Media & Advocacy Plan for PhRMA in India

By

Pragati Arora

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2017-2019

The IIHMR University, Jaipur

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IIHMR UNIVERSITY

TO WHOMSOEVER MAY CONCERN

This is to certify that **Pragati Arora** student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at **SPAG, Gurugram** from **4th Feb 2019 to 4th May 2019.**

The Candidate has successfully carried out the study assigned to her during internship training and her approach to the study has been sincere, scientific and analytical.
The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.

Dr Sandeep Narula
Dean, School of Pharmaceutical Management
The IIHMR University, Jaipur

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Guide, Associate Professor
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SPAG

A Strategic Partners Group Enterprise

The certificate is awarded to

Pragati Arora

In recognition of having successfully completed her
Internship in the department of

Media and PR

and has successfully completed her Project on

"Media & Advocacy plan for Pharmaceutical Research and Manufacturers of America in India"

From 4th Feb-4th May 2019

at

SPAG, Gurugram

She comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning

We wish her all the best for future endeavors

Shivani

SPAG CONSULTANTS PVT. LTD.

Training & Development

Rikta Gupta

SPAG CONSULTANTS PVT. LTD.

Zonal Head-Human Resources

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **"Media & Advocacy plan for PhRMA in India"**and submitted by **Pragati Arora** Enrollment No **IIHMR-U/02/2017-19/0108** under the supervision of **Dr. Sandeep Narula** for award of MBA in Pharmaceutical Management of the University carried out during the period from **4th February 2019 to 4th May 2019** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

ABSTRACT

Background: The aim of the study was to understand the Indian Intellectual property guidelines and Healthcare policies. The key issue messages were created so as to determine the story ideas for content creation and its placement in relevant channels. The key stakeholders were also identified to have a support of their quotes comprehending their knowledge and experience.

The study establishes a need for Government to spend more on public healthcare and tighten its regulations regarding quality healthcare. Moreover, India needs to revise their patent regime as per US demands specifically, compulsory license and section (3d) amendment and rewards innovation within the country and globally

Keywords: Intellectual property guidelines, Healthcare policies, patent regime, compulsory license, section (3d), medical innovation

OBJECTIVES

-To develop and place articles in relevant channels for representing PhRMA in India:-

- The commitment and contribution of the global innovative bio-pharmaceutical organizations in the country
- The current role of Government in improving availability and accessibility of medicines
- Bringing change in perception of GOI towards establishing a strong world-class intellectual property (IP) systems that encourages innovation and develop innovative products and technologies

RESEARCH METHODOLOGY

✓ **Study Type:** Descriptive study

✓ **Study Duration:** Three Months (4th February to 4th May)

✓ **Data Collection method:** Secondary research

✓ **Source of Secondary data:**

Broad array of industry sources for secondary research has been used, which typically include, however, not limited to:

- Indian Pharmaceutical Scenario to Scientific and technical writings for IP framework & regulations and related preemptions
- Authentic new articles on healthcare infrastructure of India, current market trends, clinical trials, Innovative research & technology in biopharmaceutical companies and its products in India, other related releases for market evaluation

ACKNOWLEDGEMENT

First and foremost, I venerate to the God whose mercy, compassion and benediction has guided me in each step throughout my life and this study as well.

"There are so many people who deserve a word of thanks for their part, in one way or other for completion of my Dissertation project. So, I am highly indebted to all those who made it possible for me to mold this study in the form of summer training".

I am especially grateful to **Mrs. Ritika Jauhari**, Senior Director at SPAG- Gurgaon and Singapore., for his constant guidance, support, motivation.

"I would like to express my profound sense of reverence to my project mentor **Mrs. Shivani Sharma**, Account Managerfor the valuable guidance, to keep up the interest and for boosting my morale in the completion of this project"

I an immensely thankful to SPAG forgiving me such a wonderful opportunity to work with them.

I would like to extend my heartfelt gratitude towards my guide **Dr. Sandeep Narula**, Associate Professor, IIHMR, Jaipur for his continuous support and guidance throughout this project".

I would like to thank my family, my colleagues, and students of MBA PM 09 who have willingly supported me throughout the project.

PRAGATI ARORA

Table of Contents

List of Figures

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RESEARCH PROBLEM

- Why global biopharmaceutical firms hold back from investing in the country and what initiatives need to be taken to build an innovative biopharmaceutical industry in India?
- What are the main challenges with access & affordability for medicines in India?
- What advancements can be made in the public healthcare system?

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LITERATURE REVIEW

Prakash et. al. in 2018 explained that Indian Pharmaceutical Market is dominated by the generic market and invention has a very little share in its expansion due to lack of proper multidisciplinary work between the preclinical and clinical scientists, deficient funding, heterogeneous interests of the involved sect ors, lack of systematic training of workforce, and lack of visionary. Till now, the Indian Patent System is balancing the delicate balance between the interest of the patentee and Indian population.There are several stories such as imatinib (Novartis), tadalafil (Eli Lilly), rosiglitazone (GlaxoSmithKline), fenofibrate (Abbott), sorafenib (Bayer) regarding the product patent, EMR, off-patent products, and how the inventor company tries to save their inventions from generic marketing.[1]

Arvind Kasthuri in 2018 described that India has been trying desperately to live up to their identity as health subcenters, waiting to be transformed to shrines of health and wellness, a story which we will wait to see unfold. Studies on awareness are many and diverse, but lacunae in awareness appear to cut across the lifespan in our country; barriers to access in the financial, organizational, social, and cultural domains can limit the utilization of services, even in places where they are available; the public sector offers healthcare at low or no cost but is perceived as being unreliable, of indifferent quality and generally is not the first choice, unless one cannot afford private care and warning to Indian Healthcare to get ready to face a future which is full of possibility and uncertainty in equal measure.[2]

Due to its immense growth potential, the Biotechnology and the Pharmaceuticals sectors are regarded as the two most significant sectors from the Make in India perspective. India already features among the top 12 biotechnology destinations in the world and ranks second in Asia. The sector is presently growing at a compound annual growth rate (CAGR) of 20%and is expected to reach USD 100 billion by 2025.Superior quality and technology coupled with the enormous variety of medicines makes India a leader in the pharma industry within the league of developing countries. The Indian pharmaceutical industry is the world's third-largest in terms of volume and tenth largest by value. India's generic drugs account for 20% of global exports in terms of volume, making it the largest provider of generic medicines globally. The sector has been a key contributor to the growth of the country's economy, with exports accounting for about 50% of the total production. Additionally, the rapidly growing pharmaceutical industry is predicted to be the sixth-largest market globally by 2020, with its value reaching up to USD 55 billion.[3]

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[1]Intellectual property rights and Indian pharmaceutical industry: Present scenario- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6044128/

[2]Challenges to Healthcare in India - The Five A's- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6166510/

[3]MOVING TOWARDS GLOBAL COMPETITIVENESS: BIOTECHNOLOGY AND PHARMACEUTICALS- http://www.makeinindia.com/article/-/v/moving-towards-global-competitiveness-biotechnology-and-pharmaceuticals

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COMMUNICATION APPROACH

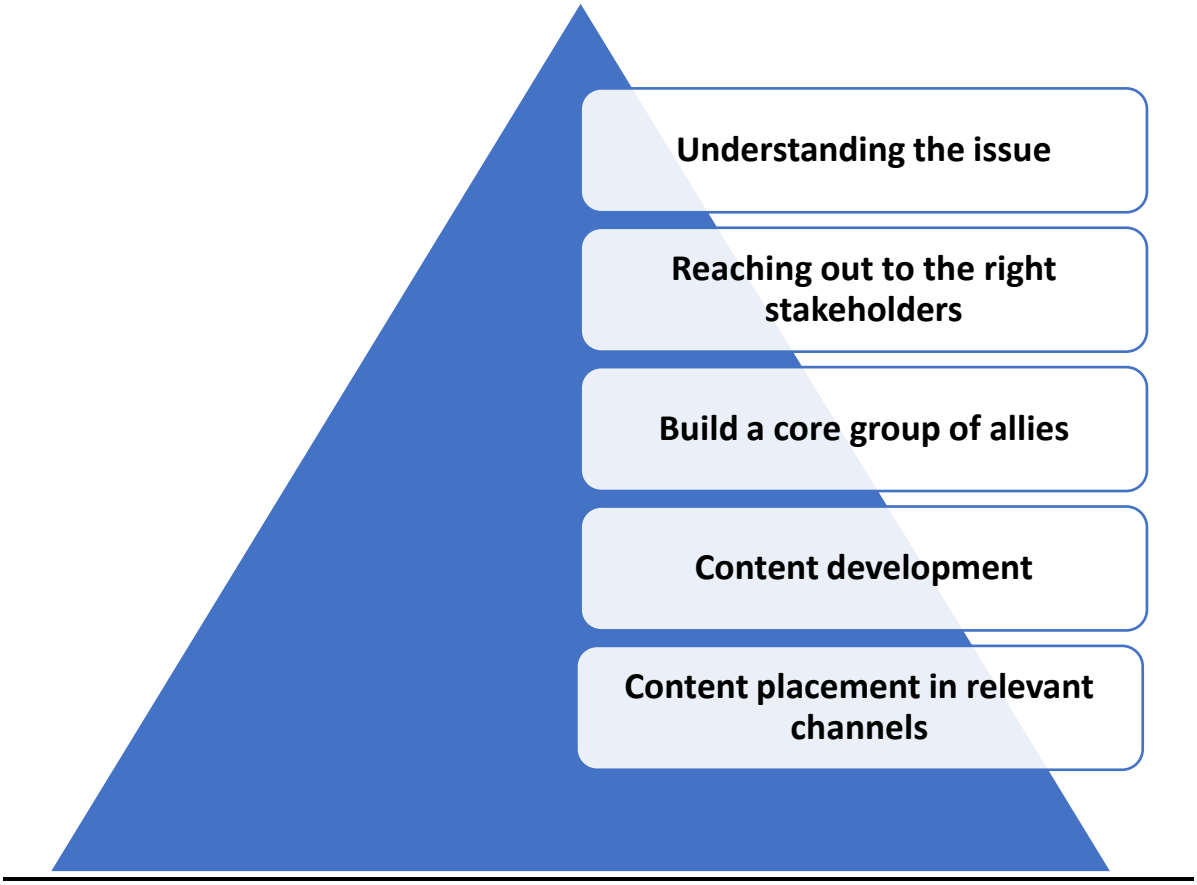

Figure 1: Communication Approach

KEY MESSAGE

(I) ISSUE & KEY MESSAGES: Despite positive signals from the GOI in 2017, there has been no change in policy and India's IPR system remains a concern. Innovation is required to meet the challenges of a growing disease burden. An innovative pharma industry needs a robust and predictable IP environment. Innovators need the assurance that research will be rewarded**. China is beginning to introduce policies favorable to research and innovation is starting to shape the Chinese pharma industry.**

Viewpoint 1: The threat of Compulsory Licenses (CL) remains for innovator companies. India's new TB initiative triggered CL demands for patented TB drugs.

Supporting Facts

a) Price and other unqualified conditions become CL triggers. When assessing 'reasonably affordable price', the price of a patented drug is compared with a competing generic that has had no R&D investment. Patient Assistance Programs are not factored while considering access or affordability.
b) It is not clear whether importation amounts to working a patent, as required in the Patent Act. Greater restrictions are placed on patent owners who import a patented invention rather than manufacturing locally. This is despite the law being amended in 2004, to remove the requirement to 'manufacture in India'.
c) Ambiguous language poses a problem. The interpretation of 'national emergency', 'extreme urgency' or 'public health crisis' must surely refer to real emergencies or pandemic-like national crises. If the number of probable patients is the consideration, would chronic non-communicable disease be considered a 'public health crisis'? The interpretation of 'public non-commercial use' has also been routinely misused to favor domestic manufacturers over patent-holders.

Viewpoint 2: Narrow patentability criteria and Section 3(d) remain a concern.

Supporting Facts

a) An amendment to the Indian Patents Act has added an additional hurdle (beyond the requirement of novelty, non-obviousness and industrial application) and this is the criterion of 'enhanced efficacy. Thus, many derivatives of known substances are presumed to be the same as the original chemical and not patentable, unless proven to differ significantly in efficacy. This additional requirement is applicable only to pharmaceuticals and discriminates against a single technology sector.
b) Section 3(d) is inconsistent with the framework of the TRIPS Article 27, which clearly provides a list of substances that can be excluded from patent coverage. Section 3(d) effectively discourages innovation for potential product improvement, not related to efficacy; such as inventions to improve safety or compliance or storage - aspects that can improve patient outcomes.

c) Significantly, the Mashelkar Committee Report of 2005 found that a large number of patent applications filed by Indian entities cover subject matter that would not be patentable under Section 3(d).

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(II) ISSUE & KEY MESSAGES: Acknowledging the enormous challenge of Healthcare Access in India, PM Modi has declared the broad 'Ayushman Bharat' initiative, in his final year of Government. This will include:

- The world's largest government-funded healthcare program, National Health Protection Scheme (NHPS) will cover 100m vulnerable families (500m people or 40% of India's population) with ₹500,000 insurance cover per family per year, including Secondary and Tertiary Care. This is expected to benefit 500 m beneficiaries or 40% of the Indian population.

- Last year's National Health Policy proposal for 150,000 health and wellness centers to provide comprehensive care for treatment and diagnostics for Non-Communicable Diseases (NCD) and Maternal and Child Health MCH). GOI has committed ₹12 billion for this program and sought contribution from the private sector, inviting them to adopt these Health & Wellness Centers as part of their CSR mandate.

- Modi just launched the 'End – TB' campaign to eradicate tuberculosis from India by 2025, five years ahead of the global deadline. GOI has allocated ₹6 billion for nutritional support to TB patients at ₹500 per month per patient, for the duration of treatment

- GOI announced 24 new Medical Colleges and Hospitals, to ensure at least one medical college for three parliamentary constituencies. The plan is to upgrade existing district hospitals

- There is to be a Health Insurance Premium Rebate for Senior Citizens, with deductions being raised to ₹50,000 for annual premium, from the previous ₹30,000. For senior citizens with critical illnesses, the deduction on premium could be as high as ₹100,000

- Health access will be increased to 4%, from the previous 3%

The Indian Government has announced a combined overall budget allocation of ₹138,000 billion for Health, Education and the Social Sector. A challenging year lies ahead and we can expect to see a balancing act between fiscal prudence and populism, as the next General Election looms less than a year away. This combination of ambitious schemes can be hugely impactful, providing India is able to implement them. The challenge will be for meaningful partnerships between the public and private sectors, to enable the success of Ayushman Bharat. There is much hope but there is also much skepticism.

More realistically, industry can continue to expect debilitating price control on medicines, devices and now diagnostics.

Viewpoint 1: Essential to the success of 'Modicare' is the allocation of resources, thoughtful implementation of the various healthcare schemes and perfect coordination between the center and the states.

Supporting Facts:

a) Enabling access to healthcare requires bigger budget allocation and public expenditure must be increased from the current 1 percent of GDP to at least 2.5 percent.
b) Studies find that increased healthcare spending has a positive impact on GDP growth. This spending must be seen as an investment that yields valuable returns, not a cost that drains resources. A healthier India will be a more productive India.
c) Government could work with the pharma industry on efficient drug procurement and distribution models to increase access to essential medicines. In one Eastern state, the annual GOI spend on drugs is a shocking Rs 14 per person.

Viewpoint 2: For India's NHPS to be a success, it will require a robust model and a wise and dedicated NHPS Council

Supporting Facts:

a) The solution has to be holistic, extending beyond the cost of medicine to the proximity of health facilities and the quality of infrastructure. The real barrier to access is the inability to pay out-of-pocket and lack of insurance cover.
b) India needs a composite and hybrid model of UHA that is efficient and affordable. The NHPS - Government-sponsored, subsidized and supported by tax payers - covers 40% of India's population and wil,l for the first time, offer primary, secondary and tertiary care.
c) Meaningful infrastructure development is needed to expand access, lower costs and establish an affordable, quality healthcare system. Public-private partnerships for capacity development and increased access could form part of the solution.

Advice, opinion and some concern from the Experts:

*****

(III) ISSUE & KEY MESSAGES: Pharma companies continue to face an unpredictable policy environment, challenging drug regulations and irrational price control. Policy decisions are often biased in favor of domestic companies. Strong, transparent and stable regulatory frameworks are essential to protecting consumers while promoting globally-competitive innovative and generic pharma industries.

Viewpoint 1: The Clinical Trials situation in India has evoked criticism across the globe, with valuable time lost and irreparable damage done.

Supporting Facts:

a) In a big setback for the industry, Clinical Trials in India were halted in recent years. If clinical research is to be revived and optimized, for the long-term benefit of patients, the country needs robust regulations that conform to international best practices, while incorporating specific changes to address national needs.
b) Confusion has reigned around what constitutes 'trial-related injury' or 'sufficient number of patients' or 'public interest' that should allow waiver of local clinical trials. There has also been extensive debate about fair quantum of compensation and the viability of an informed consent process that requires audiovisual recording.
c) India is home to less than 2% of global clinical trials, due to a burdensome and unpredictable regulatory environment and constantly changing regulations. Global scientific standards can ensure India's research is world-class and helps address the nation's medical needs. Regulations governing clinical trials must be rational, implementable and promote policy that facilitates innovation

Viewpoint 2: Indian drug prices are the lowest in the world. Yet, price control is seen consistently as the simplistic solution to make healthcare affordable to India's vast population. Arbitrary pricing decisions create an unpredictable business environment that is discouraging for global companies. 2017 has seen price-capping extend from drugs to medical devices and it now threatens diagnostics.

Supporting Facts:

a) In a complex structure, the Ministry of Health (MOH) owns the National List of Essential Medicines (NLEM), whereas the Ministry of Chemicals & Fertilizers (MOC&F) houses the Department of Pharmaceuticals (DOP), which oversees the National Pharmaceutical Pricing Authority (NPPA) responsible for capping NLEM prices.
b) The span of price control under Drug Price Control Order (DPCO) 1995 was 74 drugs. DOP promulgated DPCO 2013, with price control of 348 drugs featured in the NLEM 2011. The basis for DPCO 2013 is the National Pharmaceutical Pricing Policy (NPPP) 2012, a market-based policy with a simple, transparent and balanced formula that is easy to implement and monitor.

PROPOSED PLAN OF ACTION

Track 1 – Media Outreach and narrative build up

- Continue to build on the ongoing media narrative through third party opinion articles in relevant print and online publications – National, regional and international media in Asia-Pacific region

- Messaging to be aligned with updated priority areas of advocacy in India

- Scale up media activation in top-tier publications and build positive narrative on key issues

Track 2 - Broad-Based KOL Engagement

- Develop a comprehensive list of third party KOLs who will be our messengers against each track. The list will include local voices (in India) to support priority issues. This list will be classified based on their media pull i.e., relevance in the country's top most media outlets and amongst the policy makers

- Scale up engagement with key influencers who are favorably treated in the media fraternity and whose voice has a higher impact on policy decisions for a high impact media campaign

- Continue to leverage the existing partners for delivering our messages on the reputation track more frequently and effectively like Dr. Ratna Devi and Bejon Mishra

Track 3 – Build Media Allies

- Initiate few strategically planned editorial meetings between senior media editors/columnists of prominent newspaper outlets and PhRMA leadership (CEO and other senior executives; Company global CEOs; and other global experts in the market) This will involve setting up of in-person sit-downs with the editor and their reporting team

- Overall aim will be to build 6 media allies over the year through our engagement and knowledge sharing

Track 4 – Research & Content - Broad Base Communication agenda around other relevant indices and reports

- The approach will be to disseminate reports and information that support our key issues messaging by providing communication/media support to for these materials

    - S.P.A.G. will take a lead in mapping the reports/ global indices that are released annually and rank India on parameters such as --- biopharmaceutical competitiveness, innovation, health, ease of doing business, IPR, access to medicines etc. This would include research papers or advocacy papers showcasing the role of innovative medicines in treating specific diseases and/or contribution of the innovative pharma companies in research, job creation and finding innovative healthcare solutions

- S.P.A.G. will draw up a list of global indices, expected date of release, collate findings and define PhRMA's position on each

- The PhRMA team will also keep sharing any additional data/ information/ event update/ reports that link to our issues that can be used as reference material by SPAG internally or for media engagement. This will be helpful for SPAG in developing research-based content, storyboarding and media briefings for initiating media stories

LEVERAGING IMPORTANT DAYS/EVENTS

Moments | 2019

- Special 301 report
- Interim Budget
- Revisiting the price capping on stents
- 2nd Anniversary of National Health Policy
- 3rd Anniversary of India's IPR policy
- India-US Trade Policy Forum Meeting

Important Days/Weeks | 2019

World Cancer Day
World Health Day
National Science Day
World Tuberculosis (TB) Day
World Entrepreneurship Day
World Creativity and Innovation Day
World Intellectual Property Day
Breast Cancer Awareness Month
World Diabetes Day

Key Indices/Events & Conferences

- GIPC- IP Index launch
- Global Innovation Index
- Global Competitiveness Report

Events/Conferences

- 4th International Exhibition & Conference on Pharmaceuticals and Medical Device Sector
- 11th Global Intellectual Property Convention
- Global Entrepreneurship Summit (GES)

KEY POLICY CONVERSATION

PHARMACEUTICAL INDUSTRY		
Stakeholder	**Conversation**	**Background**
National Pharmaceutical Pricing Authority (NPPA) **BS Ajayi Kumar, CEO, HealthCare Global Enterprises Ltd. (HCG)**	Through a recent notification, National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling prices of 847 formulations under the Drugs (Prices Control) Order, 2013. The drug formulations whose prices have been fixed include Acetazolamide, Abacavir (A) + Lamivudine (B), Acetylsalicylic acid, Acyclovir, Albendazole, Amlodipine, Atorvastatin, Baclofen, Calcium gluconate, Clofazimine, Glucose, Gentamicin, Glycerin, Metformin, Morphine and numerous other medicines. Trastuzumab Injection 440 mg/50ml stands to be the most expensive drug in the revised list of drugs release. Each Pack of the Injection costs Rs 58867.50 After price cut on anti-cancer drugs, talking about the post effects Mr. Ajayi kumar said, "The drug regulator's move to cut trade margins of cancer drugs amounts to interference with the way hospitals function and will bring down the quality of care to cancer patients" with addition to this HCG has also filed a petition in Karnataka High Court after the price cut.	NPPA issued a notification on 27th February 2019 which brought 42 non-scheduled anti-cancer drugs under price control by restricting trade margins on these medicines to a maximum of 30 per cent.
Organization of Pharmaceutical Producers of India (OPPI) **Malini Aisola All India Drug Action Network**	Talking about the patent infringement and supporting the innovator companies at an industry consultation meeting held by CDSCO, OPPI said, "It is pertinent to point out here that inadequate information in respect of pending applications for such market authorizations/manufacturing licenses and grants on the CDSCO website poses a significant challenge for the innovators in tracking potential infringers and obtaining timely reliefs from the appropriate court of law. According to her OPPI's proposal is against the current regulatory framework that excludes linking marketing approvals and patents "OPPI's proposal has no legal foundation nor does it bring in any health benefits to patients. It is simply trying to use public resources towards the protection of patents which are	OPPI -which represents multinational pharmaceutical companies and advocates issues related to research and protection of intellectual property rights – recently tabled the proposal in an industry consultation meeting with the drug regulator.

	private rights," she said.	
Bhartiya Janta Party Manifesto	BJP in their manifesto has highlighted their plans for next 5 years which strongly emphasizes on healthcare. BJP has planned to set up 1,50,000 Health and Wellness Centers (HWCs) by 2022 amongst which 17,150 has already started functioning. They have also promised to set up a medical college or post graduate college in every district by 2024.They plan to eliminate Tb from India by 2025. In pharmaceutical domain, they have promised to accelerate the pharmacy and para-medical education in the county and to optimally leverage the untapped employment generation in Pharmaceutical sector. The party has promised to initiate a genome mission which plans to bring new diagnostics and treatments through encouraging innovation. In 2017 under BJP government India also increased its rank to 77 in WHO Ease of doing business list, they have promised to increase India's rank to 50 if re-elected.	The Lok Sabha elections are under process, which will form the new government and elect a new Prime Minister for the country. With active political clouds over the country the Bhartiya Janta Party came out with their Manifesto on 8th April 2019 just two days prior to first phase of election and the AAP released their manifesto in the last week of April.
Congress	Congress plans to increase the public health expenditure to 3% along with enactment of Right to Health Act for all the citizens. Congress also plans to implement Clinical Establishments Act, 2010 and formulate National Telemedicine Policy. The party has also promised to set up new industrial towns all over the country to promote manufacturing and will help India retain its leading position in pharmaceutical manufacturing. Congress will also introduce 'Make For The World' policy which will help manufacturer to make their products in Export only zones.	
Central Drugs Standard Control Organization (CDSCO) Dr. Eswara Reddy	CDSCO has issued a notification for all the manufacturers to revise the data and safety profile of all the anti-biotics as per the data from pharmacovigilance program. Additionally, the CDSCO has also asked all the manufacturers to mention these safety warnings on their labels.	Under the Pharmacovigilance Programme of India, the CDSCO collects adverse drug reactions reported from across

Drug Controller General of India	Speaking at an event with reference to the new notification by CDSCO, Dr. Reddy said "Recently, we have issued directions to manufacturers to revise safety data for various antibiotics based on the signals from the pharmacovigilance Programme."	250 adverse drug reactions monitoring centers, majority of these are in various medical colleges. Due to a large patient pool, the CDSCO can generate robust and quality data which is further analyzed for signals. According to new notification manufacturers are supposed to revise their data in accordance with the data from pharmacovigilance program.
United States Trade Representative (USTR)	The 'Special 301 Report' by United States Trade Representative (USTR) slammed India and China as leading sources of counterfeit medicines distributed globally with 20% of all pharmaceutical products sold in the Indian market estimated to be counterfeits. The report stated "In particular, China and India are reportedly leading sources of counterfeit medicines distributed globally.	The USTR report, an annual review of the state of IP protection and enforcement in US trading partners around the world, has again, put India on the 'priority watch list' for violation of intellectual property rights.
Preeti Sudan Secretary, Ministry of Health and Family Welfare	Denying the claims by special 301 report by USTR Mrs. Sudan said "We strongly disagree with the observations made by USTR. We do not know the genesis and methodology of their findings. Instead, we view this as opposition to low cost generics and the thriving Indian drug manufacturing industry which is the 'Pharmacy of the world'	

NEW VOICES IDENTIFIED

Dr. Neelam Mohan- Paediatric Gastroenterology and Hepatology- Medanta The Medicitv

Prof. Nilanjan Banik, Bennett University,

Anoop Mishra, Director Department of Diabetes & Metabolic Disease, Fortis Hospital

Ms. Malathi Lakshmikumaran, Director, Lakshmikumaran & Sridharan attorneys

Mr.Malathi Lakshmikumaran, Director, Lakshmikumaran &Sridharan attorneys

Shantanu Srivastava, Associate Director,

Dr. Ashish Bhardwaj - Director, Jindal

Ms. Ranjana Smetacek, Former Director General OPPI

Quarter Plan (April-June 2019)

Issue	Story	Messenger	Target Publications
COMPETITIVENESS	**Innovation is required to meet the challenges of a growing disease burden** An innovative pharma industry needs a robust and predictable IP environment. Innovators need the assurance that research will be rewarded	Prof. Deepak Gaur, Jawaharlal Nehru University (JNU)	Mint, The Hindu Business Line, First Post
	Innovation: a critical tool for enhancing competitiveness Innovation is being increasingly acknowledged as a critical tool for increasing competitiveness, tackling societal challenges, and driving economic growth and development. The move from a resource led to an innovation led economy can help nations in accomplishing the twin goals of sustainable and inclusive development	Prof. Chirantan Chatterjee, IIM, Ahemedabad	The Hindu Business Line, The Economic Times, BBC, Business Standard
INTELLECTUAL PROPERTY	**Section 3(d) prevents evergreening of drug patents/ Narrow patentability criteria and Section 3(d) remain a concern** India's IP regime, including Section 3(d) requiring biopharmaceutical inventions to show enhanced efficacy, and investment environment is affected continuously as it does not provide patent protection for incremental innovation	Dr. Ratna Devi, chief executive officer, DakshamAHealth, and founding member, Indian Alliance of Patient Groups	First Post, The Hindu Business Line, The Better Indian
	Creation of IP- a massive opportunity Intellectual Property (IP) is the bedrock on which the development of new treatments and cures are built. IP is critical for improving healthcare indicators of the nation. A strong IP framework will deliver tremendous benefit to India,	Ms. MalathiLakshmikumaran, Director, Lakshmikumaran& Sridharan attorneys	Mint, ET Healthworld or First Post

	including increased investment in clinical research, high-paying and skilled jobs, transfer of medical knowledge and early access to the new medicines		
	Wrong medicine: Price control The government is increasingly relying on price controls on medicines and medical devices to rein in the rising cost of healthcare in the country. Though this is well-intended, it may have several unintended consequences such as discouraging investment and R&D spending	Dr. Amir Ullah Khan, Indian Economist, Director, Aequitas Research	Newsminute, Quint, The Indian Express, The Hindu Business Line
INNOVATION	**Reward Innovation** The bright promise of an innovative biopharmaceutical industry in India will only be fulfilled if we work together to build, sustain and grow a scientific, economic and policy ecosystem that promotes and rewards medical innovation	Prof. N.K Ganguly, Former Director General, ICMR	Scroll, The Hindu Business Line, The Indian Express
	Leading the path of favorable innovation policies Much needed respite for the global research based pharmaceutical companies as the Indian govt. had announced the removal of price caps on innovative, patented drugs for the first five years of commercialization. While we are on the right track, a lot more needs to be done	Dr. Chaitanya Koduri, US Pharmacopeia	The Hindu Business Line, Business World, Scroll
	Move up the value chain by enabling innovation and new drug discovery Are patients' needs and aspirations really met? What can be done to cover the gaps? - Role of science and innovation in increasing access and filling the gaps	Dr. Ratna Devi, chief executive officer, DakshamAHealth, and founding member, Indian Alliance of	BBC, The New Indian Express, Mint

		Patient Groups	
REGULATORY	**Clinical trials are vital to determining the impact of a new potential treatment** The new clinical trial rules in India are well balanced and will further the conduct of ethical and quality clinical trials in the country which, in turn, will benefit patients	Chirag Trivedi, President, ISCR	The Hindu Business Line, First Post, The Indian Express
	Release of special 301 report With the Special 301 Report to be unveiled soon, India's views on access to medicines	Ranjana Smetacek, Former Director General, OPPI	The Hindu Business Line, Mint, Business Standard
	Encourage simultaneous global new drug development India has a unique opportunity to create a regulatory environment that promotes a stronger global innovative biopharmaceutical industry that advances new treatments in India and around the globe, while enabling Indian firms to become more competitive on a global scale through implementing measures that encourage simultaneous global new drug development	Prof. BejonMisra, Safe Medicines India	Financial Express, The Better India, Scroll

Article Pitched and Coverage Appeared

Article:-"Stir the IPR Pot for Innovation"

Coverage Appeared (Online)

Headline: Stir the IPR pot for innovation

Ranjana Smetacek - the writer is former director general, Organisation of Pharmaceutical Producers of India

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Stir the IPR pot for innovation

April 8, 2019, 12:04 AM IST Economic Times in ET Commentary | Edit Page, India | ET

By Ranjana Smetacek

Last month, the US Chamber of Commerce's Global Innovation Policy Centre (GIPC) released its 7th annual International Intellectual Property (IP) Index, which assesses the IP climate in 50 world economies. India moved from 44th rank in 2018 to 36th in 2019. But, looking at the scores across the eight categories assessed, India comes in well below the average score of the top five economies, and scores considerably lower than the Asia average.

India's national IP Rights Policy (IPR) was created in 2016. One of its stated objectives was 'to guide and enable all creators and inventors to realise the potential for generating, protecting and utilising IP which would contribute to wealth creation, employment generation and business development'. It also aimed to 'foster predictability, clarity and transparency in the entire IP regime in order to provide a secure and stable climate for stimulating inventions and creations'.

India has certainly made progress on the seven objectives laid down in the National IPR Policy across patents, trademarks, copyrights and designs. It has acted to increase public awareness, commissioned technology and innovation support centres, and instituted training programmes in some states. But much is left to be done: strengthening the legislative framework to respect IP; improving the enforcement and adjudicatory mechanisms that deal with infringements; supporting the generation and commercialisation of innovation; developing human capital to bolster capacity for research and skillbuilding. We need to recognise IP as avalue creator for India, and build the country's capability for innovation through IP creation, protection, and commercialisation.

Figure 2: Coverage Appeared-Stir the IPR pot for innovation

Page Coverage Layout


The Edit Page

Chasing Governance Or the Opposition?

How Bharatiya Will BJP Be?

For Financial Service Self-Regulation

Stir the IPR Pot for Innovation

Our Shrinking Shrimp Industry

Cat's Pyo Or The Purrfect Choice?

Figure 3: Coverage (2)

INTELLECTUAL PROPERTY RIGHTS

Stir the IPR Pot for Innovation

Ranjana Smetacek

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India has certainly made progress on the seven objectives laid down in the National IPR Policy across patents, trademarks, copyrights and designs. It has acted to increase public awareness, commissioned technology and innovation support centres, and instituted training programmes in some states. But much is left to be done: strengthening the legislative framework to respect IP; improving the enforcement and adjudicatory mechanisms that deal with infringements; supporting the generation and commercialisation of innovation; developing human capital to bolster capacity for research and skill-building. We need to recognise IP as a value creator for India, and build the country's capability for innovation through IP creation, protection, and commercialisation.

In healthcare, for instance, to develop and deliver new treatments to patients, innovator companies must be able to rely upon predictable and enforceable IP rights. Regretfully, GoI's initial momentum has not continued to translate into any meaningful change in policy or practice. The pharma industry's concerns range from weak patent enforcement, an unpredictable environment, and the threat of compulsory licensing, to non-transparent market access policies, high tariffs and taxes, and an unpredictable environment for clinical research.


FILE PHOTO

Ideas of India

India's patent examination backlog is another problem, where patents being examined currently were filed six to eight years ago. Such backlogs postpone clinical trial activity and ultimately the introduction of new medicines.

The inability to pay out-of-pocket and the lack of insurance cover will hopefully be addressed to a great extent by the Ayushman Bharat initiative. The National Health Protection Scheme (NHPS) proposes to extend health insurance cover to 40% of the population that's most in need. State governments could work with the pharma industry on optimising drug procurement and distribution to address healthcare access challenges. Increased access to medicines can go hand-in-hand with pro-innovation policies for the benefit of patients.

India's IP system needs to be thoughtfully assessed, and legal flexibilities used judiciously for humanitarian non-commercial use in treating diseases that are epidemic or communicable, with compulsory licensing being invoked only as a rare exception in rare circumstances. Not only would strong IPR make India more attractive to innovators, but a robust IP framework would also deliver increased investment in clinical research, high-paying and skilled jobs, transfer of medical knowledge and early access to new medicines.

The writer is former director general, Organisation of Pharmaceutical Producers of India (OPPI)

Figure 4: Coverage (3)

Article Pitched

Countering the Diabetes Burden with Innovation:Dr. Vishwanath Mohan

Dr. Vishwanath Mohan, Chairman & Chief Diabetologist,Dr.Mohan's Diabetes Specialities Centre

As the diabetes capital of the world, India currently has about 72 million people with the disease and the number is expected to rise to a whopping 134 million by 2045. The prevalence is growing among both older generation andthe younger ones as well. According to a report by Indian Council of Medical Research, data in its diabetes registry show that one in every four people under 25 is prone to adult-onset type-2 diabetes , unlike before when type-2 diabetes was seen only in older adults or those with obesity.

These statistics are not only worrying from a healthcare perspective, but also from an economic standpoint. What happens when the most productive section of society is affected by a lifestyle disease like type-2 diabetes, where poor diet and lack of exercise contribute to the onset of disease? The economy suffers, as people with diabetes have, on an average, two times higher healthcare costs than the ones living without the disease. This not only threatens the productivity level of our workforce but also means a significant loss of national income.

While lifestyle changes such as improving diet and increasing exercise can help reduce the onset and progression of type-2 diabetes, treatment is generally required to reduce the risk of life-threatening complications. Healthcare dynamics have undergone a significant shift in the last few decades by some of the most advanced treatments offered by the healthcare industry. Innovations are changing the way disease burdens like diabetes are perceived and treated, not only saving lives but improving the quality of life for patients with chronic conditions such as diabetes.

The new developments in insulin-delivery technology are making the impossible possible. You can now have a programmable insulin pump which drip feeds insulin continuously, simulating the lines of natural delivery of insulin by the pancreas. There are glucose monitoring systems for around-the-clock accurate control of blood glucose levels. Scientists are teaming up to make these discoveries to improve the management of diabetes and thus significantly reduces the dependence on injections.

But these innovations mean nothing if they do not come to the Indian shores. The challenge is how do we bring advanced medicines for diseases like diabetes to our people? First, let’s understand why many of these innovations do not come to India at the same time for patients in other parts of the world. One reason is because of weak intellectual property (IP) protection laws in India.

What are IP laws? And what do they mean to the healthcare world? To put things into perspective, IP laws—specifically the awarding of a patent for an invention--protect innovations from competition for a period of time, enabling and encouraging the innovator companies to make further investments in research and development for new drugs and technologies. Strong IP laws not only provide fair incentives for innovative products but also help innovators protect their rights.In a country like India where IP systems are weak, medical innovation is discouraged and this ultimately reduces patient access to new treatments and cures. Without strong IP laws, innovations coming to our country will grind to a halt.

Patents are the foundation of the research-intensive healthcare industry as they bring exclusive rights to innovators to prevent others from copying and selling the patented product, such as a new drug, for a set period. The logic is simple. Companies would not invest their time and money in R&D if they know that it's simple for a rival to swoop in and steal their innovations which took substantial time and money to bring forth.

If we use a crystal ball to gaze into the future, one can foresee exciting developments like implanted cell therapies, devices that allow the use of artificial pancreas and smarter insulin which work only when the blood glucose levels are elevated. All of these could dramatically change the course of diabetes treatment in the future.Such advancements are not possible without huge investments in innovation and in turn, these investments cannot sustain without proper support of IP laws. Innovators need protection to courageously invest in R&D. Strong IP laws help build that trust, ensuring that the innovations of companies can be protected and that patients can have sustained access to life-saving and life-prolonging medicines and technologies in the years to come.

To summarize, diabetes is no longer a mere threat for the distant future.Diabetes is already a reality, which could potentially put millions of youngsters in India out of jobs due to the consequences of this disease. With costs due to complications of the disease rising astronomically, we need newer medicines and technologies to treat diabetes more effectively and reduce both the human and economic toll of diabetes to patients, families and society.

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Dr. Vishwanath Mohan
Chairman & Chief Diabetologist, Dr.Mohan's Diabetes Specialities Centre

As the diabetes capital of the world, India currently has about 72 million people with the disease and the number is expected to rise to a whopping 134 million by 2045. The prevalence is not just growing among the older generation but is now hitting the younger generation as well. According to a report by Indian Council of Medical Research, data in its diabetes registry show that one in every four people under 25 with diabetes in India has adult-onset type-2 diabetes, unlike before when type-2 diabetes was seen only in older adults or those with obesity.

These statistics are not only worrying from a healthcare perspective, but also from an economic standpoint. What happens when the most productive section of society is affected by a lifestyle disease like type-2 diabetes, where poor diet and lack of exercise contribute to the onset of disease? Patients with diabetes are at risk for long-term complications (damage to the cardiovascular system, kidneys, eyes, nerves, blood vessels, and feet). The economy suffers, as people with diabetes have, on an average, two times higher healthcare costs than the ones living without the disease. This not only threatens the productivity level of our workforce but also means a significant loss of national income.

Figure 5: Coverage Appeared-Countering the Diabetes Burden with Innovation: Dr. Vishwanath Mohan

Draft pieces in pipeline-

Opinion Article – 1

Countering the Diabetes Burden with Innovation

Set to become the Diabetes capital of the world, shortly, India currently has about 72 million people with diabetes and by 2045 this number is expected to rise to a whopping 134 million. The prevalence is not growing just among the older generation. Diabetes is now hitting the younger generation too. According to a report by Indian Council of Medical Researcher 's young diabetes registry, "one in every four people under 25 with diabetes in India has adult-onset type-2 diabetes," unlike before when type-2 diabetes was seen only in older adults or those with extreme obesity.

The statistics are not only worrying from a healthcare perspective, but also from an economic standpoint. What happens when the most productive section of society is affected by a lifestyle disease like diabetes? The economy suffers, as people with diabetes have, on an average, two times higher healthcare costs than the ones living without diabetes.

Patients with diabetes are at risk for long-term complications (damage to the eyes, nerves, blood vessels, cardiovascular system, kidneys,and feet). This not only threatens the productivity level of our workforce but also means a significant loss of national income.

Healthcare dynamics have undergone a significant shift in the last few decades by some of the most advanced treatments are offered by the healthcare industry. Innovations are changing the way disease burdens like diabetes are perceived and treated. From machines that automatically monitor a person's blood sugar levels and administer the insulin as needed, to devices that deliver insulin, medical science has come a long way.

Innovations around the world have not only saved lives but also have helped improve the quality of life.

The new developments in insulin-delivery technology are making the impossible, possible. You can now have a programmable insulin pump which drip feeds insulin constantly. This works closely along the lines of natural delivery of insulin by the pancreas. There are glucose monitoring systems that for around the clock accurate control. Scientists are teaming up make these discoveries to help diabetes management better and thus significantly reduces the dependence on injections.

But these innovations mean nothing if they do not come to the Indian shores. The challenge is, how do we bring advanced medicines to our people?

First, let's understand why many of these innovations do not come to India. This is mainly because of weak IP laws. What are IP laws? And what do they mean to the healthcare world? To put things into proper perspective, IP laws protect innovations and enable brands to make investments and develop new technologies to defend their products. Strong IP laws not only provide fair incentives for innovative products but also help innovators protect their rights. In a country like India, IP systems are weak, and hence this discourages medical innovations as they do not provide adequate protection to the innovator. This ultimately reduces patients' access to new treatments and cures. Without strong IP laws, innovations coming to our country would grind to a halt.

Patents are the foundation of the healthcare industry as they bring exclusive rights to innovators and thus protect inventions as it deters others from copying and selling it for a set period of time. The logic is simple. Companies would not invest their time and money in R&D if they know that it's simple for a rival to swoop in and steal their innovations.

If we use a crystal ball to gaze into future, one can foresee exciting developments like implanted cell therapies, devices that allow the use of artificial pancreas and smarter insulin which work only when the blood glucose levels are elevated. All of them could dramatically change the course of diabetes treatment in the future. Such advancements are not possible without huge investments in innovation and in turn, these investments cannot happen without proper IP. Innovators need protection to courageously invest in R&D. Strong IP laws help build that trust, ensuring that the companies that have invested in life-saving products.

To summarize diabetes is a no more a threat that could come in some distant future. it is already a reality that could potentially put millions of youngsters in India out of jobs. With healthcare rates rising astronomically, we need newer medicines and technologies to treat diabetes more effectively.

To counter the burgeoning disease burden of diabetes, we need a robust patent environment, regulatory data protection, and non-discriminatory and transparent market access policies. And all this can only happen if we have a strong IP mechanism that protects innovations. It's time to look at the larger picture and help Indians live a long and healthy life despite diabetes.

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Opinion Article – 2

Time to Fight the Cancer Battle with Stronger IP Laws/The Dire Need for Robust IP Framework/Treat Cancer with Policies That Matter

Technology has dramatically empowered the healthcare industry. Today, innovations have turned untreatable into manageable long-term conditions (and potentially curable in many cases). A case in point— Cancer. If you look back only 40 years, the transformation in cancer treatments has been revolutionary. Led by innovations, these transformations have changed the way cancer is treated. Advancements like immunotherapy, targeted therapy, proton therapy, radioactive elements and other radiation therapies have picked up steam as experts work towards the cure. While researchers around the world are coming up with solutions to defeat cancer more efficiently, India is struggling to keep pace. Nearly 50 breakthrough cancer therapies were rolled out in the period of 2010-14 around the world, and India has been able to integrate only seven oncology drugs[4]. For a country which is home to over 17 lakh new cancer cases every year, which will rise to 20 lakhs by 2020, the need for innovative medication and early detection is now, more than ever.

Over the years, innovative therapies have addressed the various issues that patients face, including tumor reoccurrence after primary treatment, unwanted side effects, and others. Today, by aggressive screening and vaccination, many countries around the world like Japan, US and Europe have managed to address cervical cancer affectively, whereas, in India, a woman dies of cervical cancer every 8 minutes[5].

The reasons are many. But most importantly, we are not investing strategically in R&D, which in turn is deterring innovations from happening. R&D allows room for newer medications, smarter solutions and effective treatments that are only possible through innovation. And, for any innovation in the field of medicine, you need financial capital and technological prowess. Until India creates the effective solutions to address India's cancer burden, we need research-based global companies to enter the Indian market with therapies that can counter the cancer burden.

After all, medical innovations cannot be/should not be restricted by geographies. The next important aspect is, how can we bring these innovations to India. By protecting them, rewarding them.Hence, the need for a robust system of intellectual property (IP) rights to incentivize innovations to improve patient outcomes.

Although India has made great progress in strengthening its IP mechanism, we could improve with time.

Let's understand why IP is so important for innovation and better patient outcomes.

The lack of protection of IP means no incentive to conduct clinical trials or launch medicines in India because domestic firms receive a significant competitive advantage over innovative global

[4]https://timesofindia.indiatimes.com/india/india-got-only-7-of-50-global-cancer-drugs-in-5-years/articleshow/58087833.cms

[5]http://cancerindia.org.in/cancer-statistics/

biopharmaceutical companies. This, in turn, will stunt the growth of innovation and the introduction of medicines for Indian patients.With stronger IP laws, patients benefit from an improved quality of life by having access to new, effective and reliable treatments. In addition to the existing technologies, a stronger IP base also allows futuristic technologies to prosper and deliver patient specific outcomes.

Improved IP protection will also give India an edge over many other countries as it would make India a competitive destination for biopharmaceutical research and development. This would not only benefit the industry, but also patients across the country.

To deliver innovative treatments to patients, we need policies that encourage newer medicines to come to our markets. The oncology landscape is evolving at a blistering pace. If we do not let them come to India, we lose out on the many innovations that can potentially improve the lives of our cancer patients. While I encourage the way, domestic industries are taking it in their stride to work towards smarter solutions that promise better patient outcomes, I also support innovations from around the world. A new discovery in the medicine space could take years before it produces results. We cannot have millions of lives waiting.

The future of the most advanced cancer treatments belongs to countries who encourage global medical advancements to enter the domestic market. Is India ready to take tackle the cancer burden with the right policy framework?

RESULTS

- ✓ India has been issued compulsory license since 2001, which allows them to produce a patented product or process without the consent of innovator of that product. Compulsory licensing is also retained despite US demands for this to be watered down.

- ✓ Moreover, there is no change in revised section (3d) amendments of Indian Patent Act 2016 which prevents evergreening of drug patents. Moreover, a lack of a strong IPR regime and drug price control also delay innovation

- ✓ Compulsory licenses are used often as a barrier for innovations, majorly failing to reduce price of medicines, the intention with which it is included in the TRIPS Agreement. According to the NSSO survey, 82% of urban population and 86% of the rural population are not covered under any health insurance scheme (private or public) and millions are pushed into poverty every year to meet their medical expenses.

- ✓ India is the second largest pharmaceutical market in Asia estimated at US$ 5.40 billion and is growing by more than 13% annually. The country needs to upgrade its drug pricing policies so as to meet timely USFDA approval of orphan drugs, rare diseases and other lifesaving drugs, which in turn encourages innovation.

- ✓ Government spending on healthcare system including medicines, diagnostics and hospitals is only a meager 1.5% of GDP in India as compared to developing countries in Latin America which average about 7.5% of GDP. In fact, India, being the generic production hub, public sector facilitieshas poor availability of essential generic medicines.

RECOMMENDATIONS

- ✓ Assessment and Implementation of patent environment, high tariffs and taxes on medicines, and unpredictable environment for clinical research is important to attract US companies to tap on Indian market

- ✓ The Government needs to spend more on public healthcare and would have to tighten its regulations regarding quality healthcare. Central and state governments should be in sync about innovations in funding mechanisms and increase the health insurance coverage

- ✓ The Government must focus on encouraging private spending and their participation as the part of CSR in improving healthcare

- ✓ An innovative pharma industry needs a robust and predictable IP environment. Innovators need the assurance that research will be rewarded. A strong IP framework will deliver tremendous benefit to India, includinghigh-paying and skilled jobs, increased investment in clinical research, and transfer of medical knowledge and early access to the new medicines.

- ✓ The country needs to understand and accept the patent regime 2005 that encourages the innovation and discovery of new drugs by investing more in R&D

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