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Intellectual property evolution and innovation ecosystem as effective tools in strengthening Indian healthcare sector

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Despite India's enormous technological potential, indigenous medicinal knowledge and various initiatives by the government and industry at translational cycle, the country carries a global disease burden of 21%, majorly contributed by dual disease burden. Public health faces the major anomalies of 3A (accessibility, affordability, availability) of the healthcare sector, possibly due to restrictive coordination among stakeholders, transiting disease profile, undeveloped delivery system and regulatory mechanisms. This article emphasizes the significance of integrative approach of using our research and development strength and establishing a strong intellectual property system for conducive healthcare environment, accentuating the significance of 3P (public-private partnership) in addressing the major anomalies of 3A.

Keywords: Healthcare, innovation ecosystem, intellectual property, public-private partnership.

Health profile: impact of dual disease burden

GOOD health for the common man is of prime concern for any nation and a healthy, productive life is a rightful imperative of an individual. The draft National Health Policy (NHP), 2015 stresses the 'two-way linkage between economic growth and health status'¹ emphasizing on health statistics of our country. Also, NHP2017 flagged dual disease burden, malnutrition, child and maternal health and rural health as national priorities². The country's alarming dual disease burden is impacted by communicable and non-communicable diseases (Figure 1)³⁻⁷.

Over the past couple of decades, rapid transition can be seen in India's disease burden, such as fall in death rate, improved life expectancy of 67/70 (ref. 8), increased awareness for maternal health and child care, planned family size, decline in communicable diseases with consequent rise in non-communicable diseases, degenerative diseases of ageing and lifestyles^{9,10}. According to a World Health Organization (WHO) report, India accounts for

21% of the world's global burden of disease¹¹. The probable factors responsible for the rising disease burden are endogenous factors (health ideals and awareness, accessibility of health services, socio-economic background) along with exogenous factors (in particular, variation in disease profile between populations arising from varying levels of demographic and epidemiological transition), pointing the need to channel health research efforts, and encourage accessible and affordable healthcare solutions in accordance with changing patterns¹², to address the dual disease burden and improve quality of life. Also, disease burden can cause financial hardships, which may disturb the livelihood of a family. Therefore, it is necessary to make cost-competitive medical devices and develop new drugs to increase penetration to treat prevailing disease burden or health irregularities.

Profiling the healthcare sector

To address the issues of the health sector, a comprehensive healthcare system emerged comprising public and private sectors. The public sector, i.e. the government and its institutes working towards public health, plays a major role in research and development (R&D), medical education, affordable treatments, regulatory mechanisms, sensitization of the masses through national programmes, primary care, secondary care, quality assessment, etc. On the contrary, the private sector, i.e. the industry, is majorly involved in manufacturing devices, generics, out-sourced clinical trials, validation or up-scaling of licensed technologies, health insurance, medical tourism, tele-medicine, hospitals, chains of multi-specialty outpatient clinics, mother-and-childcare hospitals, short-stay surgery centers, fertility centres, etc.¹³.

Approximately 80% of people in urban areas use private facilities¹⁴, which are expensive compared to their public counterparts. Further, the healthcare system in the private sector is unregulated in terms of healthcare services, treatment fees, medicine cost, etc.¹⁵. Thus, every year over 63 million persons are at risk of falling below the poverty line^{16,17}. The total healthcare expenditure in India is only 3.9% of the domestic product (GDP) and out-of-pocket

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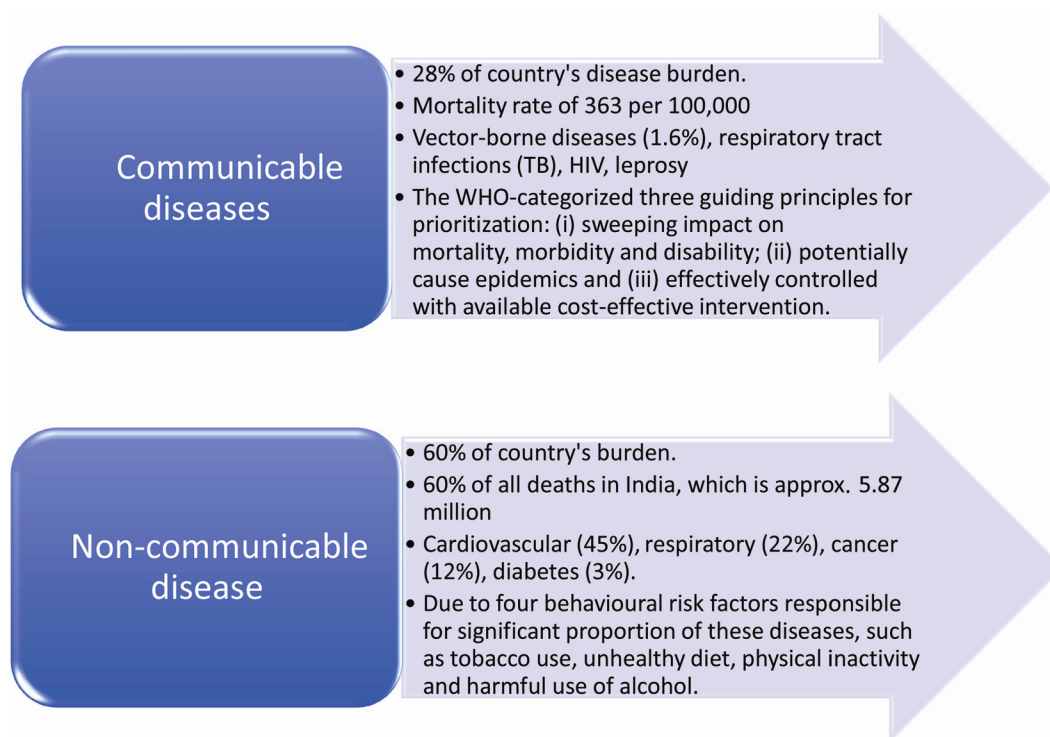


Figure 1. Dual disease burden of country³⁻⁷. This is shared by the communicable and non-communicable diseases. The share in mortality and major diseases in each category is also defined.

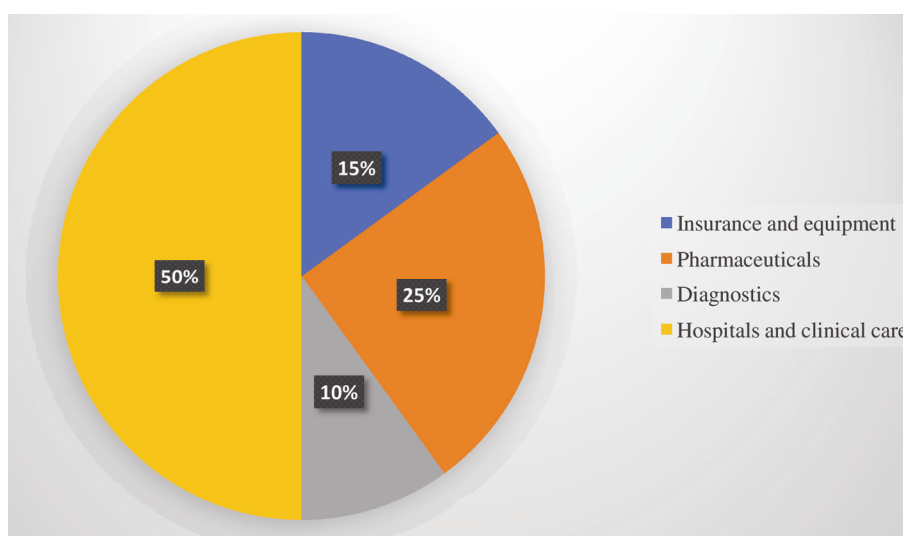


Figure 2. Contribution of various segments of healthcare industry². The major segments of healthcare industry and their share of contribution are depicted.

expenditure is as high as 61% (ref. 18), with only 25% of the population being covered by health insurance^{19,20}. Figure 2 shows various segments of industry and their contribution to the healthcare sector².

The pharmaceutical industry and medical technology industry provide evidence for phenomenal growth in the past decade (Figure 3)²¹⁻²⁴; regardless of this, the sector faces several hassles. In India, the pharmaceutical industry can be broadly sub-segmented into active pharmaceu-

tical ingredients (APIs); vaccines; excipients; formulations; biosimilars; generics and personalized medicine. Medical technology industry includes application of organized healthcare knowledge and skills in the form of devices (electro-medical equipments, nanotech-based devices), irradiation, surgical equipment, implants, medical disposables, diagnostic kits; procedures and systems designed to improve quality of care across each stage of the healthcare continuum like screening/diagnosis, treatment/care,

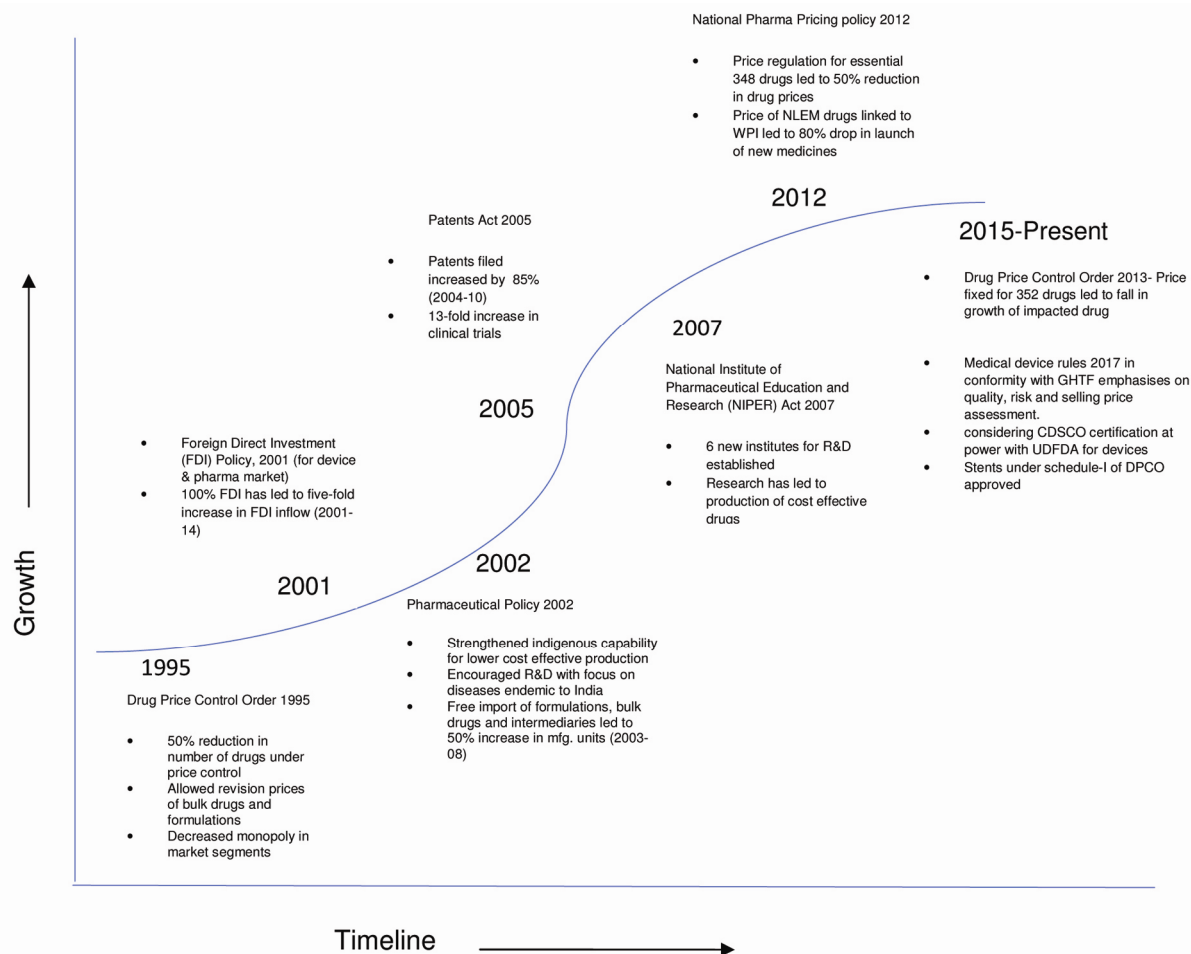


Figure 3. Journey of the pharma and medical technology industry in India²¹⁻²⁴ (adapted from Deloitte and Nathealth joint report²¹). The progressive initiatives and other milestones of the industry are outlined, which supported the growth of healthcare industry, viz. Drug Price Control Order, Foreign Direct Investment (FDI), Patents Act, Pharmaceutical Policy, National Institute of Pharmaceutical Education and Research (NIPER) Act, National Pharma Pricing Policy, medical device rules, Central Drugs Standard Control Organization (CDSCO) certification, NLEM, National List of Essential Medicines; GHTF, Global Harmonization Task Force; US-FDA, US Food and Drug Administration; R&D, Research and Development.

restoration and monitoring. The key concerns of the pharmaceutical industry are compliance issues in line with good manufacturing practice, drug quality and clinical trial quality. The industry is highly fragmented with low margin of profits due to government pricing policy of Drug Price Control Order, inadequate R&D due to pricing norms and stringent intellectual property (IP) laws. The major setback of the industry is drug failure during clinical trials in terms of safety and functionality^{25,26}. Despite industry's potential for generics, the scarcity of essential medicines or ineffective drugs have resulted in cases of antibiotic resistance. Previously, the ecosystem was not conducive for the medical technology industry to drive accessibility and affordability, as the industry is small (equipment market is just 9% of overall healthcare market²⁷) with a disproportionate reliance on imports and a complex regulatory environment. The main challenges that disabled the growth of indigenous medical device manufacturing are infrastructure, discrepant regulatory mechanism, insignificant collaborative activities, unwar-

ranted Foreign Direct Investment (FDI) restrictions, disproportionate supply of skilled manpower (Figure 4)^{21,28,29}. Currently, only 1.5–2 lakh surgeries are performed per year in India against an approximate demand of around 25 lakhs³⁰. This projects the need for a cost-effective medical system and its scope of expanding the healthcare market in the country. The major revenue-generating segments of pharmaceutical industry are generics (70%), over-the-counter drugs (21%) and patented drugs (9%)²⁷, whereas the medical technology industry is dominated by medical electronics, stents and diagnostic equipment³¹.

3A anomaly: major concerns for public health

Despite having enormous potential with vast competitive market, geographic segmentation, cultural diversity, large demographic dividend and vast population segmentation contributing to an open-ended market for diverse

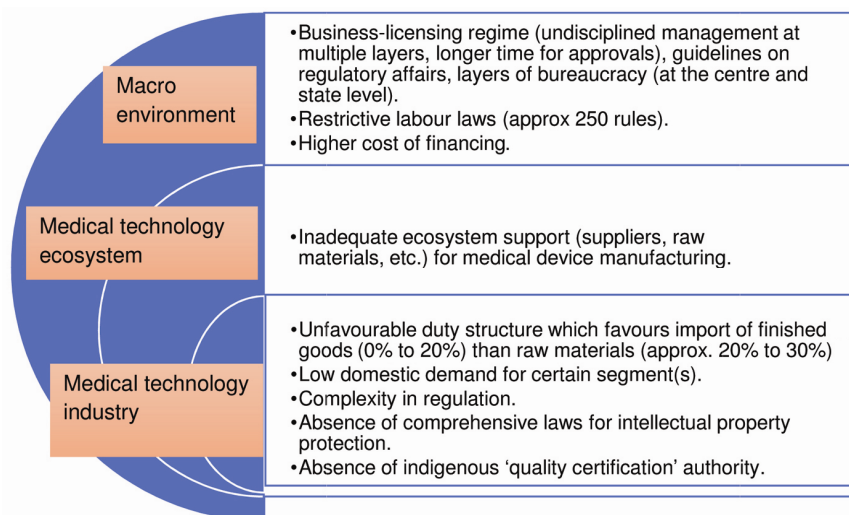


Figure 4. Challenges of medical technology industry^{21,28,29}. Challenges with respect to the macroeconomic environment, medical technology ecosystem and those specific to the medical technology industry, which disable the growth of indigenous medical devices manufacturing in India are highlighted.

need-based technologies, the present scenario leads to three major anomalies – 3A (availability, affordability and accessibility) of the healthcare sector.

(1) Availability of healthcare solutions such as drugs, vaccines, formulations, medical devices and equipment is subject to conditions of inadequate R&D activity and unnoticed underlying solutions in our laboratory inventories. The healthcare research has higher risk of failure, demands hefty investments, is time-consuming and has a stringent multiple-window regulatory system. Thus domestic players, small firms do not encourage new R&D activities, e.g. the process of developing a drug/new chemical entity (NCE) painstakingly takes about 10–15 years. Then it is examined and approved by the drug regulatory agencies (e.g. US Food and drug administration (US FDA) and Central Drugs Standard Control Organization-(CDSCO) in India) that monitor and govern the testing of the new compound through pre-clinical/clinical trials to validate their safety and efficacy for defined purpose. Several NCEs fail at various stages, rendering all the money and effort to go in vain. The chances of bringing them to the desk of the pharmacy is remarkably low as it involves a complex process³².

(2) Affordability of existing healthcare solutions is measured by the capacity of patients who can buy it and is well depicted by poverty impact of out-of-pocket-spending which does not affect the poor, but affects a substantial proportion of the middle class who are at risk of falling below the poverty line due to health expenditure^{33,34}. Healthcare industry is monopolized by multinational players with highly quoted devices and exorbitantly priced patented medicines, specifically for non-communicable diseases.

(3) Accessibility of healthcare solutions to public raises many concerns, because in spite of having a vibrant

generic industry, emerging hospital chains and other healthcare facilities, our rural population is still deprived of primitive medical facilities. The delivery mechanism has many loose ends, affecting public health with limited access and the complexities of the regulatory system worsen the situation. Available solutions are not in proportion with the demands of the population.

All three are interlinked and affected by the differences in purposes of manufacturers who are for profiteering, consumers who struggle with accessibility of affordable solutions due to lack of confidence in indigenous products and paradigm shift of policymakers to meet the national and international obligations of public health relevance.

These major irregularities can be addressed by integrative approach of using our R&D strength and establishing a favourable intellectual property system for a conducive healthcare environment. The subsequent sections significantly mention play back voice of India's R&D and IP. Both play a vital role in public health for providing an efficient healthcare system. If R&D and IP complement each other, the healthcare system can become more efficient. A country like India has enormous amount of knowledge and it requires an efficient tool to convert this knowledge into accessible deliverables. IP is considered as the most optimistic and realistic tool to strengthen the healthcare system.

India's research and development roadmap

Health research plays a key role in the development of a nation's health. In the late 1990s, several road maps were planned to encourage R&D activities. The Ministry of Science and Technology, Government of India (GoI)

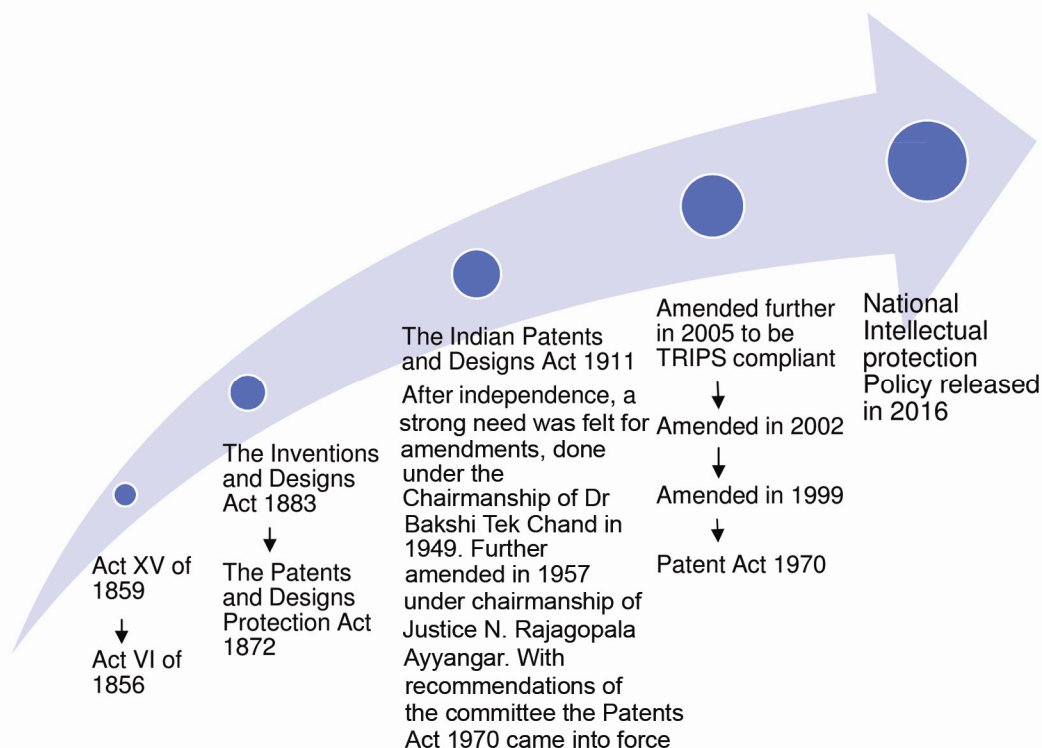


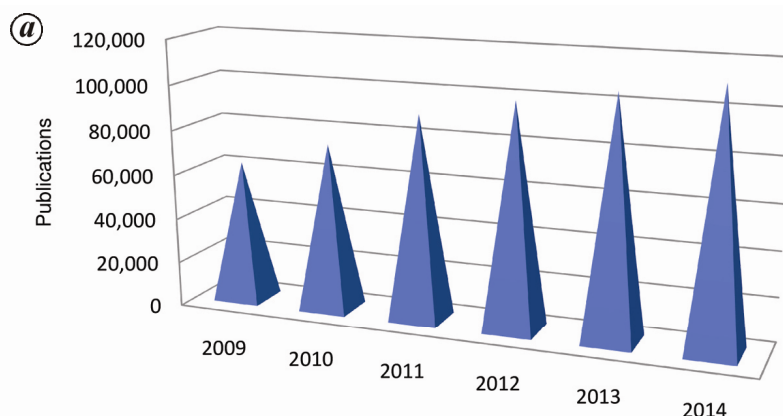
Figure 5. Journey of developing an intellectual property ecosystem. Major milestones in the establishment of robust intellectual property laws since the era of the Britisher's till the 21st century are shown.

released the Science and Technology Policy 2003, Science, Technology and Innovation Policy 2013 and pronounced science and technology-led innovations as the drivers for development declaring the period of 2012–20 as the 'decade of innovations'³⁵. In line with these efforts, several Five-Year Plans were launched for a substantial increase in rightful spending of allotted budget by establishing research laboratories/institutes. For instance, a budget of Rs 39,533 crores was allocated to the Ministry of Health and Family Welfare³⁶ out of a total budget of USD 55 billion approved by NITI Aayog under the 12th Five-Year Plan. The Ministry targeted development of 50 technologies for lifestyle diseases in 2016 (ref. 27). A total of 5710 R&D institutes were reported till year 2015 (ref. 37). Some of the scientific organizations with their individual intramural institutes mentioned in brackets, viz. Defence Research and Development Organization (4), Indian Council of Agricultural Research (97), Indian Council of Medical Research (33) and Ministry of Science and Technology (40) – majorly Council of Scientific and Industrial Research; Department of Biotechnology and Department of Science and Technology conduct life sciences research and account for major share in R&D expenditure³⁸. A progressive rise in the number of publications has been observed, which showcases significant research in life sciences³⁹ and our innovation capabilities. In 2014, 52,337 (ref. 40) publications accounted for only 4.4% of the world's science and technology scholarly

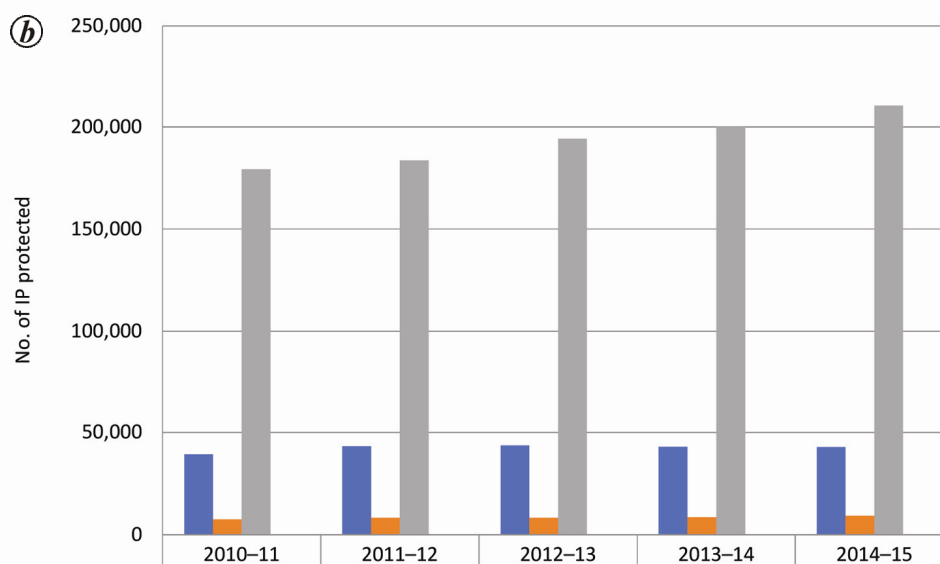
output and 13.9% compound annual growth rate compared to 4.1% for the world in 2013 (ref. 40). In the period 2005–14, 101,034 medical science papers were published, with the average number of publications per institution being 14.5 per year, majorly contributed by four medical colleges, viz. All India Institute of Medical Sciences, Post Graduate Institute of Medical Education and Research, Sanjay Gandhi Post Graduate Institute of Medical Sciences and Christian Medical College; by contrast, 332 (57.3%) medical institutes had no publications⁴¹. Collaborative research was also conducted at many institutes as public–private collaborations and generated 1250 papers accounting for 1.2% of India's S&T scholarly output³⁹. This reflects a need to encourage collaborative research and development. Thus, the rate of translation of basic and applied science into new products and indigenous technologies is not in accordance with the R&D, funds invested and time devoted. As of now very few products are visible in the market, which are the end results of performed research. This highlights a proper handholding for translation of research.

Evolution of intellectual property rights

The battle for realization of IP started in early 1990s, when instances of counterfeiting and unlawful acquisition of traditional knowledge were reported, such as



	2009	2010	2011	2012	2013	2014
■ No. of publications	62,955	74,535	90,793	99,524	106,065	112,009



	2010-11	2011-12	2012-13	2013-14	2014-15
■ Patent	39,400	43,197	43,674	42,951	42,763
■ Design	7589	8373	8337	8533	9327
■ Trademark	179,317	183,588	194,216	200,005	210,501
■ Geographical indication	27	148	24	75	47

Figure 6. *a*, Year-wise projection of publication during 2009–14 (ref. 39), showing India’s R&D strength, and available knowledge pool for translation. *b*, Comparative data of different forms of IP during the last 5 years (2010–15)⁴³. Various forms of IP (patents, designs, trademarks and geographical indications) filed in the last 5 fiscal years are shown. This projects IP protection, which is less compared to the generated research and development products.

misappropriation of indigenous knowledge prejudicing the interest of rightful custodians⁴². Thereafter, substantive laws and procedural mechanisms were developed to regulate transforming scenario of IP protection. Intellectual property rights laws were introduced as cornerstones of an efficient and balanced system. In past 20 years, society has seen significant IP development to meet national health and international trade obligations (Figure 5).

Despite these efforts, major sections of the population are unaware of the elementary knowledge of intellectual

property rights (IPR). Bibliometric analysis of data for the period 2009–14 shows India’s research outcome (Figure 6*a*)³⁹. In contrast, the comparative innovation capabilities by IP protection quotient for 2010–15 highlight the need for mass sensitization (Figure 6*b*)⁴³. The government has modified the Patents Act, 1970 through various amendments in 1999, 2002 and 2005, to comply with the requirements of Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to facilitate multilateral trade and prioritize public health. The obligation

mandated TRIPS posed major challenges in the public health sector.

The Patents Act, 1970 allowed India to legally produce generic versions of medicines that were under patent elsewhere. This facilitated the availability at a fraction of the cost of similar medicines abroad. The Indian pharmaceutical industry is in routine practice of re-engineering the process for manufacturing generic drugs⁴⁴. These drugs play a major role in lowering the price and increasing competition, availability and affordability. Till 2005, this practice was backed by the Patents Act, 1970 which only protected the formulation process and not the product. Thus, companies with good knowledge on IP worked out the solution of evergreening⁴⁴, i.e. securing sequential and overlapping patents on a single invention through minor changes, which further extended their monopoly for the pricing and availability of drugs. Thus, leading to unavailability of adequate low-cost generic drugs for public.

The 2005 Amendment⁴⁵ introduced the product patent regime for pharmaceuticals which made the Indian patent law TRIPS-compliant, but by introducing Sections 3(d) and 3(e), the grounds for patentability were strengthened and the phenomenon of ever greening was restricted. Efforts were made to improve the stringency and clarity of Section 3 which defines what is non-patentable and introduce restrictions as to the scope of falsified patentability (Section 3(d) by defining therapeutic efficacy). Section 3, provisions of compulsory licensing (Section 84-94) and pre-grant, post-grant oppositions (Section 25) provide diligent scrutiny to pharmaceutical patent filing and maintenance system, subsequently benefitting the Indian generic industry.

The last decade has witnessed many landmark decisions by the government with intent of protecting the traditional knowledge⁴⁶, to regulate monopoly⁴⁷, to make healthcare solutions affordable⁴⁸. Also, many patents have been rejected on the grounds of lack of efficacy (Section 3: Novartis–Glivec case). This leads to the inference that the government has adopted a firm attitude towards falsified acts of industry to give equal chance for domestic players, encouraging generic market for new R&D activities, product patent filing and setting an ethically strong market for the healthcare products. The present IP system in India strikes a balance between enhancement of innovation capacity and encouragement of pharmaceutical industries.

The Indian healthcare sector has been growing at a double-digit rate of 14% and is expected to be 21% in the next decade, majorly due to privatization of healthcare, access to rural market and inclusion of innovative technologies⁴⁹. It is undergoing a metamorphosis by broadening its services using technology, deliverables and newer applications indicated by 1.3% of GDP spent on healthcare together by the centre and the states in 2015–16 (ref. 50). A rise in demand for high-end drugs and advanced medical technologies is expected. Growing population,

ageing, income base and associated disposable income, increasing socio-economic inclusion of rural and deprived in mainstream economy, healthcare penetration in tier II and III cities, evolving customer landscapes, changing regulations, shifting market and changing attitude towards preventive healthcare are some of the factors which have encouraged manufacturing and innovation to develop customized products⁵¹.

Initiatives by the government and industry towards public health

The industry is contributing to strengthen the healthcare by expanding its footsteps in rural hospitals, setting up various manufacturing units, developing new drugs and promoting collaborations (Supplementary Table 1). India ranks amongst the top global generic formulation exporters in terms of volume. Our pharmaceutical exports have grown at a compound annual growth rate of 21% over the last decade. Our vaccines are exported to 150 countries with India being home to 10,500 manufacturing units and over 3000 pharma companies, growing at an exceptional rate. Among these companies, 1400 are WHO and good manufacturing practice approved manufacturing units. In addition, US FDA has approved 584 sites for manufacturing and processing, followed by accreditation by approximately 1105 certificates of suitability and 950 therapeutic goods administration approvals. Approximately, 40–70% of the vaccines for diphtheria, pertussis, tetanus and BCG, and 90% of measles vaccine are provided by India. Almost 70% of patients in developing countries receive Indian medicines through non-governmental organizations. Globally more than 90% of formulations approval for anti-retroviral, anti-tubercular and anti-malarial has been granted to India. The country's exports of pharmaceuticals stand at US\$ 16.8 billion. India exports all forms of pharmaceuticals from APIs to formulations, both under modern medicine and traditional Indian medicine. Following the introduction of product patents, several multinational companies are expected to launch patented drugs in India⁵². Whereas the medical technology industry is largely dependent on imports which constitute around 75% of sales in India, with most local manufacturers making products in the lower end of the technology value chain (Figure 7)²¹. The multinational companies share 60% of stents market, whereas the low-end equipment, consumables and disposables market is led by domestic players because of their cost-effective innovations^{25,53}, accounting for only 0.2% of the total manufacturing industry²⁵. The pharma companies have now initiated investing in the distribution network in rural areas, as 70% of India's population resides in rural markets⁵³.

The government has announced a host of measures facilitating a conducive environment for indigenous

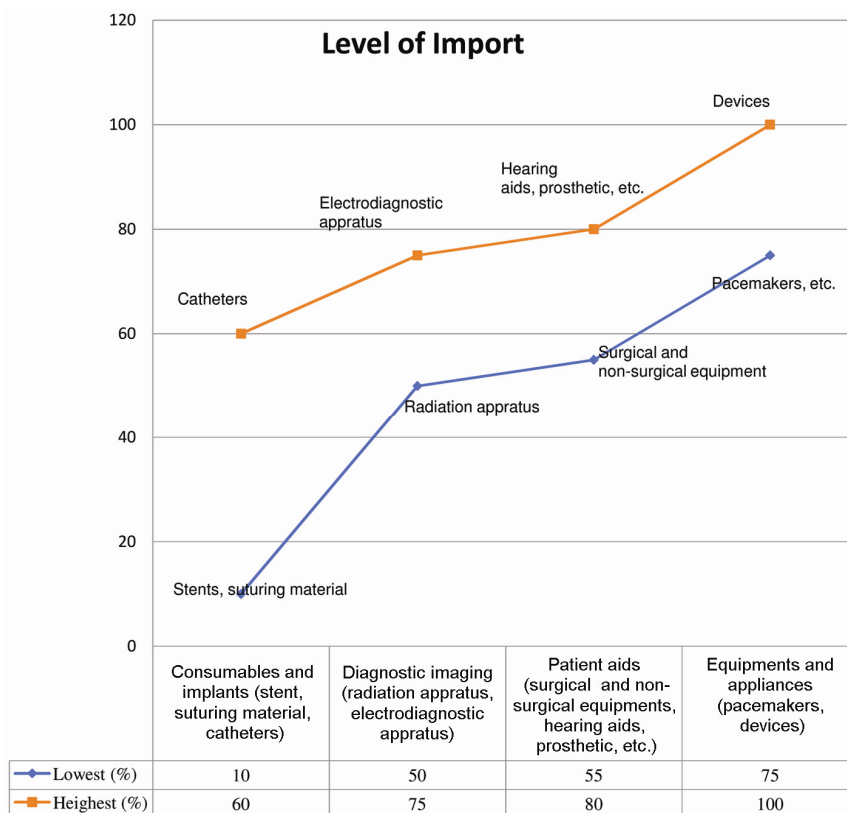


Figure 7. Segments of medical technology industry²¹. The industry is import-driven; various sub-segments of each category have been scaled according to their import frequency, e.g. catheters from the ‘consumables’ category are maximum imported compared to suturing material.

technologies⁵¹ and regulatory reforms aimed at building more hospitals, boosting local access to healthcare, improving quality of medical training, pharmaceuticals and medical devices. Also 100% FDI in medical devices is envisaged to attract huge investments. The ‘Make in India’ initiative⁵⁴ is expected to create a multiplier effect on employment generation, growth of domestic players and development of a quality standardization framework according to international standards to certify the quality, safety and performance of medical devices, thus escalating Indian share in the global market⁵⁵. The following are some of the major initiatives addressing availability, affordability and accessibility anomalies:

(1) Availability (more the R&D, better will be the availability)

- Niti Ayog proposed PPP in R&D²⁷.
- 100% FDI in R&D, manufacturing²⁷.
- Approaches of patent mortgaging, patent auction to utilize technologies from our inventories.

(2) Affordability (more the competition, in-house manufacturing, better will be the affordability).

- National Pharmaceutical Pricing Authority fixed prices of 540 essential medicines used for non-communicable diseases⁵⁶.
- Supreme Court gave pricing rights for 350 bulk drugs to the government⁵⁷.

- Drug Price Control Orders notified stents under schedule I and they are price-regulated⁵⁸.
- The government directed hospitals to use Indian devices with CDSCO certification²².

(3) Accessibility (more transparent the system, better will be the accessibility).

- The Medical Device Act provides clarity, transparency for quality, risk and price check²³.
- The government relaxed clinical trial rules, reduced approval time, established eight mini drug testing labs across ports⁵⁹.
- Tax exemption for the first five years in case of hospitals established in rural areas²⁷.
- For strengthening delivery mechanism, initiatives like the National Rural Health Mission and National Urban Health Mission were started with adequate allotment of budget^{60,61}.

Increased funding and investment are also reflected in other supply side changes in healthcare delivery in India. For example, healthcare infrastructure has made great strides in terms of the number of hospitals, hospital beds (0.8 million in 2002 to 1.6 million in 2012), corporate hospital chains, international companies and penetration of service providers in tier II and tier III cities, followed

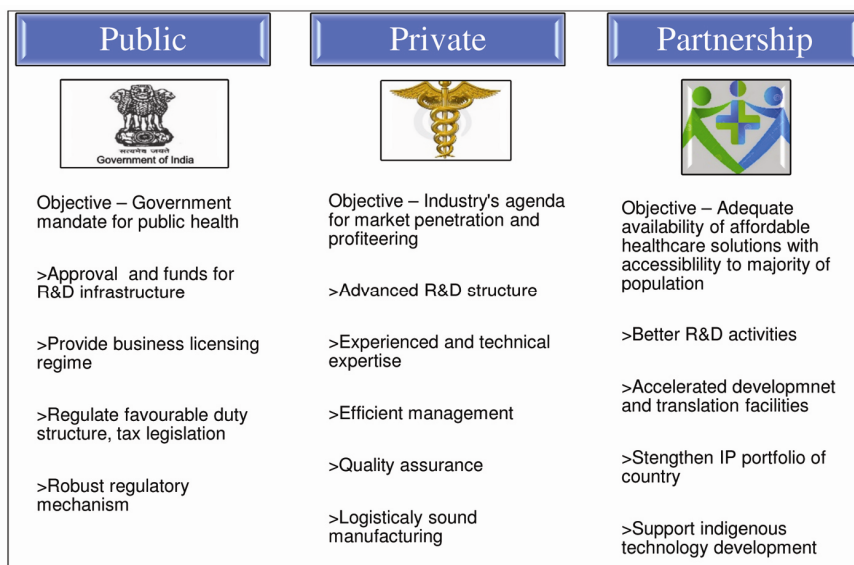


Figure 8. Envisaged 3P (public–private–partnership) framework. The objectives and strengths of government and industry are defined. The desired objectives and possible outcome of a healthy 3P framework are also defined.

by emergence of new formats like chains of multi-specialty outpatient clinics, mother-and-child hospitals, short-stay surgery centres, *in vitro* fertility centres, etc. which are driving the demand for medical devices²¹. An increase has been witnessed in the presence of diagnostics laboratory chains for imaging and pathology; there are approx. 100,000 such labs across country and the number is expected to grow at a rate of 15–16% (ref. 55). Phenomenal upgradations were seen in existing healthcare infrastructure, as hospitals and laboratories were encouraged to comply with accreditation requirements. Around 285 hospitals are National Accreditation Board for Hospitals and Healthcare Providers accredited; 472 additional proposals have been submitted for accreditation. Similarly, 347 laboratories are National Accreditation Board for Testing and Calibration Laboratories accredited with 150 additional proposals submitted²¹. However, there exists a need to regulate the standards and practices of these institutions to safeguard patient interests and keep costs down, while ensuring rapid and full delivery of modern healthcare practices to the remotest of villages. With immense R&D strength, emerging IP, and various initiatives, all we require is coordination and guidance.

3P to address the anomaly of 3A

To meet the challenges of the new scenario, embracing our strength of R&D and IPR through 3P should be encouraged. It is a well-recognized strategy by public and private sector. 3P in healthcare is an approach to address public health problems through the combined efforts of public and private counterparts with the best of their contribution and expertise. The major policies of the country such as Science, Technology and Innovation Policy 2013

(ref. 35) and National Intellectual Property Rights Policy 2016 (ref. 62) acknowledge 3P strategy to be most effective in successful implementation of their mandates. It can also be called People's Performing Partnership.

We have observed a change in conventional approach which earlier involved larger share of investment by industry with less incentives for them. Now private R&D has increased its capacities and avails government funds and other incentives like tax rebate. The Science Technology and Innovation Policy 2013, proposes to set up R&D facilities and new Technology Business Incubators with provision of equal benefit sharing by private and public sectors. It encourages the role of NGOs in the delivery of science–technology–innovations. The approach is now more inclusive and welcoming for private sector. To encourage R&D under 3P model, the Prime Minister's doctoral research fellowship has been introduced⁶³. Similarly, the National Intellectual Rights Policy envisages balancing the interests of the rightful owners with larger public interest focusing on providing protection to India's traditional medicinal knowledge from misappropriation. Adopting the approaches of IP auditing, IP auction, IP mortgaging, IPR sharing, IPR exchange, open source development, parallel importation and cross-sector partnership, will help explore and utilize the available IP for the nation's economic growth. For successful implementation of all these approaches, the potential stakeholders, contributors, seekers, providers, etc. need proper guidance.

The Twelfth Five-Year plan (2012–17)⁶⁴ also envisages establishing a system of universal health coverage (UHC) for all nationals through a 3P system. Other flagship programmes of the government include 'Start-up India' action plan⁶⁵, which aims to boost ground-breaking entrepreneurial spirit of our youth with support of public

and private sectors. A 3P model has been considered to set up 35 new incubators with public sector supporting finance and legislative responsibilities, while private sector is accountable for their smooth running by assisting in technical knowledge and mentoring. Also, to develop the culture of IP development amongst them, the rules of patent filing have been liberalized. The private health insurance schemes, constituting the bulk of insurance schemes, only cover hospitalization and associated expenses, but do not cover costs of consultation or medication. On the contrary, the government has come up with Rashtriya Swasthya Suraksha Yojana, or National Health Protection Scheme and has opened various Jan Aushadhi stores². 3P requires smartly designed dimensions for healthcare, as this sector is one of the most sensitive sectors in the country. In the current scenario, it projects a relative sense of equality, accountability and mutual commitment to agreed objectives with mutual benefit to all stakeholders (Figure 8).

Conclusion

According to the mandate of the new NHP 2017, the healthcare sector shall be designed to ensure affordable, quality medical care for all income segments with changing disease prevalence patterns and growing awareness, to focus on early detection and disease prevention. Presently, efforts are concentrated upon bare necessities of R&D output, IP generation and translational activities to fuel a vibrant knowledge economy. Despite landmark initiatives towards making India self-reliant, the prevailing healthcare sector does not sufficiently address current issues and demands. To alleviate this dichotomy, we should encourage rapid indigenization of medical technologies with single-window regulatory framework for manufacturing and concentrated multidisciplinary research efforts with integration of traditional medical system along with e-healthcare according to the good manufacturing practice guidelines and quality standards. For translational activities, it is proposed to incorporate parameters of differential pricing, quality assurance, timely delivery, manufacturing of products, royalty-on-net sales and jointly-funded validation. The Government should also offer support for market penetration (NGOs, Primary Health Centres, Community Health Centres, Tertiary hospitals, Government programmes, etc. according to the product category), regulatory clearance, tax relaxation and adequate funding.

Further, to fight disruptive events of shifts in patent laws, high cost on R&D, to enhance research diversification, robust regulatory approaches, geographic expansion, IP portfolio management and translation mechanism should consider interdisciplinary collaboration by encouraging inclusive innovation ecosystem between the industry and the government, followed by a parallel workflow. In addition to commendable progressive efforts by stakeholders, we should focus our energies on

developing new technologies. For this, we need to prepare a framework to upscale and translate our undervalued, unutilized indigenous technologies lying in our inventories, as they would cut on the cost of development and avoid redundant efforts. This will also reduce the time of translation and, most importantly, the public health issues at hand can be easily tackled within a strong network where mutual growth drives the market. The basic mandate of research and innovation should be public health-oriented, rather than driven by monetary profit, credibility and market demand.

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