

Building inclusive health innovation systems: lessons from India

A criação de sistemas inclusivos de inovação em
saúde: lições da Índia

Creación de sistemas inclusivos de innovación en
salud: lecciones desde la India

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Abstract

This article presents an overview of the changes that are taking place within the public and private health innovation systems in India including delivery of medical care, pharmaceutical products, medical devices, and Indian traditional medicine. The nature of the flaws that exist in the health innovation system is pinpointed. The response by the government, the health, technology and medical institutions, and the evolving industry is addressed on a national level. The article also discusses how the alignment of policies and institutions was developed within the scope of national health innovation systems, and how the government and the industry are dealing with the challenges to integrate health system, industry, and social policy development processes.

Biomedical Technology; Health Systems; Sustainable Development; Innovation

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Introduction

This article analyses the Indian health innovation system focusing on different actors involved in healthcare delivery, pharmaceuticals, medical devices, and traditional medicine. Compared to the first four decades of post-independence, the Indian health innovation system today is significantly different in terms of spread of market governance institutions for healthcare promotion. While, the last two decades emulated the trajectory of capitalist globalization, there has also been a countervailing power emerging in India through the resistance being put up by social movements (“health as a right”). State regulation and social control have emerged in India as major issues in health innovation policy, together with improvements in the supply of critical inputs for the organization and management of innovation activities in pharmaceuticals, diagnostics, medical devices, and traditional healthcare.

Health innovation contains most of the elements of change in healthcare. It is inherently complex to implement and operate, as it involves a combination of technological and organizational renewal within an environment featuring a diversity of stakeholders. It covers a wide range of changes in the design of services, products, and production processes (technology element); new or altered ways in organizing or administering activities (organization element); new or improved ways of interacting with other organizations and knowledge bases (system interaction element); new worldviews, rationalities, missions, and strategies (conceptual element). Changes in the health innovation system often involved the introduction of interrelated changes in technological, organizational, and institutional elements of healthcare. Many innovations are also systemic in nature, since they emerge from, and must address the complex interplay between political, administrative, technological, institutional, and legal issues. In this context the present paper undertakes a preliminary analysis of the performance of the health innovation system with due attention to its major segments, locates the nature of failures, and highlights the response from the major actors involved. In the subsequent sections, the article provides a brief overview of the components of the health innovation system and the current scenario of health innovations in healthcare delivery, pharmaceuticals, medical devices, and indigenous medicine in India, before concluding with various challenges and priorities.

Innovations in the healthcare system

The 1990s witnessed an intensified spread of health markets. Public health was reconfigured to focus on a few cost-effective priorities: Disability-adjusted life years (DALYs) saved per dollar spent provided the criterion for measuring success of reforms. During this decade, public health focused mainly on programs to reduce infant, child, and maternal mortality rates and to control malaria, leprosy, tuberculosis, and HIV. The rest was left to the private sector. Health became market-driven, with the promise of insurance vouchers for the poor. Both health professional education and medical research became increasingly market-driven, with huge regional and thematic imbalances. Innovation and research programs started to be driven by international aid.

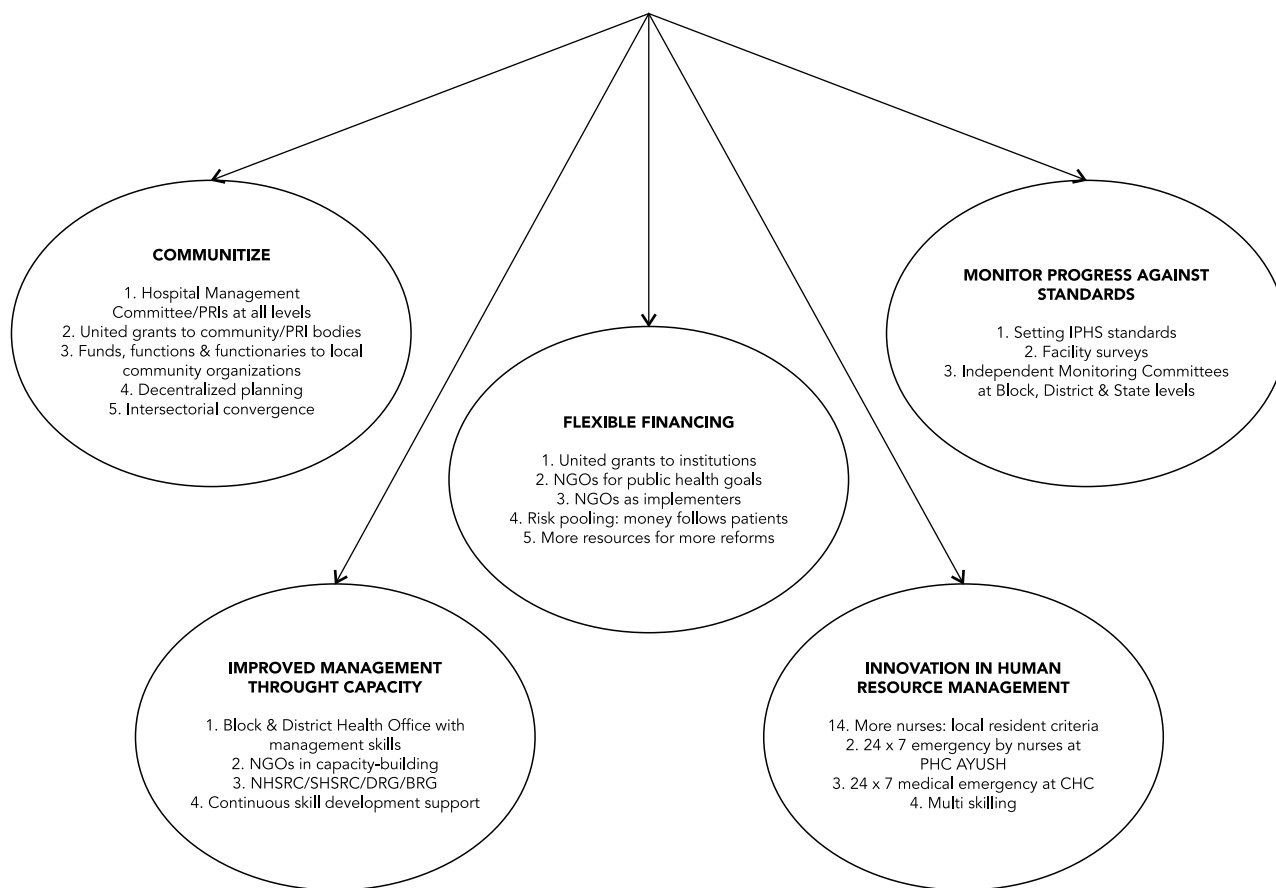
While it is true that India has much to claim in healthcare, much more remains to be done given the high infant and maternal mortality rates, faltering immunization coverage, stagnating nutritional status of children, and significant levels of mortality from communicable diseases¹. The plausible reasons include: meagre allocation in the health budget, lack of demand from the poor, and persistence of dysfunctional and unresponsive healthcare services due to the spread of unregulated markets. Low utilization of rural public health services is also due to the unwillingness of trained doctors to work in rural areas without proper infrastructure. There are also geographic and regional disparities in distribution and quality of healthcare services and social inequalities that have impact on health outcomes.

The latest effort to improve healthcare delivery is through National Rural Health Mission (NRHM), a system capable of influencing the architecture of the state level health systems. The NRHM organizes the central government health programs in a systematic manner. It calls for reform and introduction of architectural innovation in the case of health system(s) to make them functional in the states. Figure 1 presents the basic characteristics of innovations introduced via NRHM.

Another critical component in the planning and implementation of the NRHM is the National Urban Health Mission (NUHM). Scholars often point out the irony of urban healthcare. Despite the proximity of the urban poor to health facilities, their access is severely restricted by the inadequacy of health services. Here, most innovations were developed to introduce programming and financing flexibility that was accorded by the NRHM and Reproductive Child Health (RCH). Most of 227 identified innovations refer to improving service delivery.

Figure 1

National Rural Health Mission (NRHM): main approaches.



AYUSH: Ayurveda, Yoga, Unani, Siddha and Homeopathy; BRG: Block Resource Group; CHC: Community Health Centre; DRG: District Resource Group; IPHS: Indian Public Health Standards; NGO: Nongovernmental Organization; NHSRC: National Health Systems Resource Centre; PHC: Public Health Centre; PRI: Panjayati Raj Institutions; SHSRC: State Health Systems Resource Centre.

Source: the authors from Sundararaman ¹⁰.

Innovations are reported from all states, but we see a higher number of innovations being implemented in Tamil Nadu, Chhattisgarh, Madhya Pradesh, Andhra Pradesh, and some of the North Eastern states. The state of Tamil Nadu has a strong public health system, and all the innovations implemented were led by the state, with no external partner. Analysis also reveals contracting-out of health facilities to Nongovernmental Organizations (NGOs). The stimulus for such contracting-out at least to the private sector in some states appears to be external donor support, as in Uttar Pradesh, West Bengal, Madhya Pradesh, and Assam. In contrast, contracting out Public Health Centres (PHCs)

to NGOs is a state-led innovation in Karnataka, Arunachal Pradesh, and Meghalaya.

Two key innovations in outsourcing to the private sector that have been adopted for replication by several states are (i) public-private partnerships for the delivery of maternity services and (ii) emergency transport for obstetric referral. The innovation that appears to have set the stage for contracting out maternity services to the private sector began in Gujarat, with several states replicating them. It appears that many of the innovations that were scaled up for implementation in health systems were devoid of adequate evidence about their effectiveness. It should also be noted that almost all

innovations are funded through government: national or state level.

Innovations in pharmaceuticals

Technological capability-building processes have been the focus of policymakers in the Indian pharmaceutical industry since the early 1970s with the introduction of new patent legislation and the adoption of drug policy (1978). Under the *Indian Patent Act* (1970), the country's national system of innovation was free to develop alternate processes for the drugs that were still under product patent protection in developed countries. During the 1980s several domestic firms entered the local market using process technologies developed both in-house and in public research laboratories.

Table 1 presents process technologies contributed by public research laboratories for compounds manufactured for different diseases. It is evident that priority was assigned to Type I lifestyle diseases (cancer, obesity, diabetes, cardiovascular diseases, and hepatitis), especially during 1965-1994 (in the first two phases). In terms of degree of originality and novelty pursued, over 50 new processes were developed during the period of 1965-1980 in public labs that benefited Indian pharmaceutical firms.

Public laboratories are also engaged in the development of new drugs. Some of these drugs succeeded in the market with the help of national health and family welfare programs. But until the early 1990s, domestic companies, mostly of medium scale, lacked resources for product development. They started to develop capabilities required for new processes, formulations, dosages, new salts, derivatives, isomers, polymorphs, and other "less radical" products to enter the regulated markets of U.S. and Europe. However their in-house capabilities were seemingly not developed enough to give them a competitive edge over generic companies originating from Israel and Europe.

Indian pharmaceutical firms have obtained approval from the U.S. Food and Drug Administration (FDA) for more than 450 different active pharmaceutical ingredients (APIs). India can now claim to possess a rich vendor base with 3.75 drug master files (DMFs) per molecule being approved by the US regulatory body². This implies that the manufacturers can legitimately export the respective molecule to the United States.

Compared to contract manufacturing, the option of export of generics to the regulated markets of U.S. and Europe is a better route for large Indian pharmaceutical companies upgrading

capabilities related to development of advanced elements of processes, analogue product, and formulations. Even now India has only a small presence in advanced formulations, accounting for just 3% of its total sales. India is also absent from non-conventional dosage forms. India has just 48 products in specialty generics, which is insignificant as the U.S. market is close to 1,250 products³. Evidence available from the patenting activity of companies active in the Indian pharmaceutical industry shows that the domestic research and development (R&D) directions are skewed and tilted in favor of development of analogue molecules, new forms of substances, dosages, and formulations (Table 2). There is still only a small amount of activity of new chemical entities (NCEs)⁴.

Indian companies are still directing their R&D efforts to the area of generics. Basically the potential NCEs being developed at home by Indian companies have been licensed out to global pharmaceutical firms for further development. Further, in India too, traditional pharmaceutical companies are now shifting their focus to biopharmaceuticals. For example, Dr. Reddys' Laboratories (DRL) is known to be working on at least eight bio-similars for therapeutic use in oncology and autoimmune disorders. As far as bio-therapeutics is concerned, it does seem to be on the radar of Indian pharmaceutical companies in a significant way. The Indian industry is achieving better breakthroughs on vaccines⁵ as the development of a variety of vaccines from conjugated to combination and recombinant vaccines is on the radar of Biocon, Serum Institute, Bharat Serums and Vaccines, and Panacea Biotech.

In publicly financed innovation, the focus earlier was on diseases that were considered national priorities, in areas where all over the world public finance drives innovation (such as contraception, tuberculosis, malaria, and filariasis). The public sector targeted commercial products too, for example in biopharmaceuticals.

As an alternative to the model of drug discovery in which the incentive comes from the use of a strong intellectual property system, a new institutional arrangement is also now under experimentation in the form of open source drug discovery (OSDD). OSDD is a web-enabled interactive platform that will list the current design challenges for developing drugs to treat drug-resistant tuberculosis, malaria, and HIV. It has much potential to involve researchers from all over the world in product development for the benefit of neglected diseases. The first step in the OSDD initiative by the Council of Scientific and Industrial Research (CSIR) is the launch of an open source website hosting

Table 1

Type of process technologies contributed by the Council of Scientific and Industrial Research (CSIR), India.

Type of disease	Year			Total
	1965-1980	1981-1994	1995-2005	
Type I	39	21	7	67
Type II	5	2	3	10
Type III	6	4	2	12
Others (not targeted to any type of disease)	1	1	3	5
Grand total	51	28	15	94

Source: Abrol et al. 4.

Table 2

Indian pharmaceutical patents in U.S. Patent and Trademark Office (USPTO), India.

Nature of patent	1992-1995	1996-1999	2000-2003	2004-2007	Total
Process patent		11	51	133	195
NDDS patent			18	23	41
NCE patent		3	6	10	19
Method of treatment, dosage, formulation, composition, combination & product patent	14	26	102	261	403
New forms of substances		6	63	156	225
Grand total	14	46	240	583	883

NCE: new chemical entities; NDDS: nano drugs delivery system.

Source: Abrol et al. 4.

information on *Mycobacterium tuberculosis*, the bacterial pathogen that causes tuberculosis. This information includes gene sequences, expression, function, activity, and the response to drugs of all tuberculosis proteins as well as host-pathogen interactions.

Innovations in medical devices

India has less than one per cent of the global market in medical devices, despite having one-sixth of the world's total population and the fact that nearly 71% of demand is met through imports. This excessive reliance on imports for medical devices, which is also a manifestation of low technological capability, has implications for costs and access. There are approximately 700 medical device manufacturers in the industry, mainly local device makers, focusing on low-value products such as needles and catheters. Most high-value products are often imported. There is a need to build an ecosystem that fosters in-

novation, manufacture, and rational utilization of these devices.

Broadly there are four types of actors – Government research labs (e.g., Sree Chitra Tirunal Institute for Medical Science and Technology Services, Trivandrum, Central Scientific Instruments Organisation, Chandigarh), academic institutions, industrial units in the private sector and international collaborative programs with multi-disciplinary Indian institutions. Of these, Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST) has a good track record which has brought a number of products into the national market and subsequently into the international market. Their most well-known products are prosthetic heart valves and blood bags. Their main driving principle was import substitution as a form of cost reduction and better availability, but once these products were available there was international interest in their use. CSIR laboratories too have introduced innovative products, but faced difficulties in scaling up either through commercialization or through

public systems uptake. Academic institutions have commercialized a number of products.

One of the major forms of innovation in the industry has been the “jugaad” (a “frugal” form of innovation) by Punjab and Tamil Nadu small-scale entrepreneurs. The small scale units gain considerable strength from being clustered and informally networked. They are also able to draw upon tacit knowledge and unstructured experiences from a surprisingly wide area. A more recent development is the emergence of large scale innovation establishments that aim to tap Indian skills and talents in innovation for international markets and to take advantage of the huge and hitherto untapped Indian market. Leading amongst these are GE and Siemens located in Bangalore. There are also small start-up technopreneur-led companies such as Remidio, Embrace, BigTecXcyton, and ReaMetrix in Bangalore. There are similar companies in Mumbai and Delhi as well. These are very small, very innovative, home-grown companies in the diagnostic and/or device space. These are focused on being innovative and bringing out low-cost devices for the Indian market.

Another major development is academia-driven international collaboration, such as the Stanford Bio-Design project between IIT Delhi, All India Institute of Medical Sciences (AIIMS), and Stanford University with the financial support of the Department of Biotechnology (DBT). Other examples are the Johns Hopkins University collaborative programs with substantial USAID support. A third successful example is the University of Oslo, Norwegian Agency for Development and Co-operation (NORAD) supported effort at development of health informatics, which features a tie-up with the National Health System Resource Centre (NHSRC) and an Indian not-for-profit organization created partly for commercialization.

A major issue of concern is unfair competition from international corporations. The Sree Chitra Tirunal Institute for Medical Sciences and Technology's initiatives in blood bags for open heart surgery, an innovative cost-saving product, was held back due to its threat to a multinational firm's interests. Unfair marketing could also raise questions of safety and credibility of new products and prevent low-cost innovations in the market. This is not as much a problem with screening/diagnostic devices, but where invasive or therapeutic procedures (e.g. cardiac stents, implants, or staplers) are concerned, patients would be more apprehensive about quality. There is a role for the government in ensuring a level playing field for all domestic and international players, and the best approach is to ensure a transparent quality assurance and regula-

tion system, as well as watchfulness and action against monopoly practices.

Innovations in indigenous medicines

Historically, most innovations in this area were at the instance of private sector, especially from Bengal and Kerala. The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), a governmental body, was created in 1995 with the purpose of developing education and research in traditional Indian medicine systems. However, the budgetary allocations of the department have remained paltry and have never been more than 3% of the total government health budget.

It now appears that a vibrant and highly interactive innovation system with greater integration between actors within and outside the country is in the making. To illustrate, Arya Vaidya Sala, Kottakkal (AVS), and Pankajakasthuri signed an agreement with the Tropical Botanical Garden and Research Institute (TBGRI) for medicinal plant research, and Arya Vaidya Pharmacy (AVP) received financial help from the U.S. National Institutes of Health to develop and consolidate scientific collaboration between researchers at the Ayurvedic Trust, Coimbatore, and leading U.S. universities. The funding is mostly for plant conservation and standardization of medicines. Many institutions like the Department of Science and Technology (DST), Indian Council for Medical Research (ICMR), Central Council for Research in Ayurveda (CCRA), Technical Information Forecasting and Assessment Council (TIFAC), Ministry of Science, Department of Bio-technology, Ministry of Environment and Forests, etc. are actively involved in the research related to herbal medicine and products. Formation of AYUSH, medicinal plant boards, TKDL (which aims at making all documented information on Ayurveda available to patent examiners so as to prevent grant of patents on non-original inventions) and the Golden Triangle Partnership Scheme (GTP) of the DST, CSIR, and ICMR collaboration are recent important steps in this direction. Nevertheless, the academia-industry interface in this sector remains low. However, in Kerala, it is found that many manufacturing firms encourage postgraduate students to undertake their degree projects in the firms, which fund the students in process and product research⁶.

At present, R&D in Ayurveda, Siddha, and Unani focuses on new drug development, innovative processes for known drugs, and development of plant-based molecules through

leads from traditional knowledge-holders⁷. The innovative approaches in indigenous medicine research include ethno-pharmacology, reverse pharmacology, systems biology, and personalized approach⁸. Various institutions, including the ICMR and CSIR, are exploring paths that could be cheaper, faster, and more effective. CSIR and several public and private partners have just concluded a series of clinical trials on herbal products of medicinal value generated through reverse pharmacology.

R&D in the Ayurveda industry is mainly concentrated on clinical research, process-related research, and medicinal plant research. But this is very minimal compared to expenditure on non-technological innovations like aesthetic appearances and new packaging forms. Clinical research is aimed at evolving new methods and procedures for dealing with acute ailments such as cancer, rheumatic arthritis etc. Process-related research broadly covers activities like bioactive research, standardization, development of new products, etc.⁵. AVS Kottakkal has recently set up a Medicinal Plant Research Centre with a view towards conservation and sustainable cultivation of medicinal plants. AVS has research collaboration with many national and international institutions like the Council of Scientific and Industrial Research (CSIR), International Development Research Centre (IDRC), etc. Currently, India has national and state medicinal plant boards promoting sustainable cultivation as well as various incentive schemes for in-house cultivation and ex-situ conservation and research.

Concurrently, firms also concentrate on nutraceuticals and cosmetics. Government of India also adopted the Good Manufacturing Practices (GMP) for ayurvedic units from June 2002; with the objective of quality assurance. The industry has over 9,000 producers in the country, which aims at markets in Africa, Latin America, and Southeast Asia.

In general, priority in research has been to handle type I lifestyle diseases or neurological disorders and brain stimulation. Some work has been done on other diseases that are refractory to allopathic drugs, e.g., psoriasis, arthritis, and bronchial asthma. However, the research priorities in AYUSH Research Councils have often been decided on readily available leads from botanical knowledge or community knowledge, rather than desired areas of public health needs. To promote innovations through interactive learning and collaborations, AYUSH has started around ten clusters of ayurvedic products in different parts of the country. Even though the existing “reformulative” structure does not support technological innovations, the possibilities of interac-

tive learning and social innovations are evident in the industry.

Concluding remarks: innovation barriers, strengths, and priorities

We have shown that interactions, institutions, and incentives are characterized by their own national and regional rigidities specific to the current development path in India. Sub-systems of health innovation are structured very differently in areas of health system development, medical devices, health informatics, and pharmaceuticals. Health innovation systems are still working in a fragmented way. Market influence on pharmaceutical innovation has been increasing. In different areas, as for example medical devices, the patterns of mobilization being followed by different actors, ranging from independent professionals to hospitals and pharmaceutical firms, are guided by strategies that do not converge with the interest of the population as a whole. Both state and private sectors need to be closely monitored and appropriately regulated.

On the whole it appears that there are several barriers to the formation of a vibrant innovation system. One of the most important is the inertia for interactive learning between different actors involved and the lack of coordination of agencies acting on different levels of the value chain. Lack of synergy between prototype development, commercial developers/manufacturers, health economists, and social scientists that could assess the costs and social consequences of the technology are important gaps that prevent scaling up of technologies. The stronger patent regime along with the power of international corporate agencies resulting in unfair competition and uneven playing fields along with inappropriate institutional arrangements for strategic alliances and collaborations pose major challenges to health innovation in India.

Barriers are emerging due to the lack of clear protocols and supporting institutions that could systematically scrutinize and approve testing of new products, especially class II. Protocols should not only specifically mandate the minimum required tests, but should include biocompatibility guidelines, quality standards, and processes by which tests could be registered and monitored. Lack of common testing facilities that a large number of innovators can access is also a barrier both for drugs and for devices.

Despite the large number of barriers, there are also a number of great strengths that can be built upon. The first is the culture and practice of *jugaad* – the ability to innovate within

considerable resource constraints⁹. This could be complemented with India's achievements in information technology and clinical care. Many low-cost innovations continue to occur even within existing circumstances, including local adaptations and *jugaad* in health systems and service delivery. But even these require sustained financial and organizational support, for commercialization, dissemination, standardization, and scaling up. Sustained and adequate financing is required for innovation in high-cost life-saving equipment and new products as well.

Another strength is the living traditions of Ayurveda, Siddha and Unani, whose potential contribution to learning and innovation are yet to be fully tapped. There is one type of learning where there is a search for better molecules. The immense potential for such learning could be appreciated if we recall that over 80% of all modern pharmaceuticals are derived from active ingredients found in indigenous remedies that were validated on empirical grounds – a process that has been ongoing for more than 200 years. Another type of learning is the use of procedures absorbed from Ayurveda, Siddha and Unani in their entirety and context, without searching for active ingredients.

India should utilize the core of academic and research institutions which have been engaged in healthcare innovation over the last 100 years in pharmaceuticals, and over the last 30 to 40 years in medical devices, information and communications technology, and public health institutions. Though many of these were not very successful because of barriers discussed earlier, considerable social capital has been built up that can now be leveraged. Public policy needs to actively promote and welcome those innovations that serve the needs of public health policy: increased access, quality, and affordability of health care, greater health equity, increased responsiveness of the system to healthcare needs, autonomy in healthcare choices, and above all, improvements in the social determinants of healthcare.

Contributors

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Resumo

O artigo apresenta um panorama das mudanças atualmente em curso dentro dos sistemas público e privado de inovação em saúde na Índia, incluindo a prestação de serviços médicos, produtos farmacêuticos, dispositivos médicos e medicina tradicional indiana. É destacada a natureza das falhas que existem nos sistemas de inovação em saúde. As respostas do governo, das instituições médicas, de saúde e tecnologia e indústrias envolvidas, são abordadas em nível nacional. O artigo também discute como foi desenvolvido o alinhamento de políticas e instituições no escopo dos sistemas nacionais de inovação em saúde, e como governo e indústria estão lidando com os desafios para integrar o sistema de saúde, a indústria e o desenvolvimento de políticas sociais.

Tecnologia Biomédica; Sistemas de Saúde; Desenvolvimento Sustentável; Inovação

Resumen

El artículo presenta el panorama de los cambios actualmente en curso dentro de los sistemas públicos y privados de innovación en salud en la India, incluyendo la prestación de servicios médicos, productos farmacéuticos, dispositivos médicos y medicina tradicional india. Se destaca la naturaleza de las carencias que existen en los sistemas de innovación en salud. Los autores abordan la respuesta existente, a nivel nacional, por parte del gobierno, instituciones médicas y de salud y tecnología, y por la industria en este proceso de evolución. El artículo también discute cómo se desarrolló la alineación de políticas e instituciones en el alcance de los sistemas nacionales de innovación en salud, y cómo el gobierno, así como la industria, están enfrentando los desafíos que se presentan, con el fin de integrar sistema de salud, industria y desarrollo de políticas sociales.

Tecnología Biomédica; Sistemas de Salud; Desarrollo Sostenible; Innovación

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