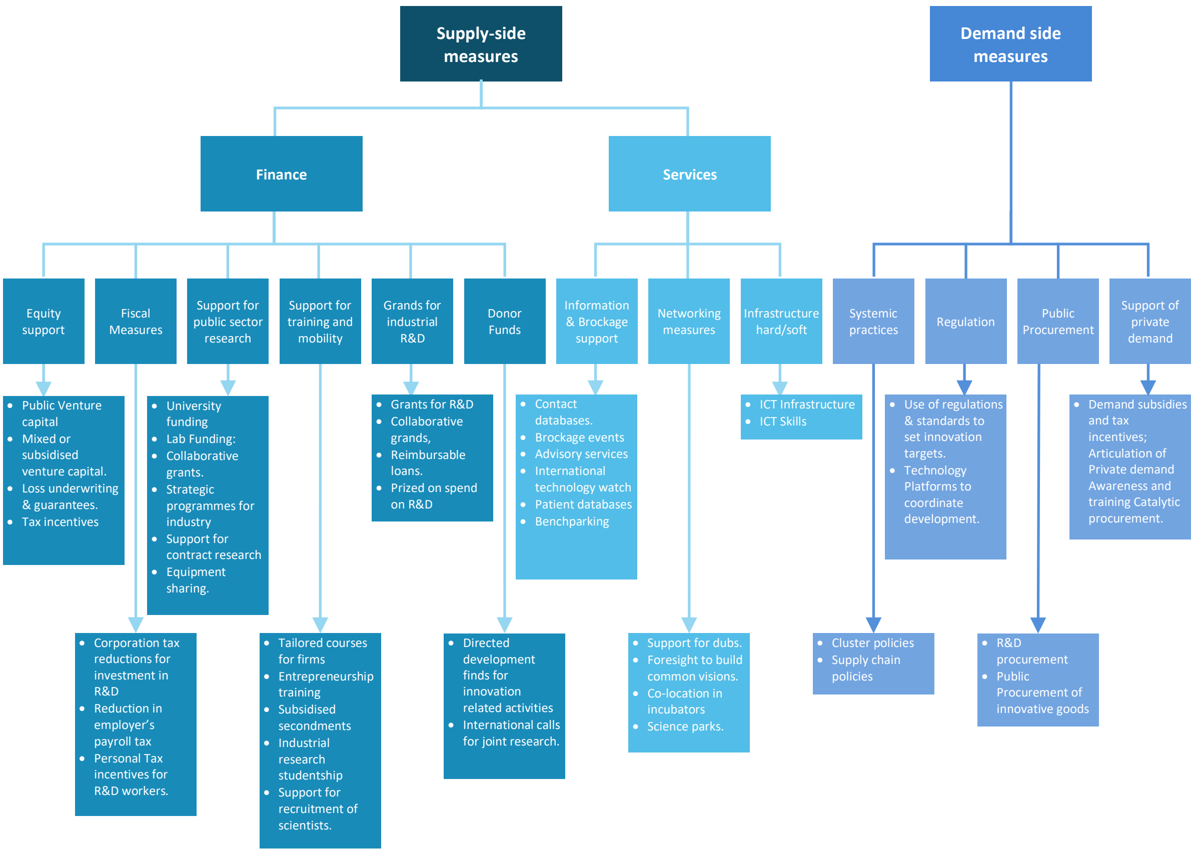
[66] "Economic and financial instruments provide specific pecuniary incentives (or disincentives) and support specific social and economic activities. Generally speaking, they can involve economic means in cash or kind, and they can be based on positive incentives (encouraging, promoting, certain activities) or on disincentives (discouraging, restraining, certain activities)" Borras and Edquist, 2013., pg.1516.

[67] "Soft instruments are characterized by being voluntary and non-coercive. With soft instruments, those who are 'governed' are not subjected to obligatory measures, sanctions or direct incentives or disincentives by the government or its public agencies. Instead, the soft instruments provide recommendations, make normative appeals, or offer voluntary or contractual agreements. Examples of these instruments are campaigns, codes of conduct, recommendations, voluntary agreements and contractual relations, and public and private partnerships. These instruments are very diverse, but generally based on persuasion, on the mutual exchange of information among actors, and on less hierarchical forms of cooperation between the public and the private actors." Borras and Edquist, 2013. pg.1516.

An alternative way to classify innovation policy is in terms of supply-side measures and demand-side measures (see figure 23). Supply-side policies are seen to create a supply push to innovate (Voß and Simons, 2014); whereas "demand-side innovation policies are defined as all public measures to induce innovations and/or speed up diffusion of innovations through increasing the demand for innovations, defining new functional requirement for products and services or better articulating demand" (Edler and Georghiou, 2007., pg. 953). Supply-side measures can be further split into the grouping of finance (equity support, fiscal measures, support for public research, support for training and mobility, and grants for industrial R&D) and services (information and brokerage support and networking measures). Demand-side policies can be presented in four main groupings: systemic policies, regulation, public procurement, and stimulation of private demand (Edler and Georghiou, 2007).

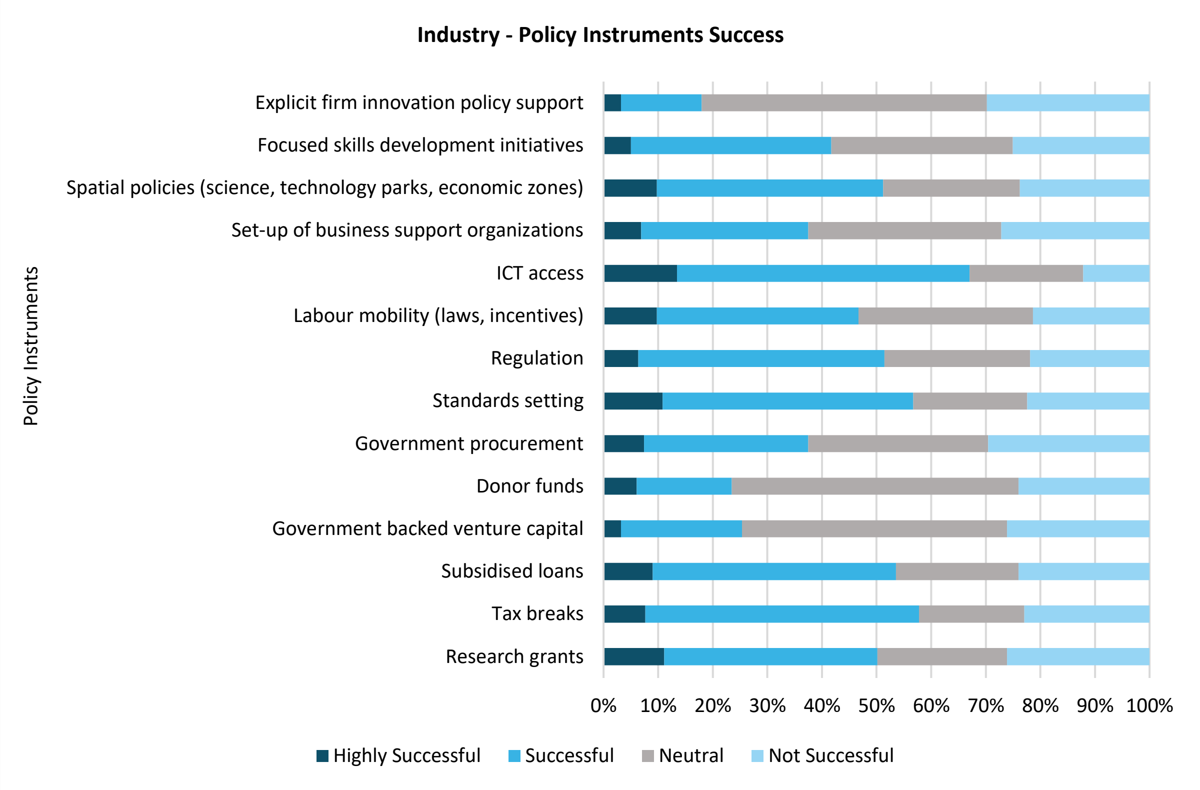
Using this classification to order policy instruments of the Indian manufacturing sector, the following groupings emerge: i) Supply-side finance policies include – research grants, subsidised loans, government-backed venture capital, donor funds; ii) Supply-side services include – ICT access and focused skills development initiatives; iii) Demand-side measures include – tax breaks, spatial policies, government procurement, standards setting, regulation and labour mobility (laws and incentives). The system as a whole, as well as the views of each of the individual actors will be reviewed to understand how successful policy is through the aforementioned lens.

FIGURE 23: Policy taxonomy



6.4.1 Industry

FIGURE 24: Success of policy instruments – Industry



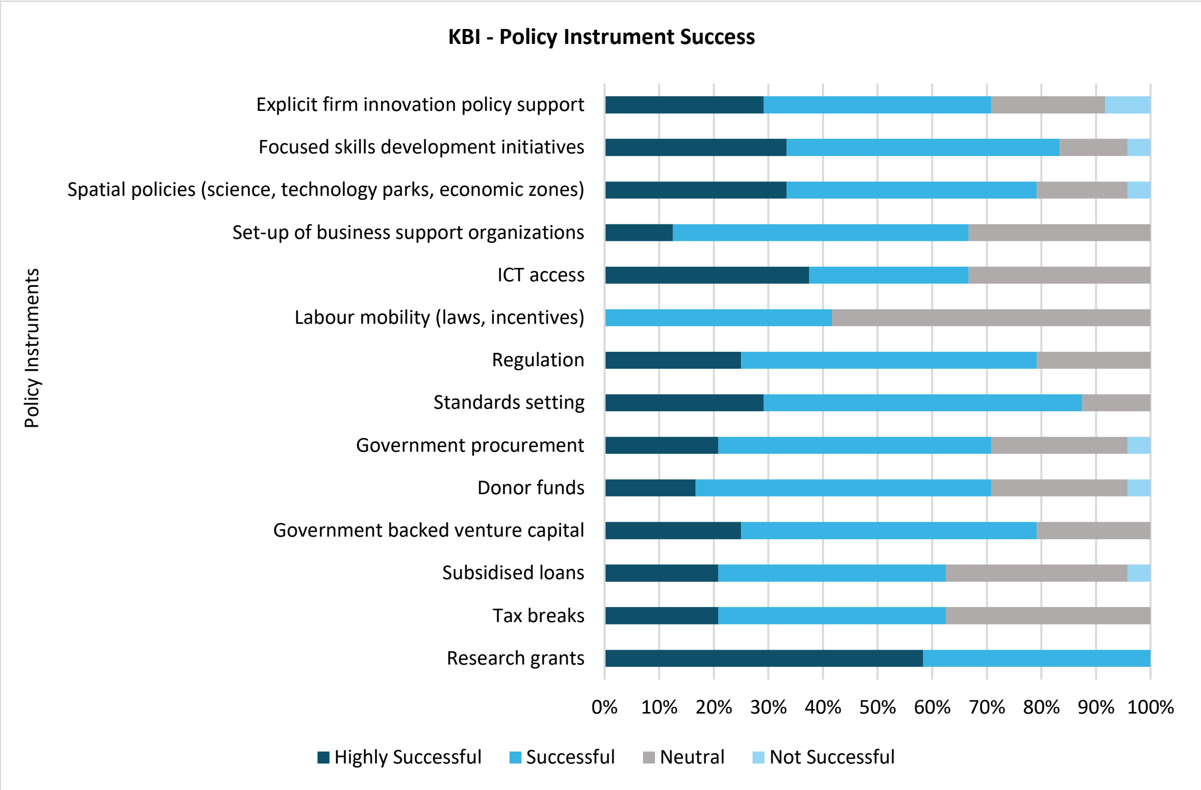
From the perspective of industry respondents (see Figure 24 above), supply-side service, namely, 'ICT access' is deemed to be the most successful as reported by 67% of survey respondents, out of which 13% of respondents call it 'Highly Successful' and 54% call it 'Successful'. On the other hand, 30% of respondents reported 'Explicit firm innovation policy support' as unsuccessful. In this case, 52% of respondents chose to remain 'Neutral' while only 18% of respondents report it as 'Successful'. This indicates the need for policy instruments that target firm level innovation and that focus on the firm as the prominent target group. Moving on to the demand-side measures, 'Government procurement' is reported unsuccessful by 30% of industry respondents. With respect to donor funds, the majority of industry respondents (53%) choose to remain neutral. This might be because donors (multilateral organizations) generally do not directly fund industry but work in close partnership with intermediaries and the government to support industry.

The importance of ICT access is recognised by the "National Policy on Information Technology 2012" as it highlights the need "to enable long-term partnership with Industry for: i. Use of ICT in cutting-edge technology for improved efficiency and productivity; ii. Driving development of new ICT technologies through strategic sectors; iii. Facilitate growth of IT SMEs and use of IT across all SMEs" (MEITY, 2012:7). The policy outlines the need to intervene and "promote use of IT in key economic sectors such as Construction, Textiles, Pharmaceuticals, Banking, Finance, Retail, Energy, Automobiles, Healthcare, Education, Agriculture, Engineering Services, Transport and Logistics for improved efficiency and productivity" (MEITY, 2012: 7). Contrary to this, it is important to highlight that in accordance with the Global Innovation Index (GII), while India has been ranked 46th out of 132 economies, the country's ICT access ranking declined from 108 in 2012 to 111 in 2021.

India is lagging in several indicators related to the assessment of the state of procurement practices' (OECD, 2019) namely: "strategic leadership, efficiency, the procurement process's openness, and the legislative framework in place, including subordinate legislation, model documents, and general contract conditions" (Nair, 2021: p.1). There is a lack of a comprehensive central legislation solely governing public procurement in India. Rather, the current public procurement regime comprises a framework of overlapping administrative rules and regulations, sector-specific guidelines and state-specific legislation (BTG Legal, 2021). The Government of India implemented the General Financial Rules (GFR) as its core procurement framework in 1947 which was only updated in 2017. The absence of a central procurement regulation enabling procuring authorities with scope to tweak guidelines and contract format, leads to confusion on the one hand and rigidity on the other. Consequently, different agencies may even prescribe varying qualification criteria, financial terms, selection procedures, etc., for similar public sector work. Further, the government has been making efforts to ensure transparency and fairness in the public procurement system. In 2012, the GoI introduced the Public Procurement Bill. Introduction of a new legislation to govern how the government buys goods and services from the private sector is one of the proposed solutions to public procurement problems (Roy and Uday, 2020). Minister of Finance, Mr Arun Jaitley, in his 2015-16 budget speech advocated the same and stated, “Malfeasance in public procurement can perhaps be contained by having a procurement law and an institutional structure consistent with the UNCITRAL model. I believe Parliament needs to take a view soon on whether we need a procurement law, and if so, what shape it should take.” (Paragraph 72). The present government is yet to introduce the bill.

6.4.2 Knowledge-Based Institutions

FIGURE 25: Success of policy instruments - Knowledge-based institution



From the view of knowledge-based institution respondents (see Figure 25 above), it is evident that the majority of policy instruments were reported ‘Successful’ with the supply-side finance instrument ‘Research grants’ emerging as the most successful. The figure shows that 58% of KBI respondents report it ‘Highly Successful’ and 42% ‘Successful’. The success of ‘Research grants’ as a policy instrument can be attributed to the funds received from the government under its various schemes such as the “Human Resource Development (HRD) Scheme for Health Research” launched by the Department of Health Research under the Ministry of Health & Family Welfare. The scheme was first approved in 2013 and underwent three extensions with the most recent one being for the period of 5 years starting from 2020-21 to 2025-26. This scheme supports the trainees to develop and undertake research projects for addressing critical national and local health problems and provides financial assistance to institutions for upgradation of infrastructure to enable them to provide training with state-of-the-art technologies. In October 2021, the Department of Pharmaceuticals released a “Draft Policy” to catalyse Research & Development and Innovation in the pharma- MedTech sector with the objective of exploring mechanisms to incentivise private sector investment in research and evaluating various funding mechanisms and fiscal incentives to support innovation. Finally, the

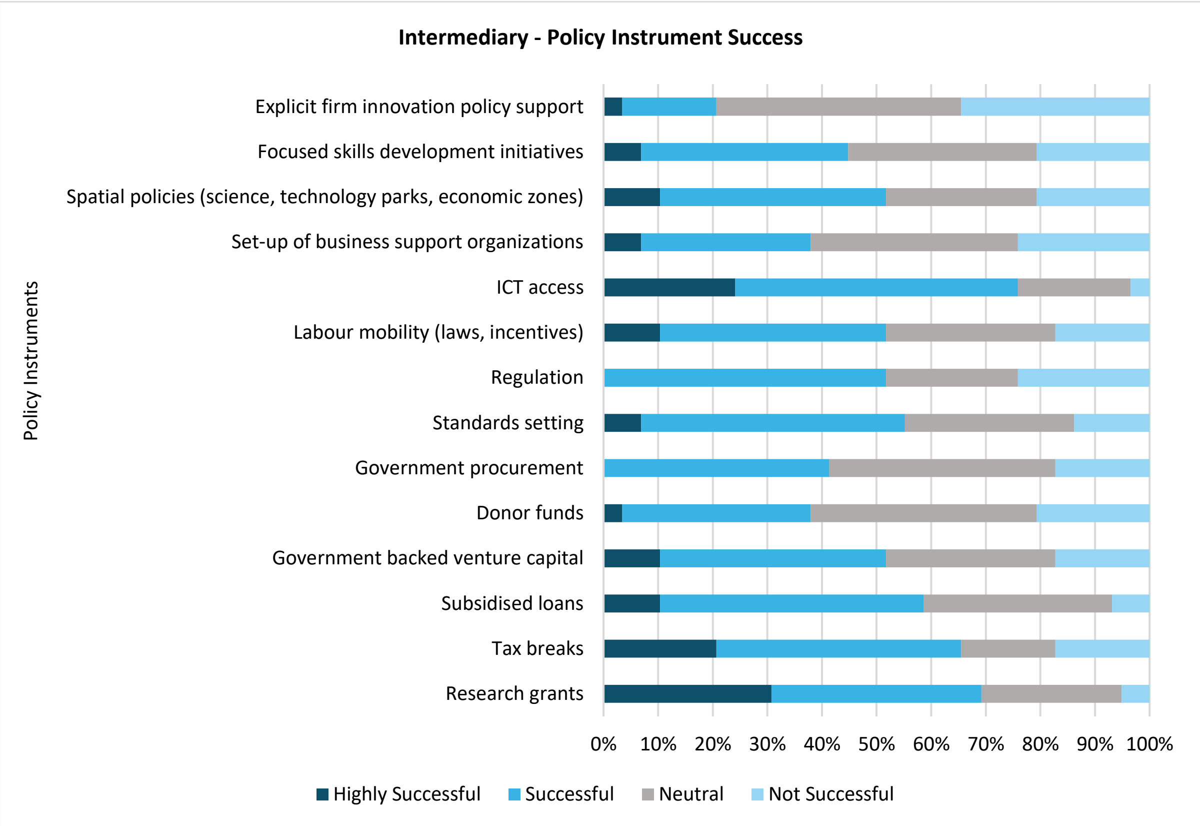
Department of Science and Technology's "Draft Science, Technology and Innovation Policy 2020" (Draft STIP 2020) also aims to encourage research and innovation in a critical sector like pharmaceuticals by giving out prestigious science fellowships to mid-career senior level academics, industry personnel and NGO scientists/technologists who can undertake such challenges (Department of Science & Technology, 2020).

'Standards setting' and 'Focused skill development initiatives' are the second and third most successful policy instruments reported by the industry at 88% and 83% respectively. 'Standards setting' is a driver for innovation and stimulates firms to change their behavioural patterns and enables them to be more technologically adaptive, leading to overall increased productivity and competitiveness. Several schemes such as the "Pharmaceutical Technology Upgradation Assistance Scheme" (PTUAS) have been launched to facilitate small and medium pharmaceutical enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)-Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets.

The GoI initiatives with regards to skill development include the "Human Resource Development (HRD) Scheme for Health Research" launched by the Ministry of Health & Family Welfare in 2013. This scheme intends to create a pool of talented health research personnel across the country by upgrading the skills of medical college faculty and institutes, scientists and medical students by providing specialised training in priority areas of health research. Furthermore, to fulfil the need for developing human resources by promoting quality and excellence in pharmaceutical education and research, the government has set-up 6 National Institutes of Pharmaceutical Education & Research (NIPERs) to host several research facilities, foster vigorous institute-industry collaboration, interdisciplinary research collaborations and industrial training opportunities.

6.4.3 Intermediary

FIGURE 26: Success of policy instruments – Intermediary



From Figure 26 above, it is evident that the most successful policy instrument reported by intermediaries is the supply-side service, namely, 'ICT access'. It has been reported as 'Highly Successful by 24% and 'Successful' by 52% of respondents. The response of intermediaries in the case of 'ICT access' is convergent with that of industry and has been explained in the section above.

This is followed by the demand-side measure of 'Tax breaks' reported 'Highly Successful' by 21% and 'Successful' by 45% of respondents. The importance of 'Tax breaks' is recognised by the NITI Aayog as a means to promote business sector R&D. Furthermore, the government could focus on specific areas under which top R&D-intensive domestic firms are eligible for tax incentives (NITI Aayog 2021). This is echoed in the STIP 2020 which stipulates that in order to incentivise investments in STI, there is a need to boost "fiscal incentives for industries investing in STI through incremental R&D-based tax incentives, tax credit for investing in facilities for commercialisation, tax holidays, tax waivers, target-based tax incentives for specific domains, tax deduction, expatriate tax regimes, remodelling of patent box regime, etc." (DST, 2020: p.21). The overall orientation of policy with respect to 'Tax breaks' are markers of success in meeting their targets.

In terms of policy failure, 35% of respondents reported 'Explicit firm innovation policy suppor'' as the most unsuccessful, while 45% of respondents chose to remain 'Neutral'.

6.4.4 Arbitrageurs

FIGURE 27: Success of policy instruments – Arbitrageurs

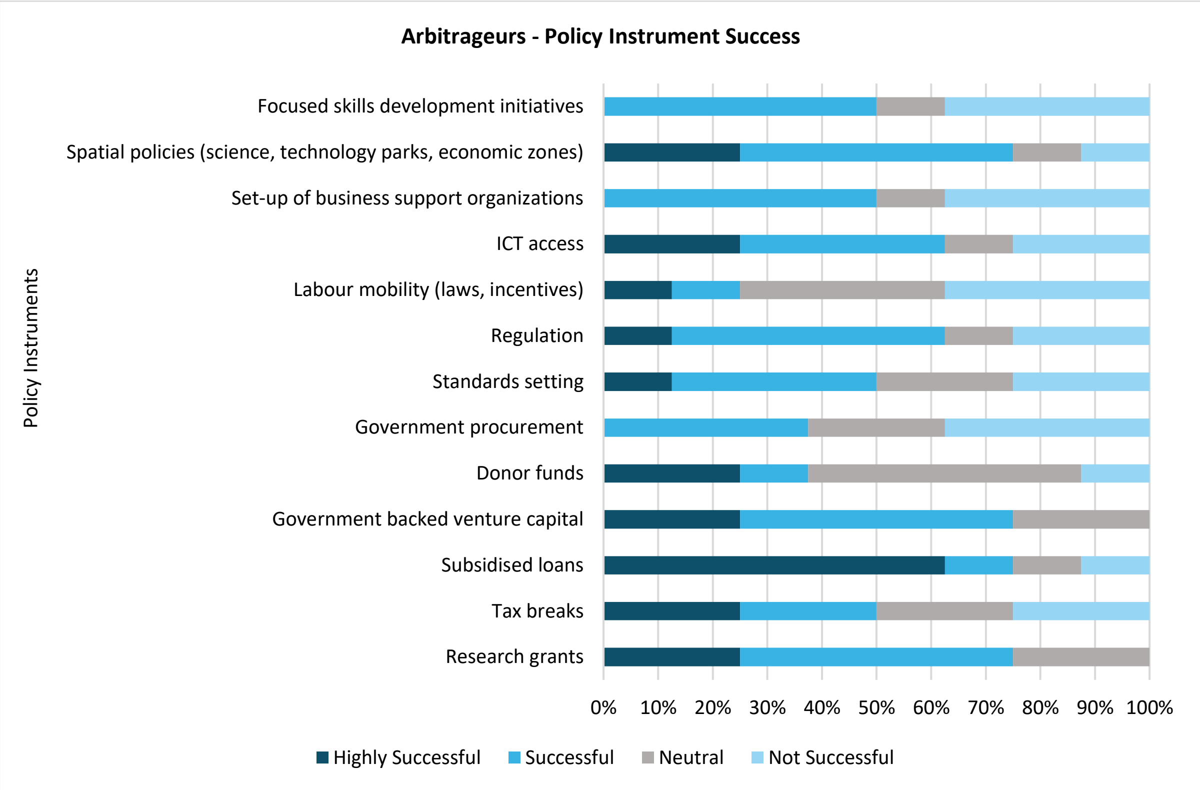


Figure 27 above shows that there are four successful policy instruments reported by arbitrageurs, starting with the supply-side finance instrument 'Subsidised loans' which has been reported 'Highly Successful' by 63% of respondents and 'Successful' by 13% of respondents. This is followed by two more supply-side finance instruments, namely 'Government-backed venture capital' and 'Research grants' and a demand-side measure of 'Spatial policies' at 75% each ('Highly Successful' and 'Successful' combined).

On 20th March 2020, the Government of India approved the first "Production Linked Incentive Scheme" (PLI 1.0) to promote domestic manufacturing of key starting materials (KSMs)/ drug intermediates (DIs) and critical active pharmaceutical ingredients (APIs) in India. PLI 1.0 was launched to attract large investment in the Indian pharmaceuticals sector by enhancing the domestic manufacturing capacity of KSMs and APIs and thus moving towards import substitution. Financial incentives are given based on sales made by selected manufacturers for 41 products, which cover all the identified 53 APIs (Department of Pharmaceuticals, 2020). Despite this, a large proportion of the demand for patented drugs is still met through imports, which is why the GoI announced the second "Production Linked Incentive Scheme" (PLI 2.0) on 3rd March 2021. The key objective of this scheme is to boost the manufacturing capabilities of the Indian pharmaceutical manufacturing firms via an increase in investment and production, contributing product diversification to high-value goods in the aforementioned sector.

Proximity is an important dimension of the effectiveness and efficiency of a system of innovation in terms of connectedness and linkages which facilitate the flow of knowledge and resources between the actors. This can be achieved through spatial policy instruments such as special economic zones (SEZs), cluster development as well as industrial and technology parks. In March 2020, the GoI announced a special "Scheme for Promotion of Bulk Drug Parks" in the country for providing easy access to world-class common infrastructure facilities to bulk drug units located in the parks. Similarly, a scheme called "Promotion of Medical Device Parks" was approved by the GoI on 20th March 2020. The medical device industry is highly capital intensive and requires development and induction of new technologies. These parks will provide common testing and laboratory facilities in one place, reducing the manufacturing cost significantly and creating a robust ecosystem for medical device manufacturing in the country.

The Indian pharmaceutical industry has majorly evolved around the industrial development clusters set-up by state governments. The Department of Pharmaceutical released guidelines for the "Strengthening of Pharmaceutical Industry" (SPI) scheme for MSMEs for the period of FY 2021-22 to FY 2025-26. The scheme addresses the demand and requirement for support for the existing 80 pharmaceutical clusters and over 10500 manufacturing facilities across the country to improve productivity, quality, and sustainability (Department of Pharmaceuticals, 2022). The scheme provides Assistance to Pharmaceutical Industry for Common Facilities (APICF) and the intended beneficiaries of the scheme are pharmaceutical manufacturing units in a cluster and pharma clusters promoted by the state governments.

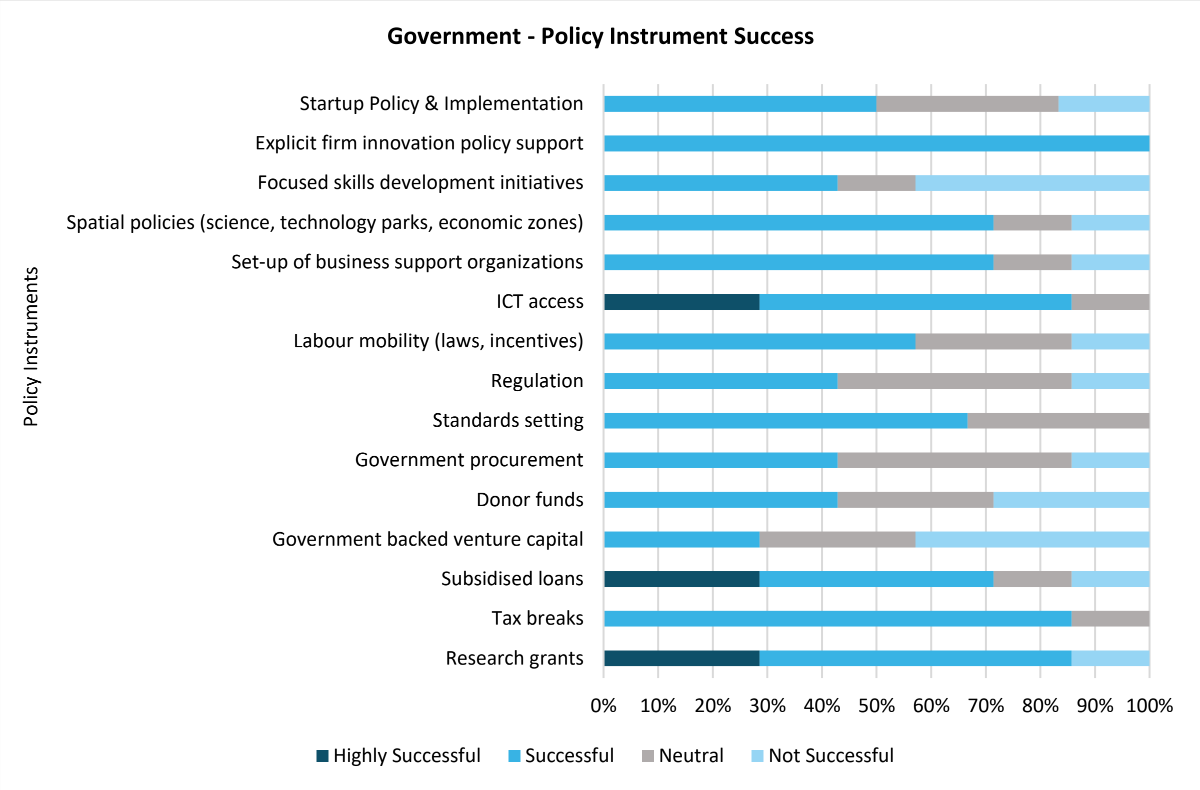
The government understands that there is a need for "avenues for entrepreneurship development through incubators and accelerators to support scaling-up and commercialisation of grassroots innovations" (STIP 2020, p.32). This process requires a vibrant venture capital landscape that not only provides access to funding in the process of ideation to market but also business support services. Within the Indian context, the majority of venture capital funds are private sector-owned[68] and concentrated in metro cities. Though there are government-driven funding mechanisms such as the "National Research Foundation" (NEP 2020) and the "Technology Acquisition Fund" (NAP 2018) that focus on indigenous R&D and technology acquisition through Public-private partnerships, it is still recognised that the absence of venture capital investment thwarts innovation in India (NITI Aayog 2021).

The viewpoint of arbitrageurs on 'Research grants' converges with that of KBIs and has been explained in the section above. On the contrary, 'Focused skill development initiatives' have been reported as unsuccessful by 38% of respondents falling in the category of arbitrageurs, which is in contrast with the response received from respondents from knowledge-based institutions, a majority of which consider this supply-side service to be 'Successful'. Other policy instruments that are deemed unsuccessful by arbitrageurs include, 'Set-up of business support organizations', Labour mobility (laws, incentives) and 'Government procurement', at 38% each, which points to the unpopularity of demand-side measures among the arbitrageurs.

[68] Government-backed venture capital funds include: SBI Capital Markets Ltd. (SBICAP), Canbank Venture Capital Fund Ltd. (CVCFL), IFCI Venture Capital Funds Ltd. (IFCI Venture), and SIDBI Venture Capital Limited (SVCL): https://www.indianweb2.com/2015/01/13-govt-venture-capital-firms-for_14.html

6.4.5 Government

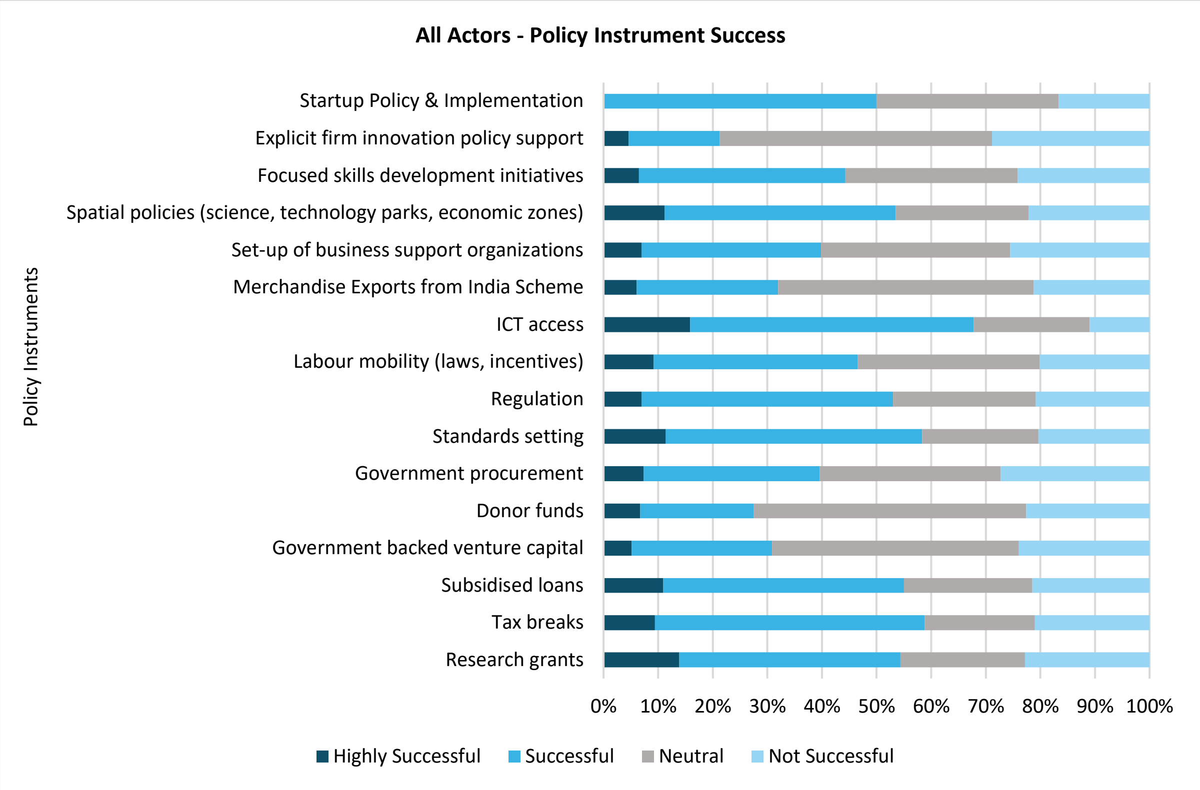
FIGURE 28: Success of policy instruments – Government



From the point of view of government respondents, almost all the policy instruments have been reported as 'Successful'. It is interesting to note that 100% of government respondents view 'Explicit firm innovation policy support' as successful whereas only 18% of industry respondents and 21% of intermediaries share this viewpoint. However, policy instruments like 'Focused skill development initiatives', 'Government-backed venture capital' and 'Donor funds' have been reported unsuccessful by 43%, 43% and 29% of government respondents respectively. Explanations for these have been provided in the previous sections. In the case of 'Donor funds' an equal percentage of government respondents also remained 'Neutral'.

6.4.6 All Actors

FIGURE 29: Success of policy instruments - All actors



Summarising the above results, the most successful policy instrument reported by all actors in the pharmaceuticals sector is 'ICT access' (at 68%), and the most unsuccessful policy instrument is 'Explicit firm innovation policy support' (at 29%) closely followed by 'Government procurement'' (at 27%). This is convergent with the policy-related issues such as 'Lack of legal framework' and 'Lack of clear national innovation strategy' that are reported as prominent barriers to innovation by all actors under the pharmaceuticals sector (Table 7: System-wide barriers to innovation).

7.

Recommendations

Recommendations

The much-acclaimed success of the COVID-19 vaccine resulted from an unusual and nimble coming together of government-academia, rapid regulatory response, industry and international partnerships. This is the most important take-home lesson of the pandemic; the pursuit of science and its rewards is not solitary and for quick accelerated results, all stakeholders, viz. government, academia, industry and international partners must work together as a single unit, as a norm and not as an exception. The outcomes of Indian R&D can grow exponentially with: (a) the GoI and industry conferring more trust and confidence in Indian science; (b) the GoI putting structures in place for ease of financial disbursement, data-sharing and regulation, and (c) industry stepping up to define research questions which are of interest to them, reaching out to the vast network of research institutions to leverage and invest in the enormous capacity of state-of-the-art infrastructure and brilliant minds (Current Science, 2022).

The literature on innovation policy draws attention to the complex and heterogeneous nature of the policy instruments at hand. It captures the growing interest in understanding the effects that different policy instruments have on innovation performance, how (combinations of) individual instruments interact with market mechanisms and the overlapping or complementary effects that can be associated with different policy instruments within systems of innovation (Borrás and Edquist 2013; Izsák, Markianidou, and Radošević 2013; Mohnen and Röller 2001). This diversity reflects the complexity of innovation systems which entail a series of elements or sub-systems that can reinforce, but also block each other (Hekkert et al., 2007; Kuhlmann and Arnold 2001). The underlying innovation-related policy objectives or policy domains subject to specific policy interventions can be grouped around one or more of the following objectives (Borrás and Edquist 2015):

- Support investment in research and innovation.
- Enhance innovation competences of firms.
- Increase adoption of Industry 4.0 through digital transformation in the pharmaceutical sector.
- Support services for innovating firms.
- Competence building through individual/ organizational learning, involving formal/informal education and training.
- Demand-side activities involving the creation of new markets.
- Provision of constituents or supporting the development of agents within the system.
- Enable integration of MSMEs into GVCs.
- Strengthen linkages within innovation systems.

This list is not exhaustive but helps to illustrate the ramifications of the policy-decision tree around innovation and industrialisation. Addressing these policy problems calls for a portfolio approach in which a combination of instruments simultaneously targets several objectives and groups of policy problems (Izsák, Markianidou, and Radošević 2013; Nauwelaers 2009).

Policy instruments result from policies aimed at facilitating different forms of innovation, including products or services, which denote the acquisition/ development of new proprietary technologies protected by patents or other forms of intellectual property rights (IPRs); yet some others are closer to business process innovations in the form of changes in operations (manufacturing techniques, optimisation of workflows and process re-engineering), product development, business process development, marketing and sales, procurement, logistics and distribution, as well as organisational innovation through changes in administration and management. Whereas some policies aim to support forms of innovation with clear and rapid market potential, some others aim to address more upstream issues with no immediate commercial value.

The possibility of combining policy instruments is what makes innovation policy systemic (Borrás and Edquist 2013). However, finding 'optimal models' for the combination of instruments, otherwise interpreted as one-size-fits-all solutions, is problematic; significant differences result from framework conditions but also from the 'quality' of implementation (Flanagan, Uyarra, and Laranja 2011), the degree of maturity reached by certain agents or the innovation system as a whole (Izsák, Markianidou, and Radošević 2013), and even the particular governance structures around innovation (Dutrénit et al., 2010). Moreover, identifying the impacts of individual innovation policy interventions on social and economic outcomes is extremely difficult. There is a complex chain of direct and indirect, vertical and horizontal effects, and the ultimate results may only be perceptible many years after implementation (Padilla-Pérez and Gaudin, 2014; Santiago and Natera, 2014). Finding an optimal innovation policy mix is not a one-off exercise, but a continuous process that adjusts to the dynamics of an innovation system. The formulation of effective policy is therefore a highly complex affair. Table 8 highlights short-, medium- and long-term recommendations based on the analysis conducted.

TABLE 8: Policy recommendations

Observation	Implications	Recommendations
Fragmented system-wide actor information	Better access to public goods in order to have an up-to-date understanding of who's who and who's where in the IPSSI. Robustness and credibility of data shared at the system level.	Need to integrate and standardise national actor databases with respect to the IPSSI. • Review and consolidation of existing data. • Regularly update centralised sectorial database. • Purpose driven platform to be developed in PPP approach (beyond search engine, for example Start-up India, IRCTC - Indigo). • To be owned by government and managed by institutions with access by all major institutions (market driven). • Integrated feedback mechanism for improvement (stakeholders at all levels).
Need to improve target response rate, especially in the case of government actor group	Better clarity in systems analysis for evidence-based policy craft incorporating longitudinal benefits of data collection	• Institutionalise the IPSSI Survey within a national institution with top-down mandate. • Make the IPSSI Survey a mandatory census (4 years) and linked to the national database. • Targeted promotion strategy (including use of multimedia and social media, dissemination of value information, creation of ownership, multiple level campaign. • Actor or entity (state level, district level etc.) level competition for response rate. • Incentivization through a sense of belongingness, continuity and follow-up. • Acknowledging and lauding of contributions by leading institutions - creation of champions. • Data collection driven regional outreach initiatives. • National level agencies to be coordinated and partnered with - ISIs, • Planning and onboarding to make utility of champions. • Upstream driven sensitization approach.
Need for better institutional coordination between regions / clusters.	Ease of skills and knowledge flow between and sharing of best practices between actors.	• Commonly agreed structured framework for joint activities • Creation and transmission of information using contemporary multimedia resources. • Sharing of failures and lesson learning. • Regular meetings in person; quarterly webinars. • Virtual dissemination of Data Information Statistics and Knowledge (DISK). • Creating champions for systematic coaching of the sectors taking into account equally successes and failures. • Make use of middle-level executives. For example, LinkedIn creator accelerator programme (CAP).
Better awareness of policy terminology (SSI) across system actors	Across the board understanding	• Have a standard definition in all documentation. • Present definition in national government bulletin. • Standardization of terminology used in policy/national documentation. • Outreach to industry via industry associations. • Development of impact driven byte size content dealing with core terminology and widely disseminated using multimedia in multi languages (30 sec short).
Lack of understanding by actors of each other's role and responsibility within the IPSSI	Limits the ability to reach out to each other. Directionality of actor relationships needs to become more bi-directional.	• SSI should be an integrated component of national events, i.e. Global Pharmaceutical Quality Summit. • National innovation event (every 2 years bringing together users, producers and service providers for innovation). It can be linked to National Science Week (10 best projects). • An integrated platform linking institutions and their services. • Developing actor level content using multimedia - easily accessible and easily digestible. For example, fail fast fail safe (moral of the story). • Learn, un-learn, and thinkers and be future relevant. • Culture of innovation (create a mascot). • Promotion in adoption of ISO 56002 (2019). • Incorporation of Theory of Inventive Problem Solving (TRIZ) within the sector. • Creation of an innovation indicator assessment scheme for all contributing actors. Participation and access to assessment score can be used to leverage benefits. Catching them young (tinkering labs, startup kits).

Industry modes of interaction that require attention: **Intra:** Despite user-producer relationship between IND actors there are few linkages in terms of tacit knowledge transfer & joint research activities. **Inter:** **IND - GOV** Poor public financing for the pharma sector. **IND - KBI** Low conversion of joint research activities into innovation outputs. **IND-ARB** Few linkages in terms of formal meetings, informal meetings & seminars/training.	Lack of knowledge sharing between industry actors. Need to foster joint research amongst industry actors with an aim to make the sector more strategically collaborative rather than competitive. Low innovation activity due to lack of public funds for industry Need to strengthen applied research. Limited flow of funds to industry	**Intra** • Establish a mechanism for increasing joint collaboration and funding from large size companies towards startups/MSMEs. **IND-GOV** • Financial Assistance scheme for SMEs in target-oriented research (Biosimilars, Cell Genes Therapy, Novel Drug Discovery). • Setting up of a venture capital fund specific to pharmaceutical/biopharma sector to support MSME's at an early stage of research-based operations. **IND-KBI** • Setting-up more national/international mobility or rotational programs to infuse cross-learning. • Replicate programmes such as those of global companies like Pfizer, Novartis who offer post-doc programs in their R&D centres, similar initiatives can be fostered at the national level with the support of financial institutions/arbitrageurs. **IND-ARB** • Setting-up non-fiscal enablers for easy access to offshore funds.
Knowledge-based institutions modes of interaction that require attention: **Intra:** Few linkages in the form of licensing agreements & recipient of funding. **Inter:** **KBI-IND** Few linkages through joint research, co-publishing, secondments and recipient of funding. Need to support secondments and placements between the knowledge base and industry in order to better orient human capital development. **KBI-INT** Few joint research & co-publishing activities. **KBI-ARB** Few seminars/training activities.	KBIs are working in silos. Impacts on generation of joint research. KBIs seen as a wider knowledge resource. Venture capital and angel investors better informed of recent research and technology shifts. Graduates are more cognizant of how to access funding for ideation to market.	**Intra** • Create technology transfer offices in NIPERs to promote knowledge/skills on technology management. • Integrate medical institutions/hospitals with NIPERs for enhancing clinical data science & research. **KBI-IND** • Foster linkage between KBIs & scientists/experts in R&D units of industry for enhancing training programs on conducting high end clinical research. • Aligning academic curriculum & industry needs. • Promote & enable secondment policy to bring flexibility for academia to work in Industry. **KBI-INT** • Establish working relationships with international regulatory institutes to understand the global landscape for regulating innovations. • Strengthen communication channels amongst the knowledge-base and intermediaries, particularly industry associations. **KBI-ARB** • Representations from Financial Institutions, Angel Investors, VCs on Academic Council, Board of Studies or Advisory Board. • Adopt innovative funding model to support innovation like IIT Delhi Alumni Endowment Fund. • Increase the channels of funding from venture capital and angel investors to support the process of ideation to market.
Intermediary modes of interaction that require attention: **Intra:** Limited joint research and co-publishing activities. **Inter:** **INT-IND** Few joint research and co-publishing activities. **INT-KBI** Few linkages as secondments, recipient of funding.	Lack of codification of knowledge together with industry Better utilization of incubators and start-ups as an industrial resource. Weak orientation of knowledge generation in line with the needs of industry.	**Intra** • Work collectively and collaboratively. • Scale up joint research activities between intermediaries. **INT-IND** • Promote joint studies based on market research for identifying export opportunities, analyzing regulatory landscape & incentives in emerging countries. • Take into consideration the value addition of stakeholders in the formulation of new projects/ activities, (not as a second thought but from the onset). • Leveraging the CSR funds of industries to address topics related to circular economy, net zero, recycling, etc. • Creation of global standardization platforms with international regulatory institutions. **INT-KBI** • Incentivize ISTC's to establish strategic cells in KBIs for facilitation of clinical trials.

Arbitrageurs modes of interaction that require attention: **Intra:** Minor interactions through formal and informal meetings. **Inter:** Overall, there are few linkages with other actors. **ARB-INTER** Linkages between these actors are missing		**Intra** • Have regular fora addressing the areas of future technology trends skills and with inclusion of other system actors. • VC's or Financial Institutions should adopt Innovation Procurement funding model to support buyers for purchasing innovative solutions/services. • Creating a pool of funds to support studies and activities pertaining to future technology trends and transformation of the pharmaceutical sector. Thus, enabling them to better assess the risk and returns of the future of investment in the sector. **ARB-INT** • Specific-policy interventions to push VC's/Angel Investor for investing in life-science start-ups. (Like Tax Incentives)

Latent barriers - All Actors
• Industry 4.0 (Cost of I4.0 technologies; lack of understanding of I4.0 technologies; lack of access to I4.0 technologies; and lack of infrastructure for I4.0)
• Policy & Function (Lack of legal framework; lack of clear national innovation strategy; restrictive public / governmental regulations; and lack of higher resolution regulations)
• ICT Resources & Capacity (ICT capacity; and rate of access to ICT)
• Market Dynamics (Lack of demanding customers; lack of innovative customers; and lack of competition)
		Industry 4.0
		• Incentivizing MSME's for faster adoption of 'Smart Factory' related technologies like Smart Predictive Maintenance, Energy Management Systems and Industrial Internet of Things (IIoT).
		• Initiate 'Booster Incentives' to encourage enterprises for investing in Industry 4.0.
		• Aim for creation of surplus skilled human capital.
		• Adopting the model of IT sector by creating a skilled human capital pipeline and bench.
		• Adoption of crowdsourcing and co-creation as a problem-solving tool.
		    ◦ Simplification - rationalization - digitalization of all processes related to clearances for bio substitutes/clinical trials.
		    ◦ Robust strategy to provide education & knowledge resources on Industry 4.0
		
		Policy & Function
		• Setting up a high-level facilitation unit comprising inter-department representatives to co-ordinate and consult on issues with regulatory, drug control & environment.
		    ◦ Ensuring efficient functioning of IP offices by faster resolution of patent applications.
		    ◦ Structural alignment between central drug authority & state drug authorities to bring harmonization in drug regulation across the country.
		
		ICT Resources & Capacity
		• Creation of Single Data Portal disseminating all information on govt. schemes & providing clearance as well R&D support.
		• Setting-up of strong data sharing infrastructure for advanced research & innovation (Data Centre of Excellence - Data CoE).
		
		Market Dynamics
		• Like ICT Academy - PPP model set up in collaboration with government, IT Industry & NASSCOM to improve industry readiness, similar initiatives can be conducted in the pharmaceutical sector.
		• Interventions to decrease dependency on external markets for intermediates & APIs.
		• Institutionalize a mechanism to encourage private financing in the form of private equity/VC and special interventions for attracting global investors.

Unsuccessful policy instruments from the perspective of Industry: • Explicit firm innovation policy support • Government Procurement • Set-up of business support organisations		• Robust process support for export-import facilitation. • Adopt MEAT Model (Most Economically Advantageous Tender) instead of L1 Model (lowest price model). • Revive the common facility centres in terms of utilization & technology. • Promote Centres of Excellences (CoE's). • Creating awareness of best practices and successes of already implemented government procurement platforms (GEM portal). • Structuring, filtering and dissemination of information related to government procurement and demand-side policy incentives.
Unsuccessful policy instruments from the perspective of KBI: • Explicit firm innovation policy support • Focused skill development initiatives • Spatial Policies		• Formulate short-term & long-term National Innovation Strategies fostering industry-academia linkages on specific focus areas. • Structuring & enabling training programs in cross-functional areas to improve job readiness & research capabilities. • Incentivizing faculty based on research performance rather than tenure. • Policy initiatives to set-up labs for highly skilled returnees (preventing brain drain & leveraging technology transfer).

Unsuccessful policy instruments from the perspective of Intermediary: • Explicit firm innovation policy support • Set-up of business support organisations • Regulations		• Strengthening of public ISTC's in terms of capacity building, infrastructure support & human resources. • Government intervention to regulate operationality in E-pharmacy, especially for start-ups emerging in this space.
Unsuccessful policy instruments from the perspective of Arbitrageurs: • Focused skill development initiatives • Set-up of business support organisations • Labor mobility laws and incentives		• Establish fermentation/drug development centres to provide clinical trial platforms for start-ups. • Accelerate reskilling programs for developing digital workforce. • Effective measures to standardize competency wages. • Incentivise VC's/angel investors to collaborate with regional incubators for investor readiness training programmes and creating local angel networks.

8.

References

References

Adams, P., Freitas, I.M.B., and Fontana, R. (2019) Strategic orientation, innovation performance and the moderating influence of marketing management. Journal of Business Research, 97, pp.129-140.

Allen, J., James, A. D., and Gamlen, P. (2007) Formal versus informal knowledge networks in R&D: A case study using social network analysis. R&D Management, 37 (3), 179-196.

Anheier, H.K. (2004) The third sector in Europe: Five theses (pp. 285-299). Springer US.

Arlett, C., Lamb, F., Dales, R., Willis, L., and Hurdle, E. (2010) Meeting the needs of industry: the drivers for change in engineering education. Engineering Education, 5 (2), pp. 18-25.

Arza, V. (2010) Channels, benefits and risks of public–private interactions for knowledge transfer: Conceptual framework inspired by Latin America. Science and Public Policy, 37 (7), pp. 473–484. Available from: https://doi.org/10.3152/030234210X511990 [Accessed 22nd October 2022]

Asian Productivity Organisation (2019) Gearing Up to Industry 4.0 Digitization Strategies for SMEs. Available from: *https://www.apo-tokyo.org/publications/wp-content/uploads/sites/5/Gearing-Up-To-Industry-4.0-Digitization-Strategies-for-SMEs.pdf* [Accessed 28th August 2021]

Assimakopoulos, D., and Yan, J. (2006) Sources of knowledge acquisition for Chinese software engineers. R&D Management, 36 (1), 97-106.

Atradius Collections (2022) Pharmaceutical Industry Trends India - 2022. Market Monitor, Available from: https://atradiuscollections.com/global/reports/pharmaceuticals-industry-trends-india-2022.html [Accessed 15th October 2022].

Bai, C., Dallasega, P., Orzes, G., and Sarkis, J. (2020) Industry 4.0 technologies assessment: A sustainability perspective. International journal of production economics, 229, pp. 107776.

Bain & Company (2022) India Venture Capital Report 2022. Available from: https://www.bain.com/insights/india-venture-capital-report-2022/ [Accessed 16th January 2023]

Bartels, F.L. Voss, H. Lederer, S., and Bachtrog, C. (2012) Determinants of National Innovation Systems: Policy Implications for developing countries. Innovation, 14 (1), pp. 2–18. Available from: https://doi.org/10.5172/impp.2012.14.1.2 [Accessed 22nd October 2022]

Basant, R., and Fikkert, B. (1996) The effects of R&D, foreign technology purchase, and domestic and international spillovers on productivity in Indian firms. Review of Economics and Statistics, 78 (2), pp. 187–199. Available from: https://doi.org/10.2307/2109920 [Accessed 22nd October 2022]

Basant, R. (1997) Technology strategies of large enterprises in Indian industry: Some explorations. World Development, 25 (10), pp. 1683–1700. Available from: https://doi.org/10.1016/S0305-750X(97)00057-0 [Accessed 22nd October 2022]

Baskaran, A., and Muchie, M. (2010) Towards a unified conception of innovation systems, IERI Working Paper 2010 0002, Institute for Economic Research on Innovation. Available from: https://eprints.mdx.ac.uk/4470/1/Baskaran_-_Mammo_Working_Paper_on_Towards__Unified_Conception_of_Innovation_Systems.pdf [Accessed 16th January 2023]

Baygan, G., and Freudenberg, M. (2000) The internationalization of venture capital activity in OECD countries: Implications for measurement and policy. OECD Science, Technology and industry Working Papers No. 2000/7, Paris, OECD.

Bekkers, R., and Freitas, I.M.B. (2008) Analysing knowledge transfer channels between universities and industry: To what degree do sectors also matter? Research policy, 37 (10), pp. 1837-1853.

Bergek, A., Hekkert, M.P. & Jacobsson, S. (2008) Functions in Innovation Systems: a framework for analysing energy system dynamics and identifying goals for system building activities by entrepreneurs and policy makers. In: T., Foxon, J., Kohler, and C. Oughton (eds.) Innovations for a Low Carbon Economy: Economic, Institutional and Management Approaches. Cheltenham, Edward Elgar.

Bergek, A., Jacobsson, S., Hekkert, M. and Smith, K. (2010) Functionality of innovation systems as a rationale for and guide to innovation policy. In The theory and practice of innovation policy. Edward Elgar Publishing.

Bhaduri, S., and Ray, A.S. (2004) Exporting through technological capability: Econometric evidence from India's pharmaceutical and electrical/electronics firms. Oxford development Studies, 32 (1), pp. 87-100.

Bhagavan, M. R. (1985) Capital goods sector in India: Past and present trends and future prospects. Economic and Political Weekly, pp. 404–421.

BioAngels (n.d.) IAN-BIRAC Partnership. Available from: https://bioangels.vc/ [Accessed 22nd October 2022]

BioAngels (n.d.) IAN recently launched an INR 450 Cr Fund. Available from: https://bioangels.vc/2022/05/11/ian-birac-to-launch-bioangels-to-raise-rs-350-cr-for-startups/ [Accessed 22nd October 2022]

Biocon Academy (n.d.) Unlock your Full Potential for Excellence in Biosciences. Available from: https://www.bioconacademy.com [Accessed 22nd October 2022]

Binz, C., Gosens, J., Yap, X.S., and Yu, Z. (2020) Catch-up dynamics in early industry lifecycle stages—a typology and comparative case studies in four clean-tech industries. Industrial and Corporate Change, 29 (5), pp.1257-1275.

Boer, E., George, K., and Giraud, Y. (2021) CEO dialogue: Perspectives on reimagining operations for growth. McKinsey. 7 April. Available from: https://www.mckinsey.com/business-functions/operations/our-insights/ceo-dialogue-perspectives-on-reimagining-operations-for-growth [Accessed 28th August 2021].

Breschi, S., and Malerba, F. (1997) Sectoral innovation systems: technological regimes, Schumpeterian dynamics, and spatial boundaries. Systems of innovation: Technologies, institutions and organizations, 1, pp. 130-156.

B.S. Sathya Durga (2022) Modernisation of India's pharma manufacturing Industry: Leader or Laggard? Available from: https://www.biopharminternational.com/view/modernization-of-india-s-pharma-manufacturing-industry-leader-or-laggard- [Accessed 22nd October 2022].

Cai, Y., & Amaral, M. (2021) The Triple Helix Model and the Future of Innovation: A Reflection on the Triple Helix Research Agenda, Triple Helix, 8(2), 217-229. Available from: https://doi.org/10.1163/21971927- 12340004. [Accessed 22nd October 2022].

Carlsson, B., and Stankiewicz, R. (1991) On the nature, function and composition of technological systems. Journal of evolutionary economics, 1 (2), pp.93-118. Available from: https://doi.org/10.1007/BF01224915 [Accessed 22nd October 2022].

Carlsson, B. (2016) Industrial dynamics: A review of the literature 1990–2009. Industry and innovation, 23 (1), pp. 1-61.

C-CAMP (2022) A BIRAC - C-CAMP Initiative. Available from: https://www.nationalbioentrepreneurship.in/ [Accessed 22nd October 2022]

C-CAMP (2022) C-CAMP – BNV Innovation Hub (CBIH). Available from: https://www.ccamp.res.in/seed-funding-CBIH [Accessed 22nd October 2022]

Chaminade, C., Lundvall, B.Å., and Haneef, S. (2018) Advanced introduction to national innovation systems. Edward Elgar Publishing.

Chappin, M.M., Hekkert, M.P., Meeus, M.T., and Vermeulen, W.J. (2008) The intermediary role of an industry association in policy-making processes: the case of the Dutch paper and board industry. Journal of Cleaner Production, 16 (14) , pp.1462-1473. Available from: https://doi.org/10.1016/j.jclepro.2007.08.004 [Accessed 22nd October 2022]

Chunhavuthiyanon, M., and Intarakumnerd, P. (2014) The role of intermediaries in sectoral innovation system: The case of Thailand's food industry. International Journal of Technology Management & Sustainable Development, 13 (1), pp.15-36.

Cohen, W. M., and Levinthal, D. A. (1990) Absorptive capacity: A new perspective on learning and innovation. Administrative Science Quarterly, 35 (1), pp. 128–152. Available from: https://doi.org/10.2307/2393553 [Accessed 22nd October 2022]

Cohen, W. M., Nelson, R. R., and Walsh, J. P. (2002) Links and impacts: The influence of public research on industrial R&D. Management Science, 48 (1), pp. 1–23. Available from: https://doi.org/10.1287/mnsc.48.1.1.14273 [Accessed 22nd October 2022]

Cooke, P., Gomez Uranga, M. G., and Etxebarria, G. (1997) Regional innovation systems: Institutional and organizational dimensions. Research Policy, 26 (4-5), pp. 475–491. Available from: https://doi.org/10.1016/S0048-7333(97)00025-5 [Accessed 22nd October 2022]

Cortina, J.M. (1993) What is Coefficient Alpha? An Examination of Theory and Applications. Journal of Applied Psychology, 78, pp.98-104.

Cowan, R., David, P. A., and Dominique, F. (2000) The explicit economics of knowledge codification and tacitness. Industrial and Corporate Change, 9 (2), pp. 211–253. Available from: https://doi.org/10.1093/icc/9.2.211 [Accessed 22nd October 2022]

Da Silveira Luz, M., and Monteiro Salles-Filho, S. L. (2011) Technological and productive density in sectoral innovation systems: The case of the Brazilian Aeronautics Industry. Journal of Technology Management and Innovation, 6 (4), pp. 60–72. Available from: https://doi.org/10.4067/S0718-27242011000400005 [Accessed 22nd October 2022]

Dai, Y., Haakonsson, S. and Oehler, L. (2020) Catching up through green windows of opportunity in an era of technological transformation: Empirical evidence from the Chinese wind energy sector. Industrial and Corporate Change, 29 (5), pp. 1277-1295.

Dalenogare, L.S., Benitez, G.B., Ayala, N.F., and Frank, A.G. (2018) The expected contribution of Industry 4.0 technologies for industrial performance. Int. J. Prod. Econ., 204, pp. 383–394. Available from: https://doi.org/10.1016/j.ijpe.2018.08.019 [Accessed 20th June 2021].

David Schatsky and Ragu Gurumurthy (2019) Pivoting to Digital Maturity - Seven capabilities central to digital transformation. Deloitte Insights, Available from: https://www2.deloitte.com/us/en/insights/focus/digital-maturity/digital-maturity-pivot-model.html [Accessed 22nd October 2022].

Deloitte (2018a) Toward the next horizon of Industry 4.0. Accelerating transformation through collaboration and startups. Available from: IL327_Toward-thenext-horizon.pdf (deloitte.com) [Accessed 20th September 2021]

Deloitte (2018b) Unlocking Industry 4.0 potential. Transforming through startup-manufacturer collaborations and the unique role of the Israeli startup ecosystem. Available from: 74d8a3d1-4ade4196-889d-044e47c5d93c (admiralcloud.com) [Accessed 20th September 2021]

De Meyer, A. C. (1985) The flow of technological innovation in an R & D department. Research Policy, 14(6), pp. 315-328.

Department of Science & Technology (2014) Understanding Innovation: Indian National Innovation Survey Report. Available from: http://nationalinnovationsurvey.nstmis-dst.org/download/indian-national-innovation-survey-report.pdf [Accessed 16th January 2022]

Department of Pharmaceuticals (DoP) Operational Guidelines for the Production Linked Incentive Scheme for Pharmaceuticals. Available from: https://pli-pharma.udyamimitra.in/Default/ViewFile/?id=OperationalGuidelinesof PLIschemeforPharmaceuticals.pdf&path=MiscFiles [Accesses 22nd October 2022]

Department of Pharmaceuticals (2022) Revised Guidelines for the Production Linked Incentive Scheme for promoting the domestic manufacture of Medical Devices. Available from: https://pharmaceuticals.gov.in/sites/default/files/Revised%20Guidelines%20of%20PLI%20Medical%20Devices%20dated%2018.08.2022.pdf [Accessed 22nd October 2022]

Desai, A. V. (1985) Market structure and technology: Their interdependence in Indian industry. Research Policy, 14 (3), pp. 161–170. Available from: https://doi.org/10.1016/0048-7333(85)90014-9 [Accessed 22nd October 2022]

Doak, S., and Assimakopoulos, D. (2007) How do forensic scientists learn to become competent in casework reporting in practice: A theoretical and empirical approach. Forensic science international, 167 (2-3), pp. 201-206.

Dosi, G. (1988) The nature of the innovative process. In: Dosi, G., Freeman, C., Nelson, R., Silverberg, G., and Soete, L. (eds.). Technical Change and Economic Theory, pp. 221-238. London: Pinter

Dosi, G., and Nelson, R. R. (2010) Technical change and industrial dynamics as evolutionary processes. Handbook of the Economics of Innovation, pp. 51–127. Available from: https://doi.org/10.1016/S0169-7218(10)01003-8 [Accessed 22nd October 2022]

Dosi, G., Marengo, L., and Pasquali, C. (2006) How much should society fuel the greed of innovators? Research Policy, 35 (8), pp. 1110–1121. Available from: https://doi.org/10.1016/j.respol.2006.09.003 [Accessed 22nd October 2022]

Dzisah, J., and Etzkowitz, H. (2008) Triple Helix circulation: The heart of innovation and development. International Journal of Technology Management and Sustainable Development, 7 (2), pp. 101–115. Available from: https://doi.org/10.1386/ijtm.7.2.101_1 [Accessed 22nd October 2022]

Dziuban, C.D., and Shirkey, E.S. (1974) When is a Correlation Matrix Appropriate for Factor Analysis? Some Decision Rules. Psychological Bulletin, 81, pp. 358-361.

Edquist, C. (1997) Systems of innovation: Technologies, institutions, and organisations. Pinter Publisher Ltd.

Edquist, C. (2005) System s of innovation. Challenges and perspectives. In: Fagerberg J., Mowery D., and Nelson R. R. (eds.), Oxford Hanbook of innovation. Oxford University Press.

Edquist, C., and Chaminade, C. (2006) Industrial policy from a systems-of-innovation perspective. EIB papers, 11 (1), 108-132.

Eisenhardt, K.,M. and Martin, J., A. (2000) Dynamic capabilities: what are they? Strategic Management Journal; 21:1105-21.

Etzkowitz, H. (2000) Tech transfer, incubators probed at Triple Helix III. Research-Technology Management, 43 (6), pp. 4–5.

Etzkowitz, H. (2002) Networks of innovation: Science, technology and development in the triple helix era. International Journal of Technology Management and Sustainable Development, 1 (1), pp. 7–20. Available from: https://doi.org/10.1386/ijtm.1.1.7 [Accessed 22nd October 2022]

Etzkowitz, H. (2003a) Innovation in innovation: The Triple Helix of university–industry–government relations. Social Science Information. 42, pp. 293–338.

Etzkowitz, H. (2003b) MIT and the Rise of entrepreneurial science. Routledge.

Etzkowitz, H. (2008) The Triple Helix: University-industry-government innovation in action. New York: Routledge.

Etzkowitz, H. (2017) Innovation Lodestar: The entrepreneurial university in a stellar knowledge firmament. Technological Forecasting and Social Change, 123 (4), pp. 122–129. Available from: https://doi.org/10.1016/j.techfore.2016.04.026 [Accessed 22nd October 2022]

Etzkowitz, H., and Leydesdorff, L. (1995) The Triple Helix: University–industry–government relations: A laboratory for knowledge-based economic development. EASST Review, 14, pp. 14–19.

Etzkowitz, H., and Leydesdorff, L. (2000) The dynamics of innovation: From National Systems and "Mode 2'" to a Triple Helix of university–industry–government relations. Research Policy, 29 (2), pp. 109–123. Available from: https://doi.org/10.1016/S0048-7333(99)00055-4 [Accessed 22nd October 2022]

Etzkowitz, H., Webster, A., Gebhardt, C., and Terra, B. R. C. (2000) The future of the university and the university of the future: Evolution of ivory tower to entrepreneurial paradigm. Research Policy, 29 (2), pp. 313–330. Available from: https://doi.org/10.1016/S0048-7333(99)00069-4 [Accessed 22nd October 2022]

Express Healthcare (2022) The science behind the healthtech startup must be understood well. Available from: https://www.expresshealthcare.in/news/the-science-behind-the-healthtech-startup-must-be-understood-well/436167/ [Accessed 22nd October, 2022]

Fagerberg, J., and Srholec, M. (2008) National innovation systems, capabilities and economic development. Research Policy, 37 (9), pp. 1417–1435. Available from: https://doi.org/10.1016/j.respol.2008.06.003 [Accessed 22nd October, 2022]

Fagerberg, J., Lundvall, B. Å., and Srholec, M. (2017) Global value chains, national innovation systems and economic development. Lunds University Papers in Innovation Studies, paper no. 2017/15.

FICCI (2018), Indian Pharmaceuticals Report 2018. Available from: https://ficci.in/spdocument/22944/india-pharma-2018-ficci.pdf [Accessed 22nd October 2022].

FICCI (2022) Impact of the Pharma Industry on the Indian Economy: KPMG-FICCI Report. Available from: https://ficci.in/spdocument/23599/Ficci_Pharma-report.pdf [Accessed 22nd October 2022].

FICCI & EY (2022) Indian Pharmaceutical Industry 2021: Future is Now. Available from: ey-ficci-indian-pharma-report-2021.pdf [Accessed 2nd November 2022]

Field, A. P. (2005). Discovering statistics using SPSS (2nd edition). London: Sage. Available from: http://users.sussex.ac.uk/~andyf/factor.pdf [Accessed 22nd October 2022]

Forbes, N., and Wield, D. (2000) Managing R&D in technology-followers. Research Policy, 29 (9), pp. 1095–1109. Available from: https://doi.org/10.1016/S0048-7333(99)00071-2 [Accessed 22nd October 2022]

Foxon, T. (2003) Inducing Innovation for a low-carbon future: Drivers, barriers and policies – A report for the Carbon Trust. Carbon Trust.

Freeman, C. (1987) Technology policy and economic performance: Lessons from Japan. London: Printer.

Freeman, C. (1995) The National System of Innovation in historical perspective. Cambridge Journal of Economics, 19 (1), pp. 5–24.

Freeman, C., and Louca, F. (2001) As time goes by: From the industrial revolutions to the information revolution. Oxford University Press.

Gaur, S., (1997) Adelman and Morris Factor Analysis of Developing Countries. Journal of Policy Modeling, 19 (4), pp. 407-415.

George, D., and Mallery, P. (2003) SPSS for Windows Step by Step: A Simple Guide and Reference. 11.0 update. 4th ed. Boston: Allyn & Bacon.

Giachetti, C., and Marchi, G. (2017) Successive changes in leadership in the worldwide mobile phone industry: The role of windows of opportunity and firms' competitive action. Research Policy, 46 (2), pp. 352–364. Available from: https://doi.org/10.1016/j.respol.2016.09.003 [Accessed 22nd October 2022]

Giuseppe Festa et. al. (2022) Envisioning the challenges of the pharmaceutical sector in the Indian health-care industry: a scenario analysis. Journal of Business and Industrial Marketing, 37 (8), pp. 16612-1674. Available from: https://www.emerald.com/insight/content/doi/10.1108/JBIM-07-2020-0365/full/html [Accessed 22nd October 2022].

Grimpe, C., and Hussinger, K., (2008) Formal and Informal Technology Transfer from Academia to Industry: Complementarity Effects and Innovation Performance. ZEW Discussion Papers, No. 08-080, Zentrum für Europäische Wirtschaftsforschung (ZEW), Mannheim

Gujral Committee (145th Standing Committee) report on Commerce (2018) Impact of Chinese Goods on Indian Industry. Rajya Sabha Secretariat. Available from: http://164.100.47.5/committee_web/ReportFile/13/97/145_2018_7_13.pdf [Accessed 22nd October 2022].

Gupta, S.V. (2022) The Department of Biotechnology, Government of India – communicating impact is important, Current Science, 123 (8), pp. 963-967. Available from: https://www.currentscience.ac.in/Volumes/123/08/0963.pdf [Accessed 16th January 2023]

Hall, A., Mytelka, L., and Oyeyinka, B. (1997) Innovation systems: Implications for agricultural policy and practice. ILAC Brief.

Hanel, P., and St-Pierre, M. (2006) Industry-university collaboration by Canadian manufacturing firms. Journal of Technology Transfer, 31 (4), pp. 485–499. Available from: https://doi.org/10.1007/s10961-006-0009-5 [Accessed 22nd October 2022].

Hansen, T., and Hansen, U. E. (2021) How many firms benefit from a window of opportunity? Knowledge spillovers, industry characteristics, and catching up in the Chinese biomass power plant industry. Industrial and Corporate Change, 29 (5), pp. 1211–1232. Available from: https://doi.org/10.1093/icc/dtaa008 [Accessed 22nd October 2022].

Hekkert, M. P., Suurs, R. A. A., Negro, S. O., Kuhlmann, S., and Smits, R. E. H. M. (2007) Functions of innovation systems: A new approach for analyzing technological change. Technological Forecasting and Social Change, 74 (4), pp. 413–432. Available from: https://doi.org/10.1016/j.techfore.2006.03.002 [Accessed 22nd October 2022].

Hiren Shah (2022) Implementation of Industry 4.0 in the pharma sector. Guest Column. Manufacturing Today. March 29, 2022. Available From: https://www.manufacturingtodayindia.com/sectors/implementation-of-industry-4-0-in-the-pharma-sector [Accessed 22nd October 2022].

Hjort, J., and Poulsen, J. (2019) The arrival of fast Internet and employment in Africa. NBER Working Paper no. w23582. American Economic Review, 109 (3), pp. 1032–1079. Available from: https://doi.org/10.1257/aer.20161385 [Accessed 22nd October 2022].

Hole, G., Hole, A. S., and McFalone-Shaw, I. (2021) Digitalization in pharmaceutical industry: What to focus on under the digital implementation process? International Journal of Pharmaceutics, 10 (3), pp. 100095

Holtkamp, B., and Iyer, A. (2017). Industry 4.0: The Future of Indo-German Industrial Collaboration. Bertelsmann-stiftung.

Hauknes, J. and Nordgren, L. (1999) Economic rationales of government involvement in innovation and the supply of innovation-related services.

IBM (2021) 2021 Digital transformation Assessment, COVID-19: A catalyst for Change. Available from: https://www.ibm.com/downloads/cas/MPQGMEN9 [Accessed 22nd October 2022].

Inc 42 (2022) Pfizer To Back Oncology, Healthtech Startups In India. Available from: https://inc42.com/buzz/pfizer-to-back-oncology-healthtech-startups/ [Accessed 22nd October 2022]

India Brand Equity Foundation (IBEF) (2021) Pharmaceuticals. Available from: https://www.ibef.org/download/Pharmaceuticals-March-2021.pdf [Accessed 6th July 2022].

Indian Pharmaceutical Alliance (2019) The Indian pharmaceutical industry – the way forward. Available from: indian-pharmaceutical-industry-way-forward.pdf [Accessed 2nd November 2022]

Indian Web2 (2015) 13 Govt. Venture Capital Firms for Startups in India. Available from: https://www.indianweb2.com/2015/01/13-govt-venture-capital-firms-for_14.html [Accessed 22nd October 2022]

Indo-French Centre for the Promotion of Advanced Research (IFCPAR/CEFIPRA) (2021) Industry-Academia Research and Development Projects. Available from: http://www.cefipra.org/Industry_Academia_Project.aspx [Accessed 22nd October 2022]

Indo-U.S. Science and Technology Forum (IUSSTF) (n.d.) Program Portfolio. Available from: https://iusstf.org/home [Accessed 22nd October 2022]

Jacob, M. (2016) Innovation system and Agriculture: Going Beyond Research for Increasing Yields. In: Francis J., Mytelka L., van Huis A and Röling N. (eds.). Innovation Systems: Towards Effective Strategies in support of Smallholder Farmers. Technical Centre for Agricultural and Rural Cooperation (CTA) & Wageningen University & Research(WUR)/Convergence of Sciences-Strengthening Innovation Systems (CoS-SIS), Wageninge.

Jansen, J.J., Van Den Bosch, F.A., and Volberda, H. W. (2006) Exploratory innovation, exploitative innovation, and performance: Effects of organizational antecedents and environmental moderators. Manage Sci; 52:1661-74.

Jensen, M. B., Johnson, B., Lorenz, E., and Lundvall, B. Å. (2007) Forms of knowledge and modes of innovation. Research Policy, 36 (5), pp. 680–693. Available from: https://doi.org/10.1016/j.respol.2007.01.006 [Accessed 22nd October 2022]

Joseph, K. J., and Abraham, V. (2009) University-industry interactions and innovation in India: Patterns, determinants, and effects in select industries. Seoul Journal of Economics, 22 (4), pp. 467.

Jishnu, V., Gilhotra, R., and Mishra, D. (2011) Pharmacy Education in India: Strategies for a Better Future. Journal of Young Pharmacist, 3 (4), pp. 334-42.

Kaiser, H.F. (1974) An Index of Factorial Simplicity. Psychometrika, 39, pp.31-36

Kang, H., and Song, J. (2017) Innovation and recurring shifts in industrial leadership: Three phases of change and persistence in the camera industry. Research Policy, 46 (2), pp. 376–387. Available from: https://doi.org/10.1016/j.respol.2016.09.004 [Accessed 22nd October 2022]

Kapoor, Radhicka (2016) Technology, jobs and inequality: Evidence from India's manufacturing sector. Working Paper, No. 313, Indian Council for Research on International Economic Relations (ICRIER), New Delhi. Available from: https://www.econstor.eu/bitstream/10419/176331/1/icrier-wp-313.pdf [Accessed 22nd October 2022]

Kapoor, Radhicka (2018) Understanding the Performance of India's Manufacturing Sector: Evidence from Firm Level Data. CSE Working Paper, 2018-2, Centre for Sustainable Employment, Azim Premji University, Bengaluru. Available from: https://cse.azimpremjiuniversity.edu.in/wpcontent/uploads/2018/05/Kapoor_Performance_Organised_Manufacturing.pdf [Accessed 22nd October 2022]

Karlsen, A., Lund, H. B., and Steen, M. (2022) The roles of intermediaries in upgrading of manufacturing clusters: Enhancing cluster absorptive capacity. Competition and Change. Available from: https://doi.org/10.1177/10245294211059138 [Accessed 22nd October 2022]

Katrak, H. (1985) Imported technology, enterprise size and R and D in a newly industrializing country: The Indian experience. Oxford Bulletin of Economics and Statistics, 47 (3), pp. 213–229. Available from: https://doi.org/10.1111/j.1468-0084.1985.mp47003003.x [Accessed 22nd October 2022]

Katz, R., and Tushman, M. (1981) An investigation into the managerial roles and career paths of gatekeepers and project supervisors in a major R & D facility. R&D Management, 11(3), pp. 103-110.

Kim J.O., and Mueller, C.W. (1978) Factor analysis: Statistical methods and practical issues. Thousand Oaks, CA: Sage Publications, Quantitative Applications in Social Sciences Series, No. 14.

Kim, L. (1992) National System of Industrial Innovation: Dynamics of Capability Building in Korea. In R. Nelson (ed.): National Innovation Systems: A Comparative Analysis (pp. 357-383). New York: Oxford University Press.

Kim, L. & Nelson, R. R. (2000) Technology, learning, and innovation: experiences of newly industrialized economies. Cambridge: Cambridge University Press.

Kline, P. (1999) The Handbook of Psychological Testing. 2nd ed. London: Routledge.

Koria, R., Bartels, F. L., Andriano, L., and Köszegi, S. (2014) Effectiveness and Efficiency of National Systems of Innovation: The importance of ICT, the Cases of Ghana and Kenya. IST-Africa Conference, 2014. IEEE Publications.

Kucirkova, A. (2019) The Ultimate Guide: Everything You Need to Know About Industry 4.0. Vol 8. Helice Issue 1. Available from: The Ultimate Guide: Everything You Need to Know About Industry 4.0 - Triple Helix Association [Accessed 25th August 2021]

Kumar, N., and Siddharthan, N. S. (1994) Technology, firm size and export behaviour in developing countries: The case of Indian enterprises. Journal of Development Studies, 31 (2), pp. 289–309. Available from: https://doi.org/10.1080/00220389408422362 [Accessed 22nd October 2022]

Kumar, N., and Siddharthan, N. S. (2013) Technology, market structure and internationalization: Issues and policies for developing countries. Routledge.

Lall, S., and Kumar, R. (1981) Firm-level export performance in an inward-looking economy: The Indian engineering industry. World Development, 9 (5), pp. 453–463. Available from: https://doi.org/10.1016/0305-750X(81)90038-3 [Accessed 22nd October 2022]

Lee, K., and Ki, J. (2017) Rise of latecomers and catch-up cycles in the world steel industry. Research Policy, 46 (2), pp. 365–375. Available from: https://doi.org/10.1016/j.respol.2016.09.010 [Accessed 22nd October 2022]

Lee, K., and Malerba, F. (2017) Catch-up cycles and changes in industrial leadership: windows of opportunity and responses of firms and countries in the evolution of sectoral systems. Research Policy, 46 (2), pp. 338–351. Available from: https://doi.org/10.1016/j.respol.2016.09.006 [Accessed 22nd October 2022]

Lema, R., Fu, X., and Rabellotti, R. (2020) Green windows of opportunity: latecomer development in the age of transformation toward sustainability. Industrial and Corporate Change, 29 (5), pp. 1193-1209.

Letaba, P. (2019) Relationship between Dominant Triple Helix Model and Type of Intermediary Organizations. 1-6. Available from: 10.23919/ PICMET.2019.8893910 [Accessed 25th August 2021].

Leydesdorff, L., and Van den Besselaar, P. (1994) Evolutionary Economics and Chaos Theory: New directions in technology studies. London Pinter Publishers.

Leydesdorff, L. (1997) Why words and co-words cannot map the development of the sciences. Journal of the American Society for Information Science, 48 (5), pp. 418–427. Available from: https://doi.org/10.1002/(SICI)1097-4571(199705)48:5<418::AID-ASI4>3.0.CO;2-Y

Leydesdorff, L. (2001) Knowledge-based innovation systems and the model of a triple helix of university-industry-government relations. Conference on New Economic Windows: New Paradigms for the New Millennium, Salerno, Italy, September.

Leydesdorff, L. (2004) The university-industry knowledge relationship: Analyzing patents and the science base of technologies. Journal of the American Society for Information Science and Technology, 55 (11), pp. 991–1001. Available from: https://doi.org/10.1002/asi.20045 [Accessed 22nd October 2021].

Leydesdorff, L. (2005) The triple helix model and the study of knowledge-based innovation systems. International Journal of Contemporary Sociology, 42 (1).

Leydesdorff, L. (2012) The triple helix, quadruple helix,…, and an N-tuple of helices: explanatory models for analyzing the knowledge-based economy?. Journal of the knowledge economy, 3 (25-35).

Leydesdorff, L. &Etzkowitz, H. (1998a) The Triple Helix as a Model for Innovation Studies. Science & Public Policy, 25(3), pp. 195-203.

Leydesdorff, L. & Etzkowitz, H. (1998b) Triple Helix of innovation: introduction. Science and Public Policy 25, pp. 358–364.

Li, Y., and Zahra, S. A. (2012) Formal institutions, culture, and venture capital activity: A cross country analysis. Journal of Business Venturing, 27 (1), pp. 95–111. Available from: https://doi.org/10.1016/j.jbusvent.2010.06.003 [Accessed 22nd October 2021].

Lundvall, B. (1985) Product Innovation and UserProducer Interaction. Industrial Development Research Series No. Available from: (PDF) Product Innovation and User-Producer Interaction (researchgate.net) [Accessed 31st August 2021].

Lundvall, B. Å. (1992) National Systems of Innovation: Towards a Theory of Innovation and Interactive learning. London: Printer.

Lundvall, B. Å. (2007) National innovation systems – Analytical concept and development tool. Industry and Innovation, 14 (1), pp. 95–119. Available from: https://doi.org/10.1080/13662710601130863 [Accessed 22nd October 2021].

Lundvall, B.-Å. (2016) National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning. In B.-Å. Lundvall (ed): From the economics of knowledge to the learning economy, pp. 85-106. London, Anthem Press

Macdonald, S., and Williams, C. (1993) Beyond the boundary: an information perspective on the role of the gatekeeper in the organization. Journal of Product Innovation Management, 10(5), 417-427.

Malerba, F. (2002) Sectoral systems of innovation and production. Research Policy, 31 (2), pp. 247–264. Available from: https://doi.org/10.1016/S0048-7333(01)00139-1 [Accessed 22nd October 2022]

Malerba, F. (2004) Sectoral systems of innovation: Concepts, issues and analyses of six major sectors in Europe. Cambridge University Press.

Malerba, F. and Mani, S. (eds.) (2009). Sectoral systems of innovation and production in developing countries: actors, structure and evolution. Edward Elgar Publishing.

Malerba, F., and Nelson, R. R. (2013) Economic development as a learning process: Variation across sectoral systems. Edward Elgar Publishing.

Malerba, F., and Nelson, R. R. (2011) Learning and catching up in different sectoral systems: Evidence from six industries. Industrial and Corporate Change, 20 (6), pp. 1645–1675. Available from; https://doi.org/10.1093/icc/dtr062 [Accessed 22nd October 2022]

Mani, S. (2005) The Dragon vs. the Elephant Comparative analysis of innovation capability in the telecommunications equipment industry in China and India. Center for Development Studies, Working Paper No. 279.

Manisha Singh, Rajeev Kumar and Pankaj Musyuni (2022) Existing Scenario and Expanding Growth Prospects for Medical Devices and Consumer Healthcare Products in India. Available from: https://practiceguides.chambers.com/practice-guides/medical-devices-consumer-health-products-2022/india/trends-and-developments [Accessed 22nd October 2022].

Market Insight (2020) Indian Pharmaceutical Industry. Available from: https://marketinsight.in/industry-reports/indian-pharmaceutical-industry-growth-size-segmentation [Accessed 22nd October 2022]

Market Monitor (2022) Pharmaceutical Industry Trends India. Available from: https://atradiuscollections.com/global/reports/pharmaceuticals-industry-trends-india-2022.html [Accessed 22nd October 2022].

Martin, B. R., and Etzkowitz, H. (2000) The origin and evolution of the university species. SPRU Electronic Working Paper Series, paper 59.

Miller, D., and Friesen, P. H. (1983) Strategy-making and environment: the third link. Strategic Management Journal, 4 (3), pp. 221-35.

Ministry of Chemical & Fertilizers (2021) Draft policy to catalyze Research & Development and Innovation in the Pharma-MedTech Sector in India. Available from: https://pharmaceuticals.gov.in/sites/default/files/Draft%20Policy.pdf [Accessed 9th July 2022].

Ministry of Chemical & Fertilizers, Department of Pharmaceuticals (2020) Recommendations of the Task Force on Enabling Private Sector to Lead the Growth of Pharmaceutical Industry. Available from: https://pharmaceuticals.gov.in/sites/default/files/ecommendations%20of%20the%20Task%20Force%20on%20Enabling%20Private%20Sector%20to%20Lead%20the.pdf [Accessed 2nd November 2022]

Ministry of Chemical & Fertilizers (2020) Department of Pharmaceuticals Annual Report (2020-2021). Available from: https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf [Accessed 2nd November 2022]

Ministry of Commerce & Industry (n.d.) Cumulative FDI Inflows - Sector-wise, Financial Year basis from April 2000-2021. Available from: https://dpiit.gov.in/sites/default/files/Chapter_1.3_A_iv_0.pdf [Accessed 22nd October 2022].

Ministry of Commerce & Industry (n.d.) Foreign Direct Investment Inflows for financial year 2020-21. Available from: https://dpiit.gov.in/sites/default/files/Drugs%20%26%20Pharmaceuticals%20%28ix%29-2020.pdf [Accessed 22nd October 2022].

Ministry of Commerce & Industry (n.d.) Cumulative FDI Inflows-Sector-wise, Calendar Year basis from January 2000 till December 2020. Available from: https://dpiit.gov.in/sites/default/files/Chapter_4_3.pdf [Accessed 22nd October 2022].

Ministry of Commerce & Industry (2021) PM Gati Shakti– National Master Plan for Multi Modal connectivity to various Economic Zones. Available from: https://dpiit.gov.in/logistics-division [Accessed 22nd October 2022]

Ministry of External Affairs (2020) India FDI Boost through Conducive Government Policies. Available from: https://indbiz.gov.in/india-fdi-boost-through-conducive-government-policies/ [Accessed 22nd October 2022]

Ministry of Family and Health Welfare (2017) India State Level Disease Burden Initiative. Available from: https://www.healthdata.org/sites/default/files/files/policy_report/2017/India_Health_of_the_Nation%27s_States_Report_2017.pdf [Accessed 5th July 2022].

Ministry of Human Resource Development (2020) National Education Policy 2020. Available from: https://www.education.gov.in/sites/upload_files/mhrd/files/NEP_Final_English_0.pdf [Accessed 9th July 2022].

Ministry of Science and Technology (2019) Monthly Cabinet Summary, January-2019. Available from: https://dbtindia.gov.in/sites/default/files/Monthly_Cabinet_Summary_January-2019.pdf [Accessed 22nd October, 2022]

Ministry of Science and Technology (2020) Research and Development Statistics (2019-2020). Available from: https://dst.gov.in/sites/default/files/Research%20and%20Deveopment%20Statistics%202019-20_0.pdf [Accessed 4 July 2022].

Money Control (2022) ONGC's nominee director appointment on HPCL board stuck in paper work. Available from: https://www.moneycontrol.com/news/business/ongcs-nominee-director-appointment-on-hpcl-board-stuck-in-paperwork-8642251.html [Accessed 4 July 2022].

Morrison, A., and Rabellotti, R. (2017) Gradual catch up and enduring leadership in the global wine industry. Research Policy, 46 (2), pp. 417–430. Available from: https://doi.org/10.1016/j.respol.2016.09.007 [Accessed 22nd October 2022]

Moschitz, H., Roep, D., Brunori, G., and Tisenkopfs, T. (2015) Learning and innovation networks for sustainable agriculture: Processes of co-evolution, joint reflection and facilitation. Journal of Agricultural Education and Extension, 21 (1), pp. 1–11. Available from: https://doi.org/10.1080/1389224X.2014.991111 [Accessed 22nd October 2022]

Mowery, D.C. (2009) Plus ca change: Industrial R&D in the "third industrial revolution. Industrial and corporate change, 18 (1), pp. 1-50. Available from: https://doi.org/10.1093/icc/dtn049 [Accessed 22nd October 2022]

Mu, Q., and Lee, K. (2005) Knowledge diffusion, market segmentation and technological catch-up: The case of the telecommunication industry in China. Research Policy, 34 (6), pp. 759–783. Available from: https://doi.org/10.1016/j.respol.2005.02.007 [Accessed 22nd October 2022]

Muchie, M., and Baskaran, A. (eds.) (2017) Sectoral innovation systems in Africa. Africa World Press.

Mushtaq, R., Gull, A. A., and Usman, M. (2022) ICT adoption, innovation, and SMEs' access to finance. Telecommunications Policy, 46 (3), pp. 102275.

Mytelka, L. K., and Smith, K. (2002) Policy learning and innovation theory: An interactive and co-evolving process. Research Policy, 31 (8–9), pp. 1467–1479. Available from: https://doi.org/10.1016/S0048-7333(02)00076-8 [Accessed 22nd October 2022]

Nakwa, K., Zawdie, G., and Intarakumnerd, P. (2012) Role of intermediaries in accelerating the transformation of inter-firm networks into triple helix networks: A case study of sme-based industries in Thailand. Procedia-Social and Behavioral Sciences, 52, pp.52-61.

Nandagopal, M., Gala, K., and Premnath V. (2011) Improving technology commercialization at research institutes: Practical insights from NCL Innovations. Innovation Educators' Conference (IEC), Indian School of Business, Hyderabad. Available from: https://www.venturecenter.co.in/pdfs/ISB-Conf-Paper-ver04.pdf [Accessed 22nd October, 2022]

National Skill Development Corporation (NSDC) (2022) Human Resource and Skill Requirements for the Chemicals & Pharmaceuticals Sector. Available from: https://www.nqr.gov.in/sites/default/files/10_NSDC%202022_3.pdf [Accessed 22nd October 2022]

Negro, S. O., Suurs, R. A. A., and Hekkert, M. P. (2008) The bumpy road of biomass gasification in the Netherlands: Explaining the rise and fall of an emerging innovation system. Technological Forecasting and Social Change, 75 (1), pp. 57–77. Available from: https://doi.org/10.1016/j.techfore.2006.08.006 [Accessed 22nd October 2022]

Nelson, R.R. (1985) An evolutionary theory of economic change. Harvard university press.

Nelson, R. R. (1993) National Innovation Systems: A Comparative Analysis. Oxford University Press, New York.

Nelson, R. R., and Rosenberg, N. (1993) Technical Innovation and National Systems. In: Nelson, R. R. (1993) (ed.) National Innovation Systems: A Comparative Analysis (pp. 3-22). New York: Oxford University Press.

Nevzorova, T. (2021) Barriers, drivers and context environment of technological innovation An analysis of the biogas industry in Russia. KTH Royal Institute of Technology. Sweden. Available from: FULLTEXT01. pdf (diva-portal.org) [Accessed 30th October 2021].

Nguyen, H. & Harrison, N. (2019) Leveraging customer knowledge to enhance process innovation: moderating effects from market dynamics. Business Process Management Journal, 25(2), 307-322. Available from: https://doi.org/10.1108/BPMJ-03- 2017-0076 [Accessed June 10th 2021].

NITI Aayog (2011) Report of Working Group on Drugs and Pharmaceuticals. Available from: https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp12/wg_pharma2902.pdf [Accessed 7th October 2022]

NITI Aayog (2018) Strategy for New India @ 75, pp. 20-24. Available from: https://www.niti.gov.in/sites/default/files/2019-01/Strategy_for_New_India_2.pdf [Accessed 16th January 2023)

N. Sarah Arden et. al. (2021) Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. International Journal of Pharmaceutics, 602, pp. 120554 [Accessed 24th October 2022].

NSTEDB (2002) Science & Technology Entrepreneurship Park (STEP). Available from: https://www.nstedb.com/institutional/step.htm [Accessed 22nd October 2022]

OECD (2009) Overcoming Barriers to Administrative Simplification Strategies guidance for policy makers. Available from: https://www.oecd.org/regreform/42112628.pdf [Accessed 30th August 2021].

OECD (2011) Policy Framework for Investment User's Toolkit. Available from: https://www.oecd.org/investment/toolkit/policyareas/publicgovernance/41890394.pdf [Accessed 30th August 2021].

OECD (2018) Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation, 4th Edition, Paris: OECD

OECD (2022) Inflation & Consumer Price Index. Available from: https://data.oecd.org/price/inflation-cpi.htm. [Accessed 22nd October 2022].

OPPI & Accenture (2020) Workforce of the Future in Indian Pharma Industry. Available from: WORKFORCE-OF-THE-FUTURE-IN-INDIAN-PHARMA-INDUSTRY.pdf [Accessed 2nd November 2022]

Parameswaran, M. (2004) Economic reforms, technical change and efficiency change: Firm level evidence from capital goods industries in India. Indian Economic Review, pp. 239–260.

Paunov, C., and Rollo, V. (2016) Has the Internet fostered inclusive innovation in the Developing World? World Development, 78, pp. 587–609. Available from: https://doi.org/10.1016/j.worlddev.2015.10.029 [Accessed 22nd October 2022]

Perez, C. (1983) Structural change and assimilation of new technologies in the economic and social systems. Futures, 15 (5), pp. 357–375. Available from: https://doi.org/10.1016/0016-3287(83)90050-2 [Accessed 22nd October 2022]

Perkmann, M., and Walsh, K. (2007) University-industry relationships and open innovation: Towards a research agenda. International Journal of Management Reviews, 9 (4), pp. 259–280. Available from: https://doi.org/10.1111/j.1468-2370.2007.00225.x [Accessed 22nd October 2022]

Perkmann, M., Salandra, R., Tartari, V., McKelvey, M., and Hughes, A. (2021) Academic engagement: A review of the literature 2011-2019. Research Policy, 50(1), pp.104114.

Pfizer (n.d.) CSR Initiatives: INDovation. Available from: https://www.pfizer.co.in/our-community-efforts/csr-initiatives/indovation-healthcare-innovations-made-in-india [Accessed 22nd October 2022]

Planning Commission (n.d.) Twelfth Five Year Plan (2012-2017). Available from: https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp12/wg_pharma2902.pdf [Accessed 17th October 2022].

PTI (2016) The Pfizer IIT-Delhi Innovation and IP Programme announces first round of grant awardees. PharmaBiz.com. 05th July 2016. Available from: http://www.pharmabiz.com/NewsDetails.aspx?aid=97755&sid=2 [Accessed 22nd October, 2022]

Press Information Bureau (PIB) (2021) India's pharma exports grow by 103% since 2013-14, pharma exports in 2021-22 sustain a positive growth despite global trade disruptions, pharma trade balance continues to be in India's favour, around 55 % of Indian pharma exports cater to highly regulated markets. Available from: https://pib.gov.in/PressReleasePage.aspx?PRID=1821747 [Accessed October 22, 2022].

Press Information Bureau (PIB) (2021) Scheme for Promotion of Medical Device Parks: a key initiative to support the medical devices. Available from: https://pib.gov.in/PressReleasePage.aspx?PRID=1757662 [Accessed 1st October 2022]

Press Information Bureau (PIB) (2022) Centre Grants 'in-Principle' Approval of three Bulk Drug Parks to Himachal Pradesh, Gujarat and Andhra Pradesh. Available from: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1856080 [Accessed 22nd October 2022]

Press Bureau of India (PIB) (2022) India's Pharma exports grow by 103% since 2013-14. Available from: https://pib.gov.in/PressReleasePage.aspx?PRID=1821747 [Accessed 22nd October 2022]

Press Information Bureau (PIB) (2022) Make in India' completes 8 years, annual FDI doubles to USD 83 billion. Available from: https://pib.gov.in/PressReleasePage.aspx?PRID=1861929 [Accessed 22nd October, 2022]

Price Water House Coopers (2020) Global Pharma looks to India: Prospects for Growth. Available from: https://www.pwc.com/gx/en/pharma-life-sciences/pdf/global-pharma-looks-to-india-final.pdf [Accessed 15th October 2022]

PTI (2010) RDPL inks pacts with Rajasthan Government for generic drugs supply. Economic Times of India. 05th July 2010. Available from: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/rdpl-inks-pacts-with-rajasthan-govt-for-generic-drug-stores/articleshow/5542482.cms?from=mdr [Accessed 30th October 2020]

PTI (2017) IAN Signs MOU with BIRAC to Bring Bio Technology Startups Closer to Angel Investors. BW Online Bureau. 05th July 2017. Available from: https://bwdisrupt.businessworld.in/article/IAN-Signs-MOU-with-BIRAC-to-Bring-Bio-Technology-Startups-Closer-to-Angel-Investors/08-08-2017-123609/ [Accessed 22nd October 2022]

Ranga, M., and Etzkowitz, H. (2013) Triple Helix systems: An analytical framework for innovation policy and practice in the Knowledge Society. Industry and Higher Education, 27 (4), pp. 237–262. Available from: https://doi.org/10.5367/ihe.2013.0165 [Accessed 22nd October 2022]

Reiljan, J., Paltser, I. (2015) The Role of Innovation Policy in National Innovation System: the Case of Estonia. – TRAMES, 19(69/64), No 3, pp 249-273. Available at: Microsoft Word - Reiljan.doc (kirj.ee) [Accessed on 30th August 2021].

Reischauer, G. (2018) Industry 4.0 as policy-driven discourse to institutionalize innovation systems in manufacturing. Technol. Forecast. Soc. Change, 132, pp. 26–33. Available from: https://doi.org/10.1016/J.TECHFORE.2018.02.012 [Accessed 22nd October 2022]

Reserve Bank of India (RBI) (2020) RBI Bulletin March 2020. Available from: https://rbidocs.rbi.org.in/rdocs/Bulletin/PDFs/02AR_110320207BF5BBAA459047E49DADA63E3E25BD95.PDF [Accessed 15 January 2023]

Rübmann, M., Lorenz, M., Gerbert, P., Waldner, M., Justus, J., Engel, P., Harnisch, M. (2015) Industry 4.0: The future of productivity and growth in manufacturing industries. Boston Consulting Group.

Ruiz, K., Corrales, R., and Orozco, J. (2017) Main components that influence the link between Public Research Bodies and Companies. University-productive sector linkage to strengthen national innovation systems: Experience of Cuba, Mexico and Costa Rica, pp. 393–422.

Rummel, R.J., (1970) Applied Factor Analysis. Evanston: Northwestern University Press

Sarpong, D., AbdRazak, A., Alexander, E., and Meissner, D. (2017) Organizing practices of university, industry and government that facilitate (or impede) the transition to a hybrid triple helix model of innovation. Technological Forecasting and Social Change, 123, pp. 142–152. Available from: https://doi.org/10.1016/j.techfore.2015.11.032 [Accessed 22nd October 2022]

Saxenian, A. (1994) Regional advantage: Culture and competition in Silicon Valley and Route 128. Harvard University Press.

Schilke O. (2014) On the contingent value of dynamic capabilities for competitive advantage: The nonlinear moderating effect of environmental dynamism. Strategic Management Journal; 35:179-203

Schot, J., and Steinmueller, W. E. (2018) Three frames for innovation policy: R&D, systems of innovation and transformative change. Research Policy, 47 (9), pp. 1554- 1567. Available from: https://doi.org/10.1016/j.respol.2018.08.011 [Accessed 10th July 2022].

Selvaraj, S., Hasan, H., Chokshi, M., Sengupta, A., Guha, A., Shiva, M., Srinivasan, S., Phadke, A., Gopakumar, K. M., Santosh, M.R., Menghaney, L., and Bhardwaj, K. (2012) Pharmaceutical Pricing Policy: A critique. Economic & Political Weekly, 57 (4), pp 20-23. Available from: https://www.haiasiapacific.org/wp-content/uploads/2019/02/PricingPolicyCommentary-2012.pdf [Accessed 13th July 2022].

Shah, H. (2022) Implementation of Industry 4.0 in the Pharma Sector. Available from: https://www.manufacturingtodayindia.com/sectors/implementation-of-industry-4-0-in-the-pharma-sector [Accessed 8th July 2022].

Sharma, T., and Srivastav, R. (2020) Non-Disclosure Agreement: A Curve in a Glossy Path. DME Journal of Management, 1 (01), 126-145.

Shekar, K.C., and Joseph, K.J. (2022) Determinants of innovation and interactive learning in informal manufacturing enterprises in India. Science and Public Policy, 49 (3), pp. 427-440. Available from: https://doi.org/10.1093/scipol/scab089 [Accessed 22nd October 2022]

Shekar, K.C. and Paily, G. (2019) The need for an innovation survey in India. Economic & Political Weekly, 54 (38), pp. 19-22.

Sneha Mordani (2022) Import of medical devices up by 41 % in 2022. India Today. Available from: https://www.indiatoday.in/business/story/import-of-medical-devices-up-by-41-per-cent-2021-2022-1978761-2022-07-22 [Accessed 22nd October 2022]

Sirmon, D.G., Hitt, M.A., and Ireland, R.D. (2007) Managing Firm Resources in Dynamic Environments to Create Value: Looking inside the Black Box. Academy of Management Review, 32, 273-292. Available from: http://dx.doi.org/10.5465/AMR.2007.23466005 [Accessed 20th June 2021].

Srinivasan, S., and Phadke, A. (2013) Pharma Policy 2012 and Its Discontents. Economic & Political Weekly, 48 (1), Pg. No. 38-42. Available from: http://www.jstor.org/stable/23391135 [Accessed 11th July 2022].

Stenzel, T. (2007) The diffusion of renewable energy technology - Interactions between utility strategies and the institutional environment. Centre for Environmental Policy. Imperial College, London.

Strategic Research Unit (2020) India: Pharmacy to the World- A Healing Touch with Healthy Profits. Available from: https://static.investindia.gov.in/2020-08/Invest%20India%20Pharma%20Report_SIRU.pdf [Accessed 22nd October 2022].

Sudip Chaudhuri (2021) India's Import Dependence on China in Pharmaceuticals: Status, Issues and Policy Options. Discussion Paper number: 268, RIS Discussion Paper Series. Available from: https://ris.org.in/sites/default/files/Publication/DP%20268%20Prof%20Sudip%20Chaudhuri.pdf [Accessed 22nd October 2022]

Surana, K., Singh, A., Sagar, A. (2018) Enhancing S&T Based Entrepreneurship: The role of incubators and public policy. DST Centre for Policy Research, Indian Institute of Technology, Delhi

Roman, M., Varga, H., Cvijanovic, V. and Reid, A. (2020) Quadruple Helix models for sustainable regional innovation: Engaging and facilitating civil society participation. Economies, 8 (2), p.48.

Tabachnick, B.G., and Fidell L.S. (2007) Using multivariate statistics. Fifth Edition. Pearson Education Inc.

The Hans India (2015) Pfizer, IIT-D launch healthcare innovation and IP programme. Available from: https://www.thehansindia.com/posts/index/Education-and-Careers/2015-11-24/Pfizer-IIT-D-launch-healthcare-innovation-and-IP-programme/188648 [Accessed 22nd October 2022]

Tushman, M. L., and Scanlan, T. J. (1981) Boundary spanning individuals: Their role in information transfer and their antecedents. Academy of management journal, 24 (2), pp. 289-305.

UNDP Planning Commission (2010) Human Development in India: Analysis to Action. Available from: https://www.undp.org/sites/g/files/zskgke326/files/migration/in/human_development_analysis_to_action.pdf [Accessed 7th October 2022]

United Nations Industrial Development Organization (UNIDO) (2022) The Future of Industrialization in a post-pandemic world. Available from: https://www.unido.org/news/future-industrialization-post-pandemic-world-industrial-development-report-2022 [Accessed 22nd October 2022]

UNIDO IAP (2023) UNIDO 'Industrial Analytics Platform'. Available from: https://iap.unido.org/ [Accessed 18th January 2023]

Vendoti, D. (2018) ORF Occasional Paper no 177: Decoding the ban on irrational fixed-dose combination drugs in India. Available from: https://www.orfonline.org/research/decoding-the-ban-on-irrational-fixed-dose-combination-drugs-in-india-45835/ [Accessed 9th July 2022].

Vijay, N. (2022) Indian pharma fuels emergence of smart factories with adoption of Industry 4.0. Available from: http://www.pharmabiz.com/NewsDetails.aspx?aid=145936&sid=1 [Accessed 8th July 2022].

Wade, C. M. (2022) Senate approves drug cost reduction plan. The Salem News. Available from: https://www.salemnews.com/news/senate-approves-drug-cost-reduction-plan/article_e31f5594-8b71-11ec-881f-1fe78bdf38ca.html [Accessed 3 July 2022].

Wandahl, S., and Faber, L. (2016) Facilitating Industrial Placement in the Construction Engineering Curriculum. In: J. L. Perdomo-Rivera, A., González-Quevedo, C. L. D., Puerto, F., Maldonado, F., and Molina-Bas O.I., (Eds.), Proceedings of the 2016 Construction Research Congress: old and new construction technologies converge in historic San Juan. (pp. 58-67). Reston, Virginia, USA: American Society of Civil Engineers.

Weber, K. M., and Truffer, B. (2017) Moving innovation systems research to the next level: Towards an integrative agenda. Oxford Review of Economic Policy, 33 (1), pp. 101–121. Available from: https://doi.org/10.1093/oxrep/grx002 [Accessed 22nd October 2022]

Webster, A. (2000) Innovation and Knowledge Dynamics. SATSU Working paper N16 2000. Soziale Technik, 4 (99), 12–11.

WHO (2022) List of Prequalified Active Pharmaceutical Ingredients (APIs). Available from: https://extranet.who.int/pqweb/sites/default/files/documents/API_PQ-List_V04_11October2022.xlsx [Accessed 22nd October 2022]

WHO (2022) List of finished pharmaceutical products under assessment. Available from: https://extranet.who.int/pqweb/medicines/dossier-status [Accessed 22nd October 2022]

WHO (2022) Pre-qualification procedural and other requirements. Available from: https://extranet.who.int/pqweb/medicines/active-pharmaceutical-ingredients-0 [Accessed 22nd October 2022]

Williamson, O. E. (1969) Allocative efficiency and the limits of antitrust. American Economic Review, American Economic Association, 59 (2), pp. 105–118.

Williamson, O.E. (1971) The vertical integration of production: Market failure considerations. American Economic Review, American Economic Association, 61(2), 112- 23.

Williamson, O.E. (1973) Markets and hierarchies: Some elementary considerations. American Economic Review, American Economic Association, 63(2), 316-25.

Winskel, M. & Moran, B. (2008) Innovation theory and low carbon innovation: Innovation processes and innovations systems. Edinburgh University.

Winter, S. G. (1987) Knowledge and competence as strategic assets. In: Teece D. (eds.) The competitive challenge-strategies for industrial innovation and renewal. Ballinger. (pp. 159–184).

Woolthuis, R.K., Lankhuizen, M. and Gilsing, V. (2005) A system failure framework for innovation policy design. Technovation, 25 (6), pp.609-619.

World Economic Forum Report (2015) Industrial Internet of Things: unleashing the potential of connected products and services. Available from: https://www3.weforum.org/docs/WEFUSA_IndustrialInternet_Report2015.pdf [Accessed 23rd October 2022].

Zhou, Y., Miao, Z., and Urban, F. (2020) China's leadership in large hydropower. Industrial and Corporate Change, 29 (5), pp. 1319-1343.

Zook, M. A. (2004) The knowledge brokers: Venture capitalists, tacit knowledge and regional development. International Journal of Urban and Regional Research, 28 (3), pp. 621–641. Available from: https://doi.org/10.1111/j.0309-1317.2004.00540.x [Accessed 22nd October 2022].

9.

Annexes

Annexes

9.1 Annex 1 – Sample size calculation

- **Overall sample sizes** for both firm level and sectorial system of innovation surveys are determined by the degree of stratification of the sample. The overall sample size depends on the decision of the sample size for each level of stratification.
- **Determining the desired sample size**: Desired sample size from a particular state, which will represent the population (total production units), is calculated through the formula developed by Cochran (1963).

  $$SS = \frac{Z^2 * p * (1-p)}{e^2}$$

  Where:

  Z = Z value (e.g., 1.96 for 95% confidence level)
  p = percentage picking a choice, expressed as decimal (.5 used for sample size needed)
  e = margin of error, expressed as decimal (e.g.,.05 = ± 5%)
- **Margin of Error** – It is defined as the range of values below and above the sample statistic in a confidence interval. It is a measure of the variability of sample statistics, and it is used to indicate the level of precision of the sample estimate. It is typically expressed as a percentage of the total sample size and is calculated by taking the standard deviation of the sample and dividing it by the square root of the sample size. Margin of error for the sectorial survey sampling is ± 5%.
- **Confidence Level** – It is the proportion of sample, which will represent the population, given the level of precision or confidence interval. A 95% level of confidence has been taken, which shows that 95 out of every 100 samples will have true population value within the level of precision.
- **Correction for Finite Population**: If the population is small then the sample size can be reduced slightly. This is because a given sample size provides proportionately more information for a small population than for a large population. The sample size obtained for different states is based on the formula –

  $$New\ SS = \frac{SS}{1 + \frac{SS - 1}{pop}}$$

  Where: pop = is the number of production units in a state (finite population)

A convenient sample was chosen for each actor category and contact details were verified through the ASI and CMIE databases.

9.2 Annex 2 – NIC code classification

NIC 2008 Codes & Its Description (Divisions and Groups)	
Division 21	**Manufacture of pharmaceuticals, medicinal chemical, and botanical products**
Group 210	Manufacture of pharmaceuticals, medicinal chemical, and botanical products

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Vienna International Centre
Wagramerstr. 5, P.O. Box 300,
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