PATIENT SAFETY AND ACCESS INITIATIVE OF INDIA FOUNDATION
a Partnership for Safe Medicines India Initiative

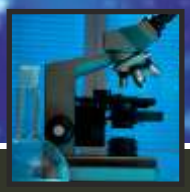
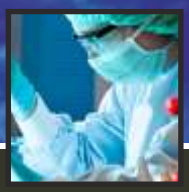
PARTNERSHIP TO FIGHT CHRONIC DISEASE

IAPG INDIAN ALLIANCE of patient groups

REPORT ON

A Multi-Stakeholder Roundtable

held on 4th August, 2017

Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World

Released on
13th June, 2018
New Delhi, India

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Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World
A Multi-Stakeholder Roundtable

Friday, August 4, 2017, New Delhi, India

Convened by
Patient Safety & Access Initiative of India Foundation (PSAIIF)
in collaboration with the
Partnership to Fight Chronic Disease (PFCD) and the
Indian Alliance of Patient Groups (IAPG)

Chair: Prof. N.K. Ganguly, former Director General,
Indian Council of Medical Research (ICMR)

Co-Chairs:
Mr. Wajahat Habibullah, Chairman and
Prof. Bejon Kumar Misra, Founder Director, PSAIIF

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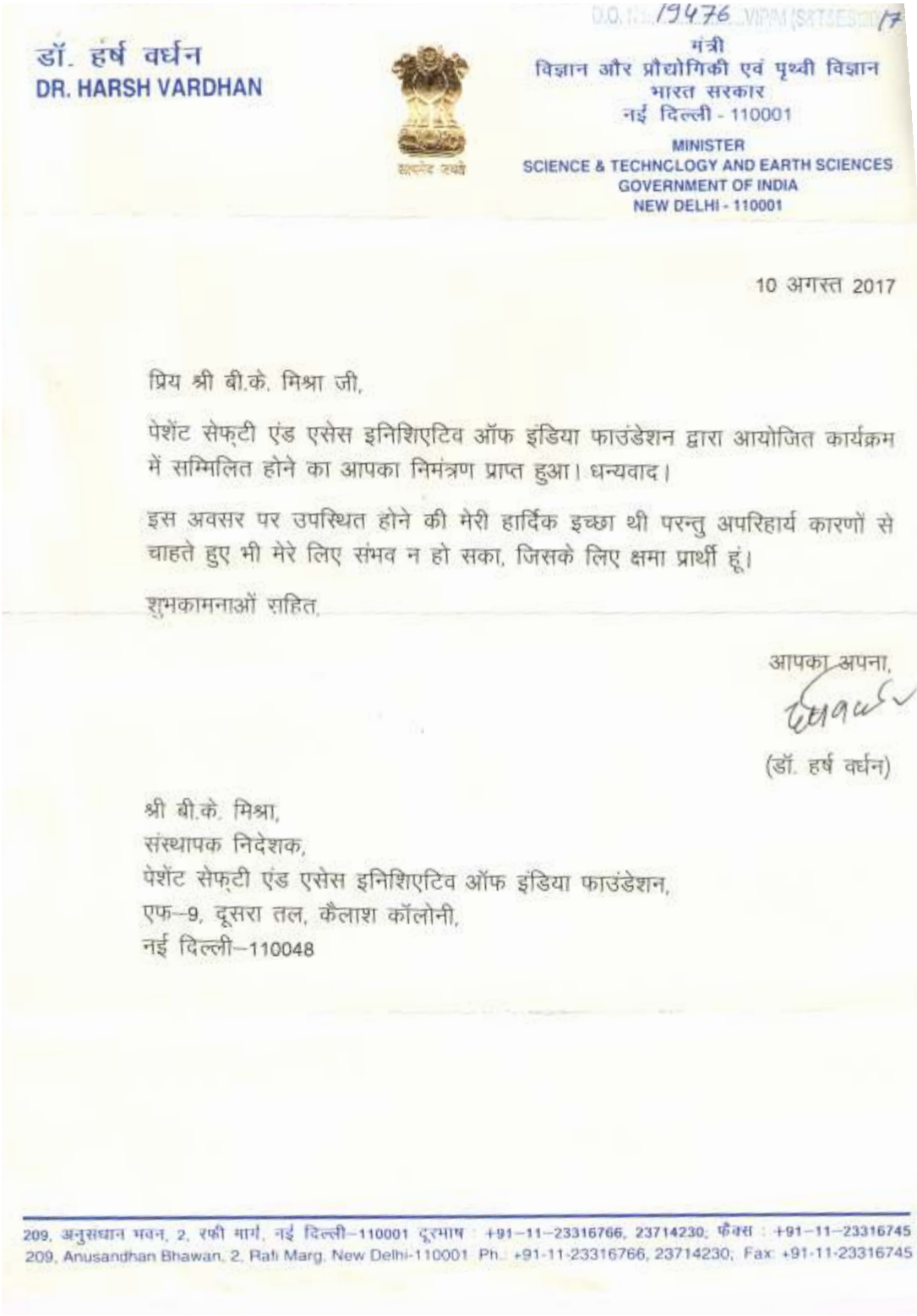

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डॉ. हर्ष वर्धन
DR. HARSH VARDHAN

मंत्री
विज्ञान और प्रौद्योगिकी एवं पृथ्वी विज्ञान
भारत सरकार
नई दिल्ली - 110001

MINISTER
SCIENCE & TECHNOLOGY AND EARTH SCIENCES
GOVERNMENT OF INDIA
NEW DELHI - 110001

10 अगस्त 2017

प्रिय श्री बी.के. मिश्रा जी,

पेशेंट सेफ्टी एंड एसेस इनिशिएटिव ऑफ इंडिया फाउंडेशन द्वारा आयोजित कार्यक्रम में सम्मिलित होने का आपका निमंत्रण प्राप्त हुआ। धन्यवाद।

इस अवसर पर उपस्थित होने की मेरी हार्दिक इच्छा थी परन्तु अपरिहार्य कारणों से चाहते हुए भी मेरे लिए संभव न हो सका, जिसके लिए क्षमा प्रार्थी हूं।

शुभकामनाओं सहित,

आपका अपना,

(डॉ. हर्ष वर्धन)

श्री बी.के. मिश्रा,
संस्थापक निदेशक,
पेशेंट सेफ्टी एंड एसेस इनिशिएटिव ऑफ इंडिया फाउंडेशन,
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नई दिल्ली–110048

209, अनुसंधान भवन, 2, रफी मार्ग, नई दिल्ली–110001 दूरभाष : +91–11–23316766, 23714230; फैक्स : +91–11–23316745
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Message

Amitabh Kant, CEO

NITI Aayog, Government of India
New Delhi

I am happy to learn that a Multi-Stakeholder Roundtable on "Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World" was convened by the Partnership for Safe Medicines (PSM) India Initiative on 4th August 2017.

India has made rapid strides on Health outcomes over recent decades. However, these outcomes have not kept pace with economic development over the same period. At the national level, there has been a significant decline in infant mortality, maternal mortality and total fertility ratesbut, the inter-state variations remain a matter of great concern. There is a need to bring about transformational change in the sector through a multi-pronged approach.

The National Health Policy-2017 (NHP-2017) announced by the Government of India, envisages attainment of the highest possible level of health and wellbeing for all at all ages, through a preventive and a supportive health care orientation and universal access to good quality health care services without anyone having to face financial hardship as a consequence.

India has an array of national laboratories having great potential for carrying out high quality research and development in the medical sciences arena. Recognizing the need to encourage and support innovators, the government has rolled out many initiatives such as Startup India, Atal Innovation Mission. Steps have also been taken to streamline the procedures to reduce significantly the time taken for obtaining regulatory approvals and IP registrations.

I would like to congratulate the Partnership for Safe Medicines (PSM) India Initiative for bringing Multi-Stakeholders together over a Roundtable in Delhi to create this report and suggest the best way forward for unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care accessibility.

Preface

Prof. Bejon Kumar Misra, Founder
Patient Safety & Access Initiative of India Foundation
New Delhi, India

Pharmaceutical research does not end once a medicine is approved by the Drug Regulatory Authority; it is built upon to improve outcomes for patients, simplify treatment regimens and monitor safety. World over, the biopharmaceutical research companies are committed to a dynamic research ecosystem that delivers safe and efficacious treatments to patients. I am happy that PSM India has published a report to explore how far we in India have advanced in fighting disease.

As an example, in recent decades, tremendous progress has been made in the fight against cancer. Continued research has expanded our knowledge of how the disease develops and how medicines can target specific cancer types – resulting in more effective therapies for patients. Biopharmaceutical companies are developing medicines and vaccines for cancer, which are in clinical trials or awaiting review in various corners of the world. Personalized cancer treatment protocols are being developed that make treatment regimens more effective and cost efficient. Blocking immune checkpoints with targeted monoclonal therapies and immuno-adjuvants have improved patient outcomes by improving specificity of the intervention. Is India at par with the world in innovation and what should be our vision in the interest of patients? I firmly believe that biopharmaceutical innovation and new drug discovery delivers far-reaching benefits to patients, improving health care systems and national economies by enabling patient access to medicines, for preventable disease. New cancer medicines, discovered and developed by biopharmaceutical research companies, are helping patients lead longer, more productive lives, controlling healthcare costs and stimulating economies. It has been clearly established that new medicines help hold down future healthcare costs – improving patient outcomes and yielding economic savings. Data, from 30 developed and developing countries, demonstrate the powerful impact of pharma innovation on longevity, productivity, and medical expenditure. Why should Indian Patients be denied such innovation?

It is time for us to revisit the Indian thought process around investment on innovation and research. It is time to examine the research on how the top innovative countries maintain their research potential. It is also an opportune time for us to reassess our regulatory pathways such that maximum experimental therapies that meet global standards are accessible to Indian citizens. The time is right for leveraging new technologies and the growing scientific understanding of many rare diseases, to develop groundbreaking therapies for the poor in India and other developing countries. India has the potential to take a leadership role in the world, to encourage innovation in the interest of the patients and operationalise the process of discovery in the area of biopharmaceutical research.

Foreword

Prof. N.K. Ganguly

Former Director General,
Indian Council of Medical Research (ICMR)

Only a healthy nation can aspire to be a prosperous nation. Although India has made rapid strides towards the United Nation's Millennium Development Goals, for child survival and the reduction in maternal mortality, there is still much to do. The social and economic disparities are increasing where few can afford health or education and millions are still deprived of even the basic necessities of sanitation, nutrition and healthcare.

India is recognized as the pharmacy to the world, for our generic medicines capability, but we are yet to make a mark in biopharmaceutical innovation. It is time for India to harness its capabilities and unlock its potential for Biomedical Science and innovation. We need to increase the investment, create the policy and make the administrative effort required for meaningful innovation. We have the ability to extend 'Make in India' to 'Innovate in India'. Our scientists and universities should also be incentivized so that we attract the brightest minds to carry out cutting-edge research in priority areas, especially in the health sector.

We need a strong intellectual property (IP) framework that respects and protects IP rights, encourages research and helps commercialize innovation to translate research output into products of value. We need to promote and build upon the basic research without which no innovation can be created. Innovation is the key to progress and for the country to become a developed economy. Emphasis on training and research requires substantial funding. Faculties in universities should be adequately funded to carry out research and all teachers should be provided opportunities for continued education to increase their knowledge base.

In the Health and Education sectors, the Centre and State have independent roles. We need to see common threads where the state and central governments work closely to ensure alignment and streamline mechanisms. Central and State governments are now working together to increase IP awareness, run teaching programs and create Technology & Innovation Support Centres to provide support in state institutions. Several states are also conducting training programs on encourage effective IP enforcement. These are all commendable steps.

Pro-innovation policies in India will help to advance the development of innovative medicines and offer new hope to Indian patients. Life-saving drugs are necessary to cure deadly diseases, but patients also need new drugs and solutions for evolving disease profiles. It is our sincere hope that our recommendations and an integrative approach will lead us on the path of progress, bringing innovation-driven cures to patients and contributing to the Prime Minister's vision of a modern and developed India.

Executive Summary

The Patient Safety & Access Initiative of India Foundation (PSAIIF) convened a Multi-Stakeholder Roundtable on *"Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World"*, in New Delhi, on August 4, 2017. The event was chaired by Prof. N.K. Ganguly, former Director General of the Indian Council of Medical Research (ICMR) and co-chaired by Mr. Wajahat Habibullah, Chairman and Prof. Bejon Kumar Misra, Founder Director of PSAIIF.

The intent of the Roundtable was to deliberate on the state of biomedical science and biopharmaceutical innovation in India, to better understand why the country has not realized its true research potential, even 70 years after Independence and despite some of the world's finest scientific minds originating here. Patients have yet to see a truly innovative 'made in India' medicine, and there is great concern that our science in the biomedical and biopharmaceutical field is lagging. This gap is particularly evident against the backdrop of ongoing global advancement in cutting edge research and the constant discovery of newer medicines to detect, treat and cure ever more complex diseases. The lack of innovation in India is even more stark in a sector where India is lauded for its generic medicines industry, commonly hailed as pharmacy to the world and perceived as a leader in the pharmaceutical and biomedical sector. While India leads in the production of quality generic pharmaceuticals, it is yet to develop a strong, research-based pharmaceutical industry that can produce innovative medicines.

Dr. Ganguly expressed the sentiment that for research and new discoveries to translate into the required health products, a strong infrastructural framework is needed, wherein the public and private sectors work in tandem to develop synergies. A health-care ecosystem is required that offers positive investment returns and ensures patent rights for inventors, while keeping the cost of innovation in check through a supportive policy environment. To bolster investor confidence in the Indian market, the country needs an Intellectual Property Rights (IPR) framework which offers predictability, clarity and transparency. A world-class drug regulatory framework, implemented by strong drug regulatory authorities, is imperative to reap the benefits of innovation. India's policies must value new biomedical innovation and incentivize continued investment in research and development. At the same time, India must have greater transparency in approval procedures for clinical trials, to ensure early access to life-saving drugs of a high standard.

The objective of the Roundtable was to generate a healthy discussion among an assembly of diverse stakeholders, all concerned with the state of bio-pharmaceutical innovation in India. The gathering included several luminaries from the Government of

India, as well as notable experts from industry, academia and the non-government sector (please see list of participants). The goal was to identify the gaps in our research ability and to emerge with a set of directional recommendations, for the Government of India, on the actions required to bridge those gaps. Clearly, India has the potential –the capacity, the talent pool and the resources – to step up its bio-pharmaceutical innovation and to take its rightful place on the world's R&D platform. India now needs to bolster this with the will, the vision and a sense of priority.

priority. Then the Roundtable was centered on two in-depth presentations:

First presentation from the Institute for Competitiveness: Dr. Amit Kapoor presented the broader context for innovation. He talked about where India is positioned on research investment, vis-à-vis other countries and the relationship between Innovation and Competitiveness. He noted that India continues to be ranked low on the Global Intellectual Property Center's (GIPC's) international Intellectual Property Rights (IPR) index and we do not fare well as patent-holders. He then narrowed in to consider innovation and competitiveness between Indian states and made a strong case for innovation to strengthen the economy.

Second presentation from PricewaterhouseCoopers (PwC): Sujay Shetty presented the PwC findings from a recently concluded project where a dedicated research team worked for several months to interview numerous stakeholders, on what was required to unlock India's innovation potential. The stakeholders represented diverse groups ranging from government, industry and academics to research centers and funding

institutions. The findings were used to define the specific policy changes needed in India.

Each presentation was followed by moderated panel discussions, as well as frank and animated opinions from the roomful of expert participants. Findings were questioned, assumptions were tested and suggestions were made. It was unanimously acknowledged that India can and must do better. It was uniformly agreed that the Government of India should make a concerted effort to incentivize innovation and to help unlock the tremendous potential in India's biopharmaceutical sector. There was also a good deal of discussion around innovative Indian approaches in addressing India's public health challenges. How can this inventive Indian spirit and determination, which has resulted in some note-worthy successes, be tapped to bring the transformative new innovation in biopharmaceuticals that can benefit India, while addressing unmet medical needs around the world?

India is credited with supplying 20% of the world's generic drugs and generic drug manufacture is a flourishing Indian industry. The country also produces 80-90% of Expanded Program on Immunization (EPI) vaccines around the globe. Indian hospitals and medical practitioners are among the best in the world and Indian doctors form the backbone of many health services systems, in developed and developing countries. Many Indian companies produce world-class generic medicines and deliver the benefits of their low cost medicines to those that most need them.

It is time now for the Indian pharmaceutical industry to expand its horizons and build further upon its reputation. A comparison of India with the established pharmaceutical innovation leaders (the US, UK, and Japan) as well as with countries that have more recently moved up the innovation ladder (Republic of Korea, China, and Singapore) shows that India's innovation ecosystem still needs to bridge several gaps. It is important to study the environment and understand the challenges faced by innovators and to take immediate steps to address these challenges. It is particularly important to identify and rectify the weaknesses in our IPR system, more than a decade after product patents were recognized. It is worth noting that China has overtaken us in strengthening its patent system and encouraging pharmaceutical innovation. They have increased their patent reviewers from 100 to now almost 2000 (the US FDA has triple that number). In addition to strengthening the IPR environment, we also need to visit several policy-related issues. Addressing these concerns will make India more competitive and attract more investment.

Considerations and Recommendations, to Bolster Biomedical & Biopharmaceutical Innovation in India

This report from the Multi-Stakeholder Roundtable on "Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World", convened on August 4, 2017, attempts to frame the discussionin a way that reiterates and reinforces the need for pro-innovation policies, to foster innovation in the biomedical and pharmaceutical sciences. The discussion was informed by the work already done by the Institute for Competitiveness and PricewaterhouseCoopers and both these organizations had representation at the Roundtable. Two primaryrecommendationsemerged from the deliberations, which demand priority from the Government of India:

I. Increase sectoral competitiveness through a more robust IPR regime

Innovation is important from several perspectives and an important aspect is that of economic growth. Innovation also helps companies overcome problems and deliver benefit to consumers. Technological innovation is the basis for growth and competitiveness among nations. Several countries have invested in research and have benefitted in the long term from the growth and development of industries around their inventions.At the forbio-pharmaceuticals sector level, India's decision to sign the TRIPS agreement certainly made it a more attractive destination for the innovative global pharma companies. Their entry generated jobs, brought focus on quality and helped the

Recommendations

Indian industry become globally competitive. Greater competitiveness promotes greater productivity and results from an interlinked system. However, for competitiveness to increase, our policies must engender greatertrust.

India needs a robust and transparent IPRsystem that is predictable and abides by the rules. Patents provide incentive for companies to invest in the creation of new solutions and are of strategic importance in innovative sectors. The state must play a supportive role to ensure that patentable medical innovation can be linked with affordable treatments. Increased competition, a weak patent system and poor IPR protection act as disincentives to innovators. Companies are reluctant to incur the additional cost of gaining access to markets if they run the constant risk of patent violations. Currently, only 5% of the medicines used in India are patent-protected.Today, India has over three million cancer patients and one in every 13 cancer patients is Indian. However, only seven new cancer drugs have entered India in recent years,though over 50 breakthrough therapies have been made available globally.

India needs to act on the commitments it has laid down in the National IPR Policy, in both letter and spirit, if we are to unleash our research potential and bring about a congenial environment that enables discovery. The bright promise of an innovative Indian biopharmaceutical industry will only be fulfilled if we create an ecosystem that promotes and rewards innovation. It would be a great pity if India, with its enormously successful generic pharma industry, does not contribute to future innovation in new medicines simply because we are unable to address the systemic pitfalls. We need a balance between the current and future needs of patients and the timely introduction of existing as well as new pharmaceutical drugs.

II. Strengthen the pharma innovation ecosystem across four key dimensions

It is important to foster better cooperation and collaboration among the many stakeholders that contribute to building a vibrant, innovation-driven pharmaceutical

Recommendations

industry in India – government, industry, academia, financial institutions and communities of medical professionals. The innovations resulting from this multi-stakeholder and multi-dimensional framework, will lead to improvement in the health and wellbeing of patients across India.

The report[1] by PwC presents a vision for an innovative pharmaceutical industry in India, showing how an innovative ecosystem can improve the health and productivity of patients in India and around the world. Such an environment would also generate economic benefits by making India an attractive destination for R&D investment, creating more jobs and driving research output of global significance. Thereport provides an achievable policy road map to guide policymakers and industry. The recommendations from the study highlight four areas of focus – infrastructure, financing, human resources, and legal & regulatory – toenable the growth of a domestic innovative pharmaceutical industry with global significance.

Infrastructure

- Strengthen R&D centers and biotech clusters by establishing a single body accountable for the performance of public research centers and facilitate better tech-transfer infrastructure and collaboration among academia, research centers, and industry.
- Bolster clinical trial infrastructure by developing specific courses in clinical trials, improved infrastructure in hospitals and increased public investment.

[1] PricewaterhouseCoopers, Vision 2025: Unlocking India's potential for leadership in pharmaceutical innovation, October 2016, available at: http://www.pwc.in/assets/pdfs/vision-2025-unlocking-indias-potential-for-leadership-in-pharmaceutical-innovation.pdf, last retrieved: 23 September 2017.

Recommendations

- Improve the availability of data for research, enabled through implementation electronic health records (EHR) standards and certification of EHR products

Financing

- Increase the types of R&D financing resources to encourage and support an increase in pharmaceutical research. This can be achieved through various financing schemes such as subsidies for start-ups focusing on R&D, increased limits for grants/loans and tax incentives, among others.
- Adopt health care financing policies that improve coverage for primary health care and increase penetration of health insurance programs, which will enable growth, access to and use of pharmaceutical innovation.

Human Resources

- Improve the education and skills level of the workforce to meet the needs of the domestic and global pharmaceutical industry, by introducing new national training programs with expanded access to grants and scholarships.
- Enhance incentives to attract and retain scientific talent, both from foreign institutes and individual scientists and researchers.

Legal and Regulatory framework

- Develop robust and effective IPR policies and laws, by establishing specialized IP courts, streamlining administrative processes to file patents and removing barriers to patentability.

Recommendations

- Develop guidelines to facilitate knowledge and technology transfer to bridge the gaps between the discovery, development and commercialization of innovative drug products.
- Strengthen the regulatory framework, to streamline and expedite the development and launch of new products, that are benchmarked with internationally available practices; and increase resources for the regulatory agencies.

Bio-pharmaceutical innovation and new drug discovery delivers far-reaching benefits to patients, improving health care systems and national economies by enabling patient access to medicines. New cancer medicines, discovered and developed by global bio-pharmaceutical research companies, are helping patients lead longer and more productive lives, controlling healthcare costs and stimulating economies. It is clearly established that new medicines help hold down future healthcare costs – improving patient outcomes and yielding economic savings. Data, from 30 developed and developing countries, demonstrate the powerful impact of pharmaceutical innovation on longevity, productivity, and medical expenditure.

It is time for India to revisit the thinking around investment on innovation and research. It is time to examine how the top innovative countries maintain their research potential. It is also an opportune time to reassess our regulatory pathways such that maximum experimental therapies that meet global standards are accessible to Indian citizens. The time is right for leveraging new technologies and the growing scientific understanding of many diseases, to develop groundbreaking therapies for patients. India has the potential to take a leadership role in the world, to encourage innovation in the interest of patients and operationalize the process of discovery in the area of bio-pharmaceutical research.

Agenda

Time	Event
08:30 – 09:00	**Registration/coffee**
09:00 – 10:00	**Inaugural Session** Welcome and Introductions – Mr. WajahatHabibullah, Chairman, PSM India Initiative & Mr. L. Mansingh, Chairman, Consumer Online Foundation Objectives of the roundtable – Prof. N.K. Ganguly, former Director General, India Council of Medical Research Setting the Context: *India and the Biomedical and Biopharmaceutical Innovation Today and Vision for the Future* • Dr. Harsh Vardhan, Union Cabinet Minister, Ministry of Science & Technology • Mr. Amitabh Kant, CEO, NITI Aayog • Dr.RandeepGuleria, Director, AIIMS, New Delhi • Dr. G. N. Singh, Drugs Controller General India • DR. K. V. SurendraNath, Senior Vice President - Global Sites, United States Pharmacopeial Convention, • Dr. K.K. Aggarwal, President, Indian Medical Association • Dr. Vinod Kumar Paul, Dept. of Pediatrics, AIIMS, New Delhi
10:00 – 10:15	**Tea Break**
10:15 – 11:15	**Panel I: *Innovation Performance in India Today: Global, National and State Perspectives*** **Presenter:** Dr. Amit Kapoor, CEO, India Council on Competitiveness **Moderator:** Dr. Ali Mehdi, Project Leader, Health Policy Initiative, ICRIER **Discussants:** • Dr. Sreesha Srinivasa, Associate Vice President, R&D and Head, Translational Sciences, Biocon • Mr. Neeraj Sinha, Scientist G/Advisor, Office of the Principal Scientific Advisor to the Prime Minister, Government of India **Roundtable discussion**

Agenda

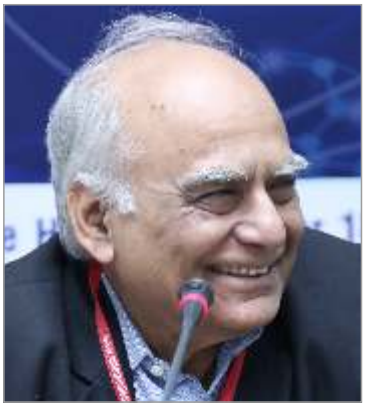
11:15 – 12:15	**Panel II:** ***Drivers of Innovation –What Stakeholders in India Say is Needed***
	Presenter: Mr. SujayShetty, Partner and Leader, Pharmaceuticals and Life Sciences, Pricewaterhouse Cooper
	Moderator: Ms. Ranjana Smetacek, Senior Advisor, Albright Stonebridge Group
	Discussants:
	• Dr. Vijay Chandru, Chairman & Managing Director, Strand Life Sciences
	• Mr. Vishal Gandhi, Founder & CEO, BioRx Ventures
	Roundtable Discussion
12:15 – 12:30	***The Patient Perspective on Biomedical Science and Innovation***
	• Dr. Ratna Devi, CEO, DakshamA Health and Founder, IAPG
	Key takeaways and the way forward
	• Dr. Vinod Kumar Paul, Chair, Dept. of Paediatrics, AIIMS, New Delhi
	• Mr. Bejon Misra, Founder, PSM India
12:30 – 13:30	**Lunch**

Important Participant Profiles

Dr. Vinod Kumar Paul

Member, NITI Aayog,
Government of India

Dr. Vinod Paul is a Professor and Chair of the Department of Pediatrics at the All India Institute of Medical Sciences (AIIMS), New Delhi. He leads the WHO Collaborating Centre on Newborn Health for South East Asia Region; and the Centre for Advanced Research in Newborn Health (Indian Council of Medical Research). He is also a visiting professor at the Public Health Foundation of India. Dr. Paul is the recipient of the highest award of the Indian Council of Medical Research (ICMR), namely, the Dr. B. R. Ambedkar Centenary Award for Excellence in Biomedical Research. He was recently conferred the Public Health Champion Award by WHO India.



Prof. N.K. Ganguly

Former Director General,
Indian Council of Medical Research
(ICMR)

Prof Nirmal K. Ganguly is Advisor, Translational Health Science and Technology Institute and President, Jawaharlal Institute of Post Graduate Medical Education and Research in India. He is a former Director General of the Indian Council of Medical Research. Prof. Ganguly has published numerous papers and guided doctoral projects. His major research areas are tropical diseases, cardiovascular diseases and diarrhoeal diseases. Prof. Ganguly has won numerous national and international awards and since 2008, is a recipient of the prestigious "Padma Bhushan" award in the field of 'Medicine'.

Important Participant Profiles

Mr. Wajahat Habibullah

IAS (Retd.)
Chairman, PSM India Initiative

Wajahat Habibullah is the Chairman of PSM India Initiative. Earlier, he was the Chairperson of the National Commission for Minorities. Prior to this, he held the position of the first Chief Information Commissioner of India. He was an officer of the Indian Administrative Service (IAS) from 1968 until his retirement in August 2005. He was also Secretary to the Government of India in the Ministry of Panchayati Raj (Local Government). He has been awarded with Rajiv Gandhi Award for Excellence in Secularism -1994 Gold Medal for Distinguished Service.

Mr. L. Mansingh

IAS (Retd.), Former Chairperson,
Petroleum and Natural Gas Regulatory Board,
India

L. Mansingh, 1970 batch of the Indian Administrative Service of the Gujarat cadre. He was Secretary to Government of India in the Ministry of Consumer Affairs, Food & Public Distribution, Department of Consumer Affairs. He was Director General of Foreign Trade. He was Under Secretary and Deputy Secretary in the Ministry of Commerce looking after Indo-US Trade, engineering and project exports. He was Joint Secretary (Industrial Policy) in the Department of Industrial Development in charge of Secretariat for Industrial Approvals (SIA).

In Government of Gujarat, Shri Mansingh has worked in various capacities. He was appointed as the first Chairperson of Petroleum and Natural Gas Regulatory Board.

He now functions as a self-employed consultant engaged in rendering advisory and consultancy at the level of Govt. of Gujarat and Govt. of India.

Important Participant Profiles

Meenakshi Datta Ghosh

IAS (Retd.)
Former Secretary to the Government of India

Ms. Meenakshi Datta Ghosh, a career civil servant, has close to 40 years of professional experience in public management and administration. While focusing on improving the process as well as the outcomes for sustainable development, she has addressed diverse aspects of G to C [Government to Citizen] service delivery (policy and program, project and program development, implementation and evaluation). Ms. Ghosh has made very significant contribution across the social sector, with reference to population stabilisation and gender justice, maternal and child health, prevention and control of HIV/AIDS, urban local government, rural local government, and public grievance redressal.

Education: Meenakshi Datta Ghosh holds an M. Phil. In Social Sciences; a Masters' in Public Administration, from Harvard Kennedy School (HKS), Cambridge MA, USA; a Masters in Sociology (Delhi School of Economics), University of Delhi; a Bachelor In History (Hons.), Fergusson College, Poona University; and Diplomas in Russian and French. She speaks Hindi, English, Punjabi, Bengali, Marathi, Tamil, and French.

Dr. Randeep Guleria

Director, AIIMS, New Delhi

Randeep Guleria is the Director of All India Institute of Medical Sciences, New Delhi. He is a pulmonologist and the Head of the Department of Pulmonology and Sleep Disorders at AIIMS. He is credited with the establishment of India's first centre for pulmonary medicines and sleep disorders at AIIMS. Dr. Guleria is the first Indian to get a Doctorate of Medicine (DM) in Pulmonary and Critical Care Medicine. Dr. Guleria was conferred with the prestigious "Padma Shri" Award in 2015 by the President of India and recently with "Dr. B.C. Roy Award in the category Eminent Medical Person" for the year 2014.

Important Participant Profiles

Prof. Bejon Kumar Misra

International Consumer Policy Expert
Visiting Professor, Institute of Management (BHU), Varanasi

Awarded the "Distinguished Alumni Award" 2012 by the Institute of Management, BHU. Award Winner of World No-Tobacco Day 2013; from the South-East Asia Region of World Health Organisation (WHO). At present Governing Board Member of the Quality Council of India (QCI), Board Member of National Accreditation Board for Hospitals & Healthcare Providers (NABH) and National Accreditation Board for Education and Training (NABET). Former Member of the Food Safety and Standards Authority of India (FSSAI); At present a Member of the Central Advisory Committee (CAC) of FSSAI; Adviser to the Government of Odisha on Consumer Friendly Interventions. Senior Advisor to Alliance for Safe Online Pharmacies (ASOP), a global network in Washington DC, India Chapter. Founder Publisher: of an English Monthly Consumer Magazine; THE AWARE CONSUMER. Founder Board Member of Consumer Online Foundation, Partnership for Safe Medicines (PSM) India Initiative; Healthy You Foundation and Patient Safety and Access Initiative of India Foundation.

Dr. Rakesh Kumar Srivastava

Former Director General, Health Services, Government of India

Former Senior Policy Analyst at NIHFW, Former Chairman, Medical Council of India, Former Director General of Health Service, Ministry of Health & Family Welfare, Government of India. At present, advising WISH FOUNDATION on public health innovation and how it can be applied in Indian public health care to improve its efficiency and quality. He was also working with Indian Council of Medical Research for establishing a national rehabilitation and disability research system, so that research evidences can be systematically generated, disseminated, compared and compiled as data base for complementing national public health programme, which directly/ indirectly deals with disability. He was also involved with networking with 25 state medical councils in India, so that Live Indian Medical Register can be established and online medical registration is put up in place. As DGHS, he was involved with all public health emergencies, programmes, hospitals, human resource for health, medical equipment and diagnostic kits, surveillance protocols and monitoring and evaluation of all health related activities in India.

Important Participant Profiles

Dr. K.K. Aggarwal

Former President,
Indian Medical Association

Dr. Krishan Kumar Aggarwal is currently the National President of the Indian Medical Association (IMA) and is also a Senior Consultant Physician and Dean Board of Medical Education MoolchandMedcity. He is a creative writer and pioneer in medical journalism. He is a prolific writer on community health subjects. He regularly sensitizes public on Do's & Don'ts on prevention. He has contributed over 400 articles in newspapers and magazines and appearances in Radio & TV talks on health. He is one of the most quoted doctors in the field of health and has been quoted over 12,000 times in the national media. He is also the Editor-in-Chief of the IJCP Group of Publications - with over 30 journals, newspapers and health care educational products catering to doctors. He is the winner of the prestigious award Padma Shri and Dr. B C Roy National Award as well.

Dr. G. N. Singh

Former Drugs Controller General
of India

Dr. Gyanendra Nath Singh has been given additional charges of the Drug Controller General of India (DCGI). Dr. G. N. Singh established Indian Pharmacopoeia Commission (IPC) in the year 2009 with aim to set and promote quality standards for drugs and pharmaceuticals in the country. Apart from handling the responsibilities as the DCGI of the country, he also handles the responsibilities of IPC as the secretary-cum-scientific. Dr. Singh also served/ serving as a member of various national and international committees, to name few- Drugs Technical Advisory Board, Drugs Consultative Committee, Expert Core Committee of National List of Essential Medicines, Pharmacy Council of India, Expert Core Committee of National List of Essential Medicines as well as advisory boards of various academic institutions.

Important Participant Profiles

Mr. Neeraj Sinha

Scientist G/Advisor, Office of the Principal Scientific Advisor to the Prime Minister, Government of India

Mr. Neeraj Sinha is in the Office of the Principal Scientific Adviser to the Government of India. He has over 25 years of varied experience of working in scientific organizations of the Government of India. He has been involved in a wide cross-section of scientific activities. Mr. Sinha has actively contributed to the preparation of the National Action Plan on Climate Change, which was released by the Prime Minister of India on the 30th of June 2008. He has co-authored more than 20 scientific papers on this subject and is a life Member of the Institution of Engineers (India) and the Administrative Staff College of India, Hyderabad.

Dr. Shakti Kumar Gupta

Medical Superintendent,
Dr R P Centre, AIIMS

- MBBS from Govt. Medical College, Jammu.
- Masters in Hospital Administration from AIIMS.
- WHO Fellowship from USA.
- Management Development Programme from National University of Singapore.
- Professor and former HoD, Department of Hospital Administration, AIIMS.

AWARDS

- PRATIBHASHI SAMMAN–2002
- CHIKITSA RATAN – 2010
- SHRAM SREE-2010
- International Partner of the Year Award, University of Applied Science Germany.
- The State Award for meritorious public service on the eve of Republic Day by Jammu & Kashmir Government (2014).

Authored eight books in Hospital Administration.

Important Participant Profiles

Dr. Amit Kapoor

CEO, India Council on Competitiveness

Dr. Amit Kapoor is the President & CEO of India Council on Competitiveness and is also the Honorary Chairman at Institute for Competitiveness, India and Editor-in-Chief of Thinkers. He is the chair for the Social Progress Imperative and Shared Value Initiative in India and sits on the board of Competitiveness initiatives in Mexico, Netherlands, Italy & France and University of Vermont's SEMBA Advisory Board. Dr. Amit is the author of several state competitiveness reports. Based on his work, three awards have been constituted within the country titled State Competitiveness Awards by Mint & Hindustan Times wherein the Chief Ministers are awarded; City Competitiveness Awards by ABP wherein City Heads are awarded and Institute for Competitiveness ¬Mint Strategy Awards wherein the corporates are awarded for their strategic acumen.

Dr. Sreesha Srinivasa

Associate Vice President, R&D and Head, Translational Sciences, Biocon

Dr. Sreesha Srinivasa is Associate Vice President, Research and Development at Biocon Research Limited. He is having 20 years of global experience in drug discovery and development. He has a successful track record of developing strategies, teams and organizations. Apart from all these achievements, he has seen delivering clinical candidates, progression through clinical development and approval.

Important Participant Profiles

Dr. Ali Mehdi

Project Leader, Health Policy Initiative, ICRIER

Dr. Ali is a Fellow at Indian Council for Research on International Economic Relations (ICRIER), and has been associated with the institute since 2007. He established the Health Policy Initiative at ICRIER in 2014, and has been leading it since.

He has more than 10 years of analytical and multidisciplinary research experience, focusing on a broad range of health and demographic issues – the process, design and analytical frame for assessment of health policies; prevention of chronic diseases along with the policy instruments and institutional design for its promotion; social determinants of health; the metrics and measurement of health inequities; health financing, governance and manpower; fertility and mortality patterns; demographic dividend; drug regulation; etc.

Mr. Sujay Shetty

Partner and Leader, Pharmaceuticals and Life Sciences, PwC

Mr. Sujay Shetty is the Pharma, Life sciences and Medical Devices sector leader for PwC India, based out of Mumbai. He is a member of the Global Pharma Leadership team of PwC. Mr. Sujay is a member of the Vision group for biotechnology for the state of Karnataka. He is an Executive council member of Association of Biotechnology Led enterprises (ABLE). Mr. Sujay has over 20 years of industry experience in the Pharmaceutical & Medical Devices industry in India, US, UK & South-East Asia. He has led four international companies at the board level (three of which were in the Pharma / Medical device industry) including two startups where he was responsible for leading senior management teams & creating & executing corporate strategy.

Important Participant Profiles

Dr. Vijay Chandru

Chairman & Managing Director,
Strand Life Sciences

Vijay Chandru is an academic turned entrepreneur. A professor of computational mathematics first at Purdue University and then Indian Institute of Science, Vijay is a fellow of the national academies of science and engineering in India. A Technology Pioneer of the World Economic Forum since 2006, Vijay has been on the global agenda council for the future of healthcare at WEF for 2014-2016. He is a founder and former Honorary President of ABLE (the apex body for the biotechnology industry in India) from 2009-2012 and continues as a special invitee to the executive council. As an entrepreneur, Vijay leads the new generation healthcare company Strand Life Sciences. Since 2007, Strand has been a global leader in bioinformatics products licensed to over 2000 research labs and hospitals worldwide. With a team of over 200 high calibre scientists, Strand is leading the charge in precision medicine in India with over 300 referring hospitals and clinics. Strand has the only CAP and ISO 15189 accredited lab for clinical genomics using NGS technologies in South Asia.

Mr. Vishal Gandhi

Founder & CEO, BioRx Ventures

Mr. Vishal Gandhi is the Founder and CEO of BIORx Venture Advisors Pvt Ltd (BVA) and leads an accomplished team of MBAs, Chartered Accountants and Life -Sciences Domain Experts. Mr. Vishal is a member of various sectoral taskforces of the respective industry associations, including CII, FICCI, ABLE, OPPI, IDMA, and Department of Biotechnology, USIBC taskforce for Biotechnology and Nanotechnology, among others. Mr. Vishal was actively involved in taking up policy issues with the various government departments to create a better business environment for the Biotechnology, Healthcare & Pharmaceuticals sectors. He has been a part of various business delegations to USA, China and U.K for facilitating Biotechnology and Pharma Bilateral trade.

Important Participant Profiles

Dr. Ratna Devi

CEO, DakshamA Health; and
Founder, IAPG

Dr. Ratna Devi is the CEO and Co-founder of DakshamA Health and Education, an organisation that is dedicated to working for access to health, patient education and advocacy. She leads a cross disease Patient Alliance in India called the Indian Alliance of Patient Groups (IAPG) and works towards policy change, human resources capacity building and system strengthening. IAPG is a network of patient led and patient supported organisations working for Access, Quality and Safety of Patients in India. Being a medical doctor, public health and management professional, Dr. Devi brings more than 22 years of experience working to improve health outcomes in India. She spent her initial 10 years in the government and for the past 12 years, she has worked with national and international NGOs on donor-funded public health initiatives.

Dr. Linda M. Distlerath

Deputy Vice President, PhRMA, USA

Linda M. Distlerath is Deputy Vice President for Global Alliances at PhRMA, leading third-party engagement and coalition development around the globe to improve access to quality healthcare and medicines. She was senior vice president in the health care practice of APCO Worldwide, headquartered in Washington, D.C. office, and previously held vice president positions at MSD. Dr. Distlerath holds a Bachelor of Science in Medical Technology from the University of Michigan and a Doctor of Philosophy in Environmental Health from the University of Cincinnati. She completed a post-doctoral fellowship in biochemistry at Vanderbilt University and holds a Juris Doctor from Rutgers Law School-Newark. She is a member of the Council on Foreign Relations and the Economic Club of Washington, DC, and an advisory board member for the Partnership to Fight Chronic Disease (PFCD). She also served as the Global Executive Director for the Partnership for an HIV-Free Generation, a public-private partnership between the US Office of the Global AIDS Coordinator and 18 private sector partners focused on HIV prevention in sub-Saharan Africa, and as a member of the Private Sector Delegation Advisory Group to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Important Participant Profiles

Dr. K.V. Surendranath

Senior Vice President - Global Sites, United States Pharmacopeial Convention (USP)

Dr. K.V. Surendranath serves as Senior Vice President, Global Sites for the United States Pharmacopeial Convention (USP). He provides leadership to USP's international sites in India, China and Brazil, and is responsible for expanding USP's collaborative laboratory capabilities to support the development of USP monographs and reference materials. Dr.Surendranath holds a Ph.D. and master's degree in chemistry from the University of Roorkee (IIT, Roorkee) and a bachelor's degree in Chemistry Honors. Before joining USP, Dr.Surendranath accumulated more than 15 years of pharmaceutical industry experience in India, and served in a variety of roles.

Dr. Harish Nadkarni, CEO

National Accreditation Board for Hospitals & Healthcare Providers (NABH), Quality Council of India

Former CEO and Founder, Quality Care
Mumbai, Maharashtra, India
Consultant, Healthcare Quality, Accreditations, Certifications and Lean Six Sigma
Gynecologist with Six Sigma Black Belt providing healthcare quality management consultancy
Chairman of Technical Committee for Wellness Standards, National Accreditation Board for Hospitals and Health Care Providers (NABH), 2011-2012
Principal Consultant, National Accreditation Board for Hospitals and Health Care Providers, 2010-2012
Principal Assessor, National Accreditation Board for Hospitals and Health Care Providers, 2007-2010
Faculty for Quality Management for Hospital Management to national institutes like Tata Institute for Social Sciences (TISS), Indian Institute for Health Management and Research (IIHMR)
Consultant for NABH and JCI Implementation.

List of Participants

A Multi-Stakeholder Roundtable

Unlocking India's Potential in Biomedical Science & Innovation to Improve Health Care in India and for the World

4th August, 2017 • India International Centre, New Delhi, India

S. No.	Name & Designation	Organization
1.	Prof. N. K. Ganguly, Former Director General	Chair Core Group
2.	Dr. G. N. Singh, Scientific Director	Indian Pharmacopoeia Commission
3.	Dr Prahabkaran Dorairaj, Director	Centre for Control of Chronic Conditions
4.	Prof (Dr) Dileep Mavalankar, Director	Indian Institute of Public Health
5.	Prof Vivekanand Jha, Executive Director	The George Institute for Global Health
6.	Mr Ali Mehdi, Fellow and Project Leader, Health Policy Initiative	Indian Council for Research on International Economic Relations
7.	MrD S Negi, CEO	Rajiv Gandhi Cancer Institute & Research Centre
8.	Dr. Koduru V. Surendranath, Senior Vice President. Global Sites	US Pharmaceopeial Convention (Hydrabad)
9.	Dr. Randeep Guleria, Director	All India Institute of Medical Sciences
10.	Dr. Linda M Distlerath, Deputy Vice President	PhRMA, USA
11.	Dr. Ajay Sharma, Director, Government Affairs	Organisation of Pharmaceutical Producers of India
12.	Ms. Nitika Garg, Director, Research	Organisation of Pharmaceutical Producers of India
13.	Mr. Ashok Madan, Executive Director, Delhi Office	Indian Drug Manufacturers' Association
14.	Mr. Wajahat Habibullah, Chairman New Delhi	Partnership for Safe Medicines India Initiative,
15.	Mr. L. Mansingh, Chairman	Consumer Online Foundation, New Delhi
16.	Ms. Meenakshi Datta Ghosh, Board Member	PSM India Initiative, New Delhi
17.	Prof. Bejon Kumar Misra, Founder India Foundation	Patient Safety and Access Initiative of

List of Participants

S. No.	Name & Designation	Organization
18.	Mr. Aman Gupta, Country Representative	Partnership to Fight Chronic Disease
19.	Dr. Ratna Devi, CEO Indian Alliance of Patient Groups	Dakshama Health &
20.	Dr. K. K. Aggarwal, National President	Indian Medical Association
21.	Dr. Sreesha Srinivasa, Assoc VP, R&D and head, Translational Sciences	Biocon
22.	Mr. Vishal Gandhi, Founder & CEO	BioRx Ventures
23.	Mr. Neeraj Sinha, Scientist/Advisor to the PM, Government of India	Office of the Principal Scientific Advisor
24.	Dr. Harish Nadkarni, CEO	NABH, Quality Council of India
25.	Dr. Amit Kapoor, Chairman/CEO	Indian Council on Competitiveness
26.	Mr. Sujay Shetty, Partner and Health Care Practice Leader	PricewaterhouseCoopers
27.	Mr. Deepak Manot, Associate Director, Pharma & Life Sciences	PricewaterhouseCoopers
28.	Dr. Vijay Chandru, Chairman & Managing Director	Strand Life Sciences
29.	Dr. Vinod Kumar Paul, Chair, Dept of Pediatrics	All India Institute of Medical Sciences
30.	Ms Komal Kalha, Senior Counselor, USPTO	US Embassy
31.	Mr. Saif Habibullah, Project Coordinator	Consumer Online Foundation
32.	Mr. Gaurav Chaudhary, Senior Manager	Partnership to Fight Chronic Disease, India
33.	Mr. Subash Chand, Head Therapeutic Monoclonal Atibody Lab	National Institute of Biologicals
34.	Dr R. K. Srivastava, Former DGHS	Government of India
35.	Mr. Pyush Misra, Director India Foundation	Patient Safety and Access Initiative of
36.	Dr R N Tandon, Hony. Secretary General	Indian Medical Association (IMA)
37.	Dr N V Kamat, Principal Advisor	Indian Medical Association
38.	Dr K KKalra, CEO	IMA Accreditation & Academic Council
39.	Mr. Chaitanya Kumar Koduri,	United States Pharmacopeial Convention
40.	Dr. Shakti Kumar Gupta, Medical Suptd.	All India Institute of Medical Sciences
41.	Mr. Rudraneel	Quality Council of India

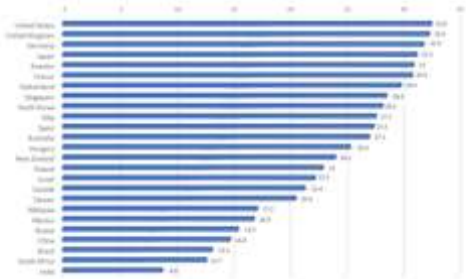
Unlocking India's Potential in Biomedical Science and Innovation to Improve Healthcare in India and Across the World

Amit Kapoor
Institute for Competitiveness, India
August 4, 2017

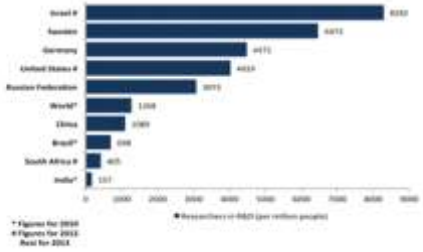
WHAT IS COMPETITIVENESS ?

- Competitiveness is the productivity (value per unit of input) with which a nation, region, or cluster utilizes its human, capital, and natural resources. Productivity sets a nation's or region's standard of living (wages, returns on capital, returns on natural resources)
  - Productivity depends both on the value of products and services (e.g. uniqueness, quality) as well as the efficiency with which they are produced.
  - It is not what industries a nation or region competes in that matters for prosperity, but how firms compete in those industries
  - Productivity in a nation or region is a reflection of what both domestic and foreign firms choose to do in that location. The location of ownership is secondary for prosperity.
  - The productivity of "local" industries is of fundamental importance to competitiveness, not just that of traded industries
  - Devaluation and revaluation do not make a country more or less "competitive"
- Nations and regions compete in offering the most productive environment for business

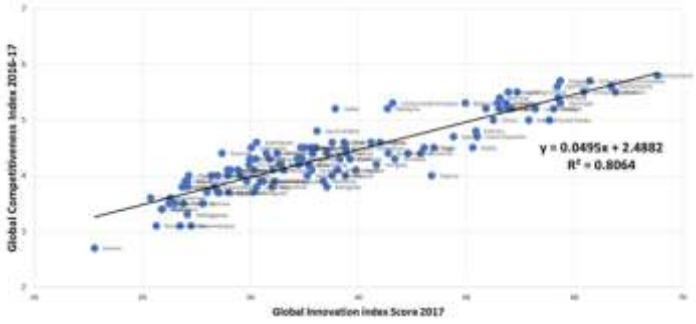
GIPC INTERNATIONAL IP INDEX 2017



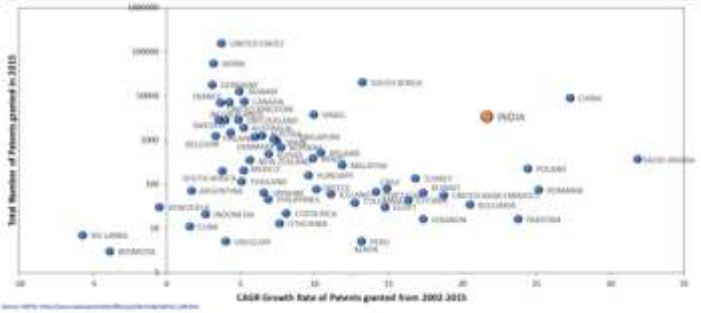
RESEARCHERS IN R&D (PER MILLION PEOPLE) IN 2013



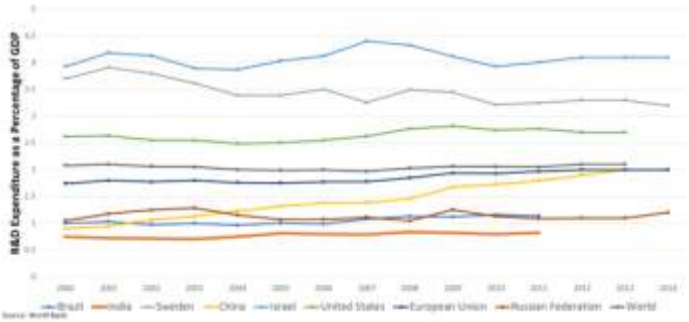
Link between Innovation and Competitiveness at Global Level

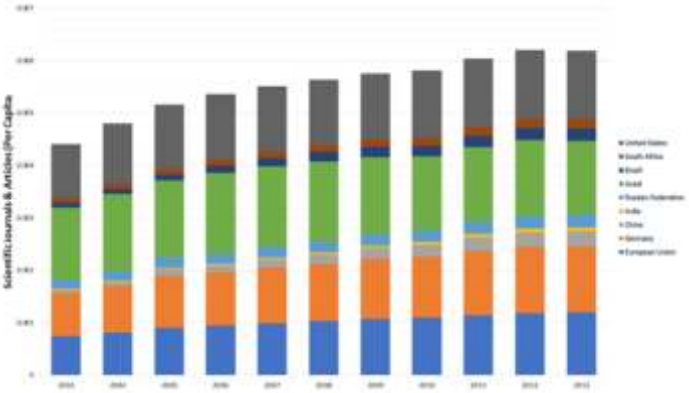


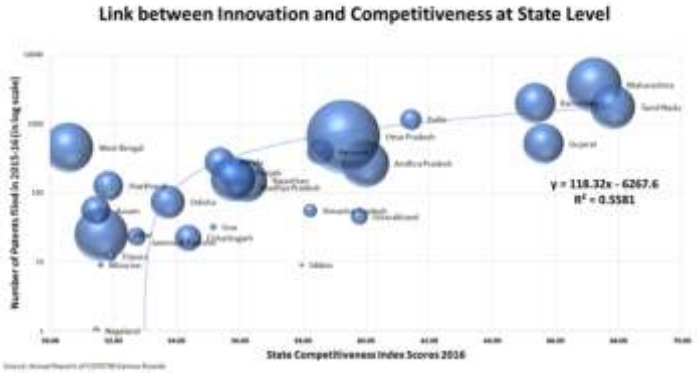
COUNTRY-WISE GROWTH IN PATENTS



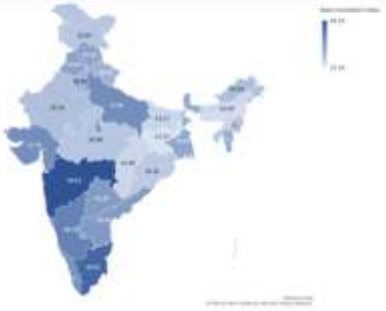
Country-wise R&D Expenditure as a Percentage of GDP



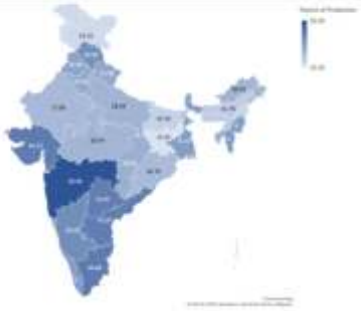




STATE INNOVATION INDEX



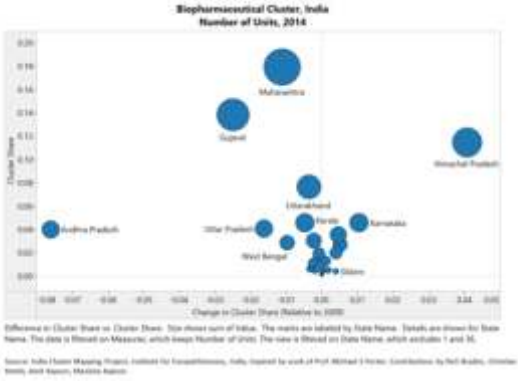
FACTORS OF PRODUCTION

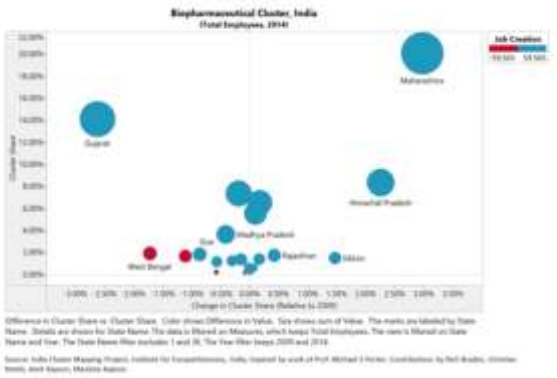


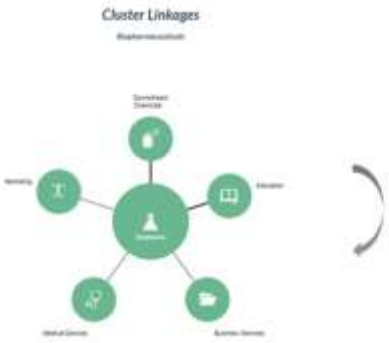
DEMAND CONDITIONS

INDUSTRIES, INNOVATION AND ENTREPRENEURSHIP

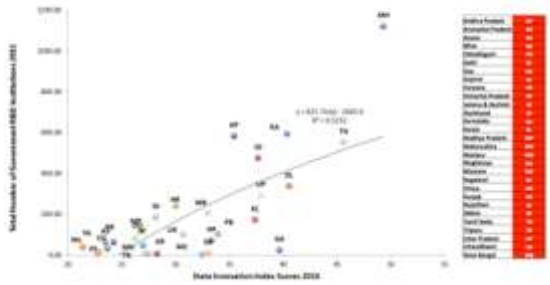
SOCIAL AND POLITICAL INSTITUTIONS



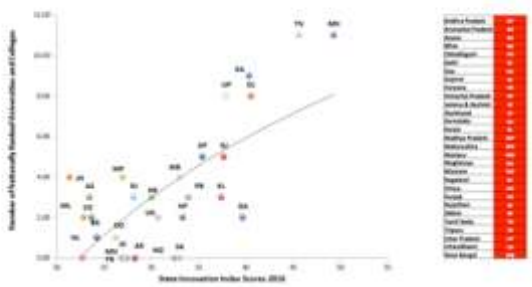




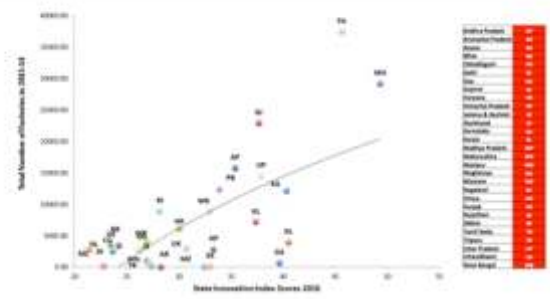
GOVERNMENT R&D INSTITUTIONS AND INNOVATION



NATIONALLY RANKED UNIVERSITIES AND INNOVATION



FACTORIES AND INNOVATION

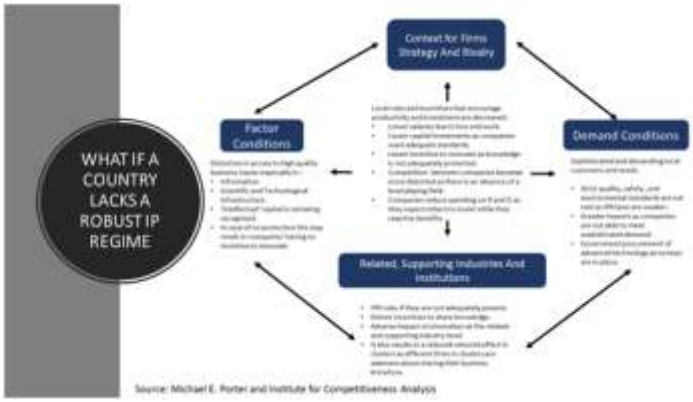


LEVELS OF SHARED VALUE

1	2	3
Reconceiving Needs, Products, and Customers	**Redefining Productivity in the Value Chain**	**Improving the Local Business Environment**
• Products and services that meet societal needs • Providing products to unserved or underserved customers and communities	• Accessing and utilizing resources, energy, suppliers, logistics, and employees differently and more productively	• E.g., improving skills, local suppliers, and supporting institutions in the areas where the company operates • Enhancing cluster sophistication in the sector

INTEGRATING ACROSS THE LEVELS

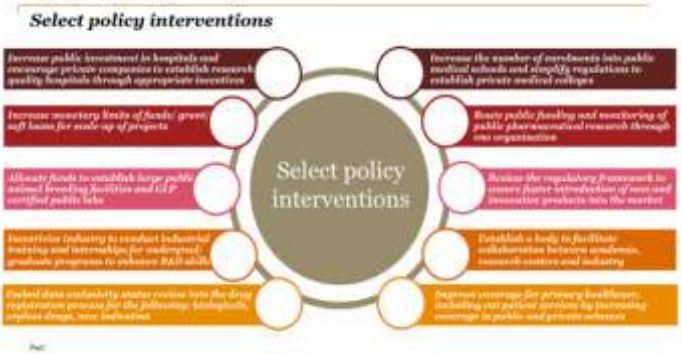
SHARED VALUE IN THE VALUE CHAIN

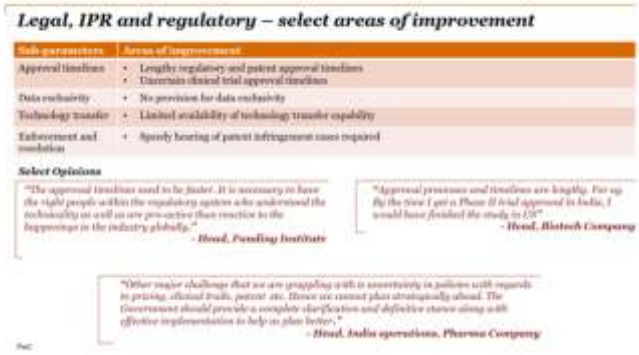


DOES LACK OF TRUST UNDERMINE COMPETITIVENESS?

IMPACT OF TRUST ON THE VALUE CHAIN OF A FIRM


Drivers of Innovation
What stakeholders in India Say is needed
pwc


Select policy interventions
Select policy interventions


Legal, IPR and regulatory – select areas of improvement
Sub-parameters
Areas of improvement
Approval timelines
Lengthy regulatory and patent approval timelines
Uncertain clinical trial approval timelines
Data exclusivity
No provision for data exclusivity
Technology transfer
Limited availability of technology transfer capability
Enforcement and resolution
Speedy hearing of patent infringement cases required
Select Opinions
"The approval timelines need to be faster. It is necessary to have the right people within the regulatory system who understand the technicality as well as are pro-active than reactive to the happenings in the industry globally."
- Head, Funding Institute
"Approval processes and timelines are lengthy. For eg. By the time I get a Phase II trial approved in India, I would have finished the study in US"
- Head, Biotech Company
"Other major challenge that we are grappling with is uncertainty in policies with regards to pricing, clinical trials, patent etc. Hence we cannot plan strategically ahead. The Government should provide a complete clarification and definitive stance along with effective implementation to help us plan better."
- Head, India operations, Pharma Company


Human resource – select areas of improvement
Sub-parameters
Areas of improvement
Availability of research talent
Gap in skills between available talent and industry requirement
Shortage of research personnel with doctoral qualifications
Limited availability of qualified personnel to carry out clinical trials
Incentives to attract talent
Low compensation to scientific talent and few mobility schemes for researchers
Lack of incentives for foreign institutes to set up campuses in India
Select Opinions
"Great seeds but not in the right soil. India's talent potential is immense, with people really driven to innovate. This should be recognized and people should be rewarded in order to retain the brightest talent."
- EVP/ CMO, global bio-pharma
"The entire culture of technology transfer offices within the COE is missing. There are lot of excellent ideas that are lying in the laboratory because of this gap."
- Head, Central Government Institute
"The incentive and the freedom enjoyed is limited. One of the reasons the US system is successful is there is a freedom to academicians, there is a concept of academic entrepreneurs. Having the right incentive for the innovator is also important. The capability development outside the academic institutions is important. The training aspect outside of University is required. This bridging course is essential because as we go for scale the employability of University output is limited."
-Head, Research Centre


Financing – select areas of improvement
Sub-parameters
Areas of improvement
R&D Financing
Limited fund availability for scale-up of projects
Low spend on R&D by pharmaceutical business enterprise on SMEs
Healthcare financing
Low level of public and private health care expenditure
Limited health insurance coverage
Pricing and reimbursement
Frequent revisions in pricing
Select Opinions
"The funding by the Govt in R&D is broken. The money is being distributed to many research institutions. The outcome is none of them get adequate money."
- Head, Biotech Company
"Funding is more of a challenge for small companies. After initial funding there is worry who would do the next round of funding. The first stage of funding is available and Government is doing a great job by making the fund available. The problem is the next stage."
- Head, Funding Institute
"At least for the public funding we should identify 3-4 priority areas required for the country and ask the institutes to collaborate on the same. That kind of program only should be funded with adequate money. Because of scarcity of resources that kind of top down approach is necessary."
-Head, Central Government Institute
"Industry has to change its mindset and actively invest in innovation. They have to drive by a long-term perspective rather than balance sheets."
-Head, Central Government Institute


Infrastructure – select areas of improvement
Sub-parameters
Areas of improvement
R&D centers and support infrastructure
Non-availability of large animal breeding facilities, GLP certified animal and protein characterization labs
Limited collaboration between academia, research centers and industry to utilize public R&D centers
Absence of a single authority and mechanism to oversee the establishment of public pharma R&D centers
Biotech clusters
Absence of specific guidelines for establishment of biotech parks around centers of excellence
CT infrastructure
Shortage of clinical trial infrastructure
Availability of EHR
Absence of a clear roadmap for implementation of EHR standards, data protections laws and sharing of EHR
Select Opinions
"We have very few incubation centres. Each Institute/ University should compulsorily have incubation centres. That will facilitate and motivate students to validate their ideas."
-Head, Central Government Institute
"But there are difficulty in getting access to appropriate cell lines etc. Even in center of excellence there is good quality infrastructure but the processes around making this available for academic researchers, private companies is very cumbersome. The limited amount of good quality infra that we have in the country remain beyond access to researchers."
- Head, Biotech Company
"The outreach of the Government institutes is less and very few people are aware of the kind of work/ facilities that are provided by Government."
-Head, Central Government Institute
"A lot of these biotech parks should have been in a cluster of institutions rather than in isolation. Today, an academician in one part of the city may not go to the other part of the city where the biotech park is located. So, that park will be used by large companies who can operate in isolation as well. These biotech parks need to look for a mechanism to connect with these institutions and research centers. It has been rolled out in some places. However, this needs to happen nationally."
- Head, Biotech Company

With an objective to bring health and economic dividends

Key areas of impact	Indicators	Current Status	Probable future status based on Model Countries
Creation of more value added jobs	• R&D employment as % of total	• R&D employment as % of total ~1%	• ~4% (China) to ~10% (Developed economies)
Attract FDI in R&D	• FDI in R&D	• NA	• China $1.8Bn in 5 years. With 1/3rd the market size India may expect $500-600Bn
Higher research output	• No. of scientific publications (quantity) • % Top cited publications (quality) • % of total Life Sciences PCT application	• No. of scientific publications (quantity) ~15000 • % Top cited publications (quality): 7% • % of total Life Sciences PCT application: 1.3%	• No. of scientific publications (quantity): >25000 • % Top cited publications (quality): >10% • % of total Life Sciences PCT application: >4.5%
Increase in clinical trials bringing more investment	• % of total global clinical trials	• % of total global clinical trials: 1.5%	• % of total global clinical trials: >5%
New Medicines improving Health outcomes	• No. of NME	• NA	• 10-15% share of NME every year which amounts to 3-4 NMEs every year i.e. 15-20 NMEs between 2020-2025. This would have a potential to add $1.5-2Bn by 2025

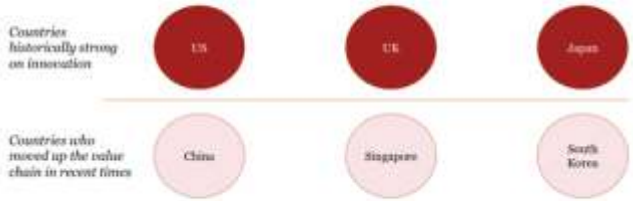
PwC

Vision 2025 was defined and ~40 policies across 10 policy areas were laid down to strengthen the ecosystem

The objective was to strengthen the 4 building blocks of ecosystem

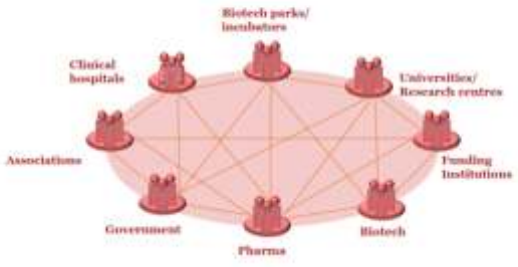
PwC

Innovation ecosystem of model countries were also studied



PwC

Stakeholder across the ecosystem were interviewed



PwC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Potential in
Biomedical Science & Innovation to
Improve Health Care in India and for the World
A Multi-Stakeholder Roundtable
Friday, 4th August, 2017
New Delhi
Dr. Randeep Guleria
L. Mansingh
Prof. N. K. Ganguly
Dr. G. N. Singh
Bejon Kumar Misra