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Is there a Bright Future Ahead for India's Pharmaceutical Market?

An Overhaul of Policies vs. a Mere Facelift

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Abstract

The Indian pharmaceutical market is a bright spot in making India 'a developed country in one generation'. A healthy population and a thriving economy are core drivers of growth. Over the last decades, fierce policy reforms have lifted the industry out of its dependence on import and built domestic competence.[1] India became a strong global competitor and conquered the international market as a low cost producer labelled as 'the pharmacy of the world.'

Yet, changing global dynamics and internal structural market deficiencies challenge pharmaceutical policies and divide government institutions on India's way forward.

This paper analyses the underlying discourses in India's on-going public policy reforms and debates in the pharmaceutical sector. It identifies the dominant discourse and discusses its impact on consumers in the context of India's contemporary epidemiological and demographic transition, political agenda, economic ambitions, market dynamics and legal framework.

Core questions at stake form the common thread through the paper and should lead the policy reform debates moving forward: Which agenda is the Modi government pushing forward? Who are beneficiaries and what is the impact on consumers? How can India leverage and build its strengths in becoming a global manufacturing and innovation leader? Will its policy approach allow for the development of an innovative and self-efficient pharmaceutical market? Is there an integrated policy approach across policymakers mandated to regulate the pharmaceutical industry? How does this fit into India's broader development agenda for health and growth?

Introduction

Prime Minister Narendra Modi's goal is to make India a 'global leading hub for manufacturing pharmaceuticals and innovation in medical research'.[2] The government's focus – as advocated by its 'Make in India' initiative – is on economic growth. A strong correlation exists between the domestic pharmaceutical market and growth trends in the India's gross domestic product (GDP).[3] A vibrant, competitive and innovative pharmaceutical industry will be a key driver for job creation, population health, skill enhancement, and attraction of capital.

> India to be amongst top five global pharma innovation hubs by 2020

India's past policies have shown immense success in lifting the industry to become the world's largest provider of low-priced generic medicines. As a major driver of access to medicines worldwide, it has been given the name of 'Pharmacy of the World'.

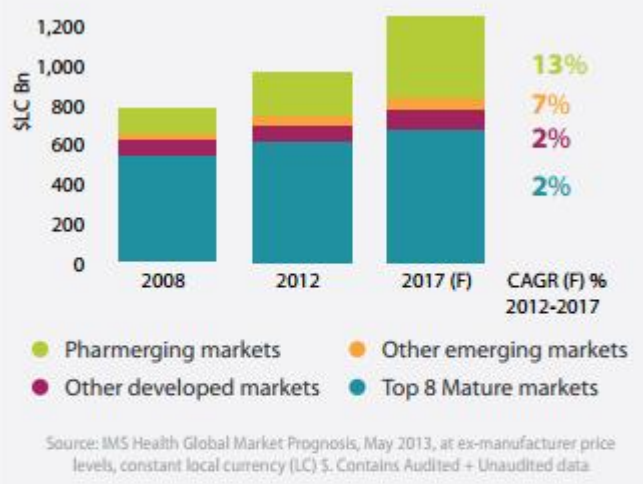
India is the world's third-largest pharmaceutical market globally in terms of volume, accounting for about 10 percent of the world's pharma industry. By 2020, the Indian pharmaceutical market is expected to rank amongst the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size.[4]

Today, Indian pharmaceutical sector is situated in a rapidly changing economic, demographic, epidemiological and political context. If India wants to achieve PM Modi's ambitious goals it will need to address deeply rooted challenges of some of the sectors in consonance with changing global and domestic market realities.

The Global Pharmaceutical Market –Big Pharma's Innovation Deficit

Estimated to exceed US$1.3tn in 2020, the global pharmaceutical market is expected to continue its successful growth.[5]

The pharmaceutical industry has been highly dependent on its R&D segment – a key driver for profit – which has been dominated by developed countries' multinational companies ('pharma MNCs' or so called 'big pharma'). The US, Japan and Europe (the 'Triad') are the sector's largest markets, accounting for over 80 percent of pharma sales. Developing countries have traditionally been focussed on generic medicine manufacturing and not been major contributors to pharma innovation.[6]



Source: IMS Health Global Market Prognosis, May 2013, at ex-manufacturer price levels, constant local currency (LC) $. Contains Audited + Unaudited data

Between 2012 and 2017, Pharmerging markets have growth rates far higher than in mature markets: forecast 13% CAGR 2012-2017 vs. 2% for the top 8 mature markets.

However, the recent global economic turndown has elevated the sector's internal structural deficiencies, leading to a stagnation of innovation and a growth slowdown in developed economies. On one hand, government attempts to contain escalating public expenditure on drugs and increasingly complex and costly drug discovery processes decreased returns on investment in pharma R&D which led big pharma to substantially decrease its R&D spending. Expiry of blockbuster patents and market entry by fierce international competition in generics from strong and rapidly emerging markets in developing countries (pharmerging) such as China, India, Russia, Brazil and South Africa have further pushed pharma multinational companies (MNCs) to actively pursue alternative growth strategies in these promising markets.[7]

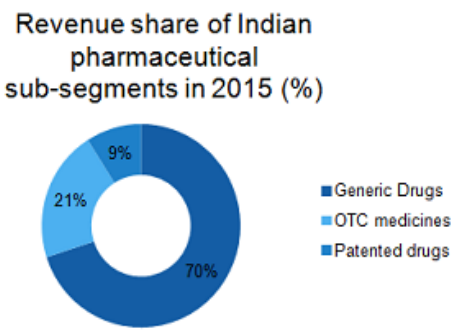
Worldwide waves of mergers & acquisitions (M&As), increased patent filings and fierce market strategies have demonstrated the industry's attempts to boost pipeline diversity, scale and pricing power. All this has led to and continue to be driven by the consolidation of the global pharmaceutical industry, which risks the dilution of traditional competitive dynamics between originators and generic manufacturers in concentrated markets.[8]

India's rising prevalence of western 'lifestyle' chronic diseases, the growth of its middle class with rising health expenditures, and its strong product-driven generic manufacturing market make it an attractive destination for foreign multinationals. Unfortunately, so far, foreign innovation companies seem to focus on market expansion rather than increase of innovation either through technology transfer or increased R&D activity.[9]

The Indian Pharmaceutical Market

India is a strong generic medicines' manufacturing hub. Generic medicines form 70 percent of its pharmaceutical market (in terms of revenues). Accounting for 20 percent of global exports (in terms of volume), India is the world's largest provider of generic medicines.[10] It has a strong drug manufacturing infrastructure with skilled labour and low resource/production costs. Upcoming patent expiries are opening up sizeable market opportunities for growth for generics and biosimilars (i.e. similar to approved biotherapeutic products) markets. However, profits in generic medicine manufacturing are declining due to a number of reasons:

- complex and timely procedures for regulatory approval of biosimilars,
- strong competition from foreign generic markets (in particular 'pharmerging' markets[11] like China, Brazil and Russia),
- import-dependency for active pharmaceutical ingredients (hereafter 'API' or bulk drugs) from China,[12]
- quality issues and substandard medicines,
- increased US FDA scrutiny, and
- price controls by the Indian government.



Source: Business Monitor International, FCCI Indian Pharma Summit 2014-15, TechSci Research

This changing landscape of fierce competition with low margins and high pricing pressure requires generic companies to diversity their product range, adopt differential strategies and focus on evolving as innovations. Global medicine spending and growth are expected to shift to a continued growth in innovation-driven spending for immunology or biological treatments.[13]

In other words, innovation is the key to success for India's economic growth. Unfortunately, 'Innovate in India' is a challenge. India only ranks 14th by value worldwide (accounting for 1.5 percent). While its well-developed scientific base, strength in information technology, strong biodiversity and highly skilled human capital could provide fertile territory for biotech research,[14] pharma R&D intensity remains rather low. The average R&D expenditure by Indian pharma companies is only six percent of total revenues compared to the typical 20 percent of western pharma companies.[15]

India's demographic and epidemiologic context will provide opportunities but is likely to put more pressure on the pharmaceutical industry.[16] The industry is crucial for India's economic development as a core foundation for a healthy population ('life line' industry).

Population growth and increased financial capacity has increased India's domestic demand for high-quality medicines. Over the last two decades, worldwide per capita spending on pharmaceuticals has increased by at least 50 percent with the largest increase occurring in middle-income countries like India.[17] Global medicine spending grew by about nine percent in 2014 and 2015, outpacing both overall health expenditures and economic growth.[18]

New medical needs emerge in India as the disease burden shifts from communicable to non-communicable diseases ('lifestyle' diseases such as cancer, diabetes, cardiovascular and chronic respiratory diseases). With 1.3 billion people India has a rapidly growing and greying population.[19] On top of its traditional public health challenges (e.g. water borne, malnutrition, sanitation, etc.), India has to address the escalating epidemic of non-communicable diseases (60 percent of all deaths and significant morbidity in India) and some infectious diseases (persistent levels of TB transmission and incidence of drug resistance).[20] Tackling these diseases requires access to innovative medicine.

At the same time, increasingly costly new generation treatments remain out of reach for both the middle-class and the poor (e.g. drugs for cancer and hepatitis C in India).[21] Countries around the world are facing challenges in balancing the dichotomy between innovation and affordable access. However, it is an even greater challenge for India that has a very large poor population. Affordability of medicines remains a major concern[22] as out-of-pocket (OOP; i.e. direct payments made by individuals to healthcare providers) expenses on medicine are high (with in rural India almost 80 percent of total OOP and in urban areas around 75 percent of total OOP).[23] The lack of capacity and outreach of the public healthcare system is partly responsible for these high rates. Action is required on many fronts, as present measures leave wide gaps in access to drugs for many common and significant diseases.[24]

Regulatory Reforms – Time to Adapt or Reinvent?

Regulatory framework

- Ministry of Chemicals and Fertilisers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority
- Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, Foreign Investment Promotion Board
- Ministry of Finance
- Ministry of Health & Family Welfare
- *NITI Aayog*

Multiple regulatory agencies are mandated to regulate matters that affect the pharmaceutical sector. Recent policy reforms aim to provide a more suitable climate for investment for pharma innovation and sector growth.

Under the tag line 'minimum government maximum governance', the government has aimed to reduce excessive regulation and ensure maximum governance.

Recent policy reforms have focussed on liberalisation of foreign direct investment (FDI), scale-up of intellectual property rights (IPRs), introduction of an attractive tax regime, and reform of the price control regime. Disbandment of inter-ministerial specialised regulatory agencies has further been put forward to ensure effective governance.

IPR Policy

To foster innovation and generate wealth, the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce & Industry has recently adopted a new National Intellectual Property Rights Policy (NIPR Policy, 2016).[25] It goes by the tagline of 'Creative India, Innovative India'.

Intellectual property protection – in particular patent rights – is critical to the development of an innovative pharmaceutical industry as it attracts investment and boosts local businesses. As costs of developing new drugs are high and costs of duplicating are low, exclusive patent rights stimulate investment for R&D.[26] In 2015, patented drugs (developed and patented in India) constitute only nine percent of total pharmaceutical market revenues in India of US$20bn. While the number of patent filings in India has increased in the last few years, the percentage of filings by Indian residents is relatively low. Of 42,854 patents applications made in India in 2014, only 28 percent were filed by domestic entities. There is further a general distrust amongst foreign innovator companies towards the Indian patent regime.[27]

The NIPR Policy, therefore, aims to expedite IPR filings by overcoming lack of awareness about the importance of IPR as a marketable financial asset and distrust in the effectiveness of IPR laws and enforcement. This would foster innovation and generate wealth for the Indian economy.

However, IPRs are a means to foster innovation and creativity, rather than an end in itself. The NIPR Policy fails to situate IP within the larger context of the innovation ecosystem (i.e. financing, venture capital, education, infrastructure etc.) and ignores the fact that IP is a market-driven model (i.e. guided by market competition and consumer needs).[28]

The policy focus on generation and protection of IPRs as an end is may adversely affect competition and even stagnate innovation and growth in the Indian pharmaceutical industry. More IPRs (or heavy focus on protection of *invention*)[29] does not necessarily result in more innovation and may even curve innovation y making it too costly and risky to innovate.[30] It may further unnecessarily exclude competition and undermine growth in India's predominantly generic market.[31]

Moreover, so far the scale-up of IPRs (protection) in India seems to have had little influence on innovation incentives in the pharmaceutical industry.[32] Evidence shows that patent protection has not led MNCs to enhance their R&D activities in India. As for Indian companies, innovative growth has largely been focused on lower-risk technologies with less than 15 percent of the patent applications by Indian companies pertained to potential new drugs. Even worse, much of the growth accounted for by increased filings being manufacturing processes for existing pharmaceutical patent applications and crystalline forms relating to existing drugs. The amount of Indian companies investing in R&D as percentage of sales is only six percent compared to 20 percent typical of western pharmaceutical companies abroad.[33]

Such an approach is further likely to distort the cost-benefit balance of an effective IP system. It will increase the burden on the IP administrative system and have adverse effects on innovators (e.g. most public entities are already losing more money on IP registrations than they make through IP royalties).

To ensure India's economic growth and health needs, the NIPR policy further needs to address the patent regime's core dilemma of balancing innovation with affordable access. The NIPR Policy should focus on the purpose of IPR in society. IPR regimes aim to promote innovation by carefully balancing the rights of the innovator with the rights of the public to access and build on these innovations. Public interest is central to the IPR regime and needs to be strengthened as far as possible, in particular in relation to access to medicines.[34]

While the NIPR Policy recognises the need for the reinforcement of a vibrant intellectual property ecosystem conducive to innovation and creativity as to enhance economic development (attracting investment and boosting local businesses) and protect public interest (enhancing access to healthcare), it fails to provide clarity as to how it will implement this vision according to India's economic context and health needs. Legal uncertainty and controversy for businesses and consumers around government use[35] of legal provisions that override patent protection and allow competition are therefore likely to continue to prevail (e.g. prevention of evergreening and grant of frivolous patents under Section 3d of the Patent Act; compulsory licensing under Sections 84, 92, 92A, 100 of the Patent Act; exhaustion and parallel import; "Bolar exemption" under Section 107A of the Patent Act).[36]

The NIPR Policy seems to suffer from lack of conceptual clarity and vision of an innovative ecosystem and has no realistic approach to access, innovation and growth. Intellectual property is of critical importance for the Indian pharmaceutical sector from an economic, social and political point of view. Unfortunately, the NIPR Policy

fails to translate that into a policy orientation that reflects its national priorities in a realistic manner. It thereby fails to set a framework for the evolution of future IP norms that would ensure India's role in the global economy while at the same time protecting her national interests.

FDI Policy

To bolster investments in the pharmaceutical sector, the DIPP and the Ministry of Finance have been actively taking measures to liberalise the FDI policy and improve the business climate. At a meeting chaired by PM Modi, DIPP relaxed brownfield pharma FDI norms (i.e. investment in operational firms), permitting up to 74 percent under automatic route (beyond which government approval is required), a measure that is likely to boost mergers and acquisitions (M&As) and private equity investments. FDI for greenfield pharma FDI (i.e. establishing new production and operational facilities) was already permitted up to 100 percent under automatic route.[37]

The opening up of the Indian pharmaceutical market for FDI has directed a lot of capital and interest into the industry. A sharp increase in presence of foreign MNCs through M&A, partnerships (e.g. joint ventures) and collaborations (e.g. contract research) has benefited the industry and the Indian economy at large. Foreign investment in pharma has the potential of raising the industry's profile by increasing productivity, quality, and patenting of medicines. It further generates employment. This benefits consumers through ensuring lower prices, more innovation and better products, as well as increasing incomes and buying power.[38]

Evidence shows that greenfield investments have been low. Between April 2012 and April 2013 more than 90% of FDI in the pharma sector flowed into brownfield investments. This phenomenon could have been led by the fact that Greenfield investments face additional administrative hurdles such as in acquiring land, obtaining permissions for manufacturing, and receiving environmental clearances, etc. [39]

Moreover, foreign pharma firms seem to be looking abroad for market expansion rather than innovation. Evidence of merger (pre- and post) analysis in the Indian pharmaceutical market shows that acquisitions of domestic pharmaceutical companies by foreign MNCs have generally not increased technology transfer and innovation. While there is conflicting evidence on whether foreign takeovers have reduced R&D expenditure in acquired firms, there have been cases where mergers have resulted in termination or cuts in R&D development. It further seems that the performance of multinational drug companies is worse than that of their Indian counterparts in regard to R&D investment and exports.[40]

To increase innovation and sector growth, the policy needs to understand and elaborate the market environment. India cannot ignore the decline in R&D investments in traditional markets and global consolidation (i.e. shift to fewer and larger firms; this is likely to lead to concentration with a small number of firms control most of the sales) in the sector. Declining innovation, increasing costs, patent expiry of blockbuster drugs, and other events have led traditional innovator companies to diverge investments by looking to acquire generic divisions or partner with generic companies for local manufacture and distribution of cheaper drugs. The advent of difficult to copy biologics

and more regulatory burdens diverted generic companies to consider partnering with innovators.[41] Moreover, India should understand the deficiencies in its innovation ecosystem and business climate.

Thus, relaxing the norms is, therefore, unlikely to lead to technology transfer or new R&D facilities, nor is it likely to increase companies' global competitiveness. The FDI policy may actually reside to mere capital flow from India to developed countries. It could also further increase consolidation in the Indian pharma industry, risking dilution of traditional competitive dynamics between originators and generics (M&A between innovators or between innovators and generic companies).[42] All this would risk the growth of India's predominantly generic industry.

Drug Price Control Regime

To address criticism that the price control regime undermines investment and growth in its attempt to broaden affordable access, the Department of Pharmaceuticals (hereafter DoP, in the Ministry of Chemicals and Fertilisers) is currently reviewing the National Pharmaceutical Pricing Policy (NPPP, 2012).[43]

Price control is a common practice worldwide to lower individual drug prices when market forces are too weak to ensure price competition. In India listing of essential medicines and price control are also common strategies used for making non-patented *essential and lifesaving* medicines[44] affordable at a 'fair' price. About 17 percent of the total domestic market or 370-plus essential drugs are currently under price control.[45] The formula, provided by an administrative Order[46] under Essential Commodities Act (1955),[47] allows the National Pharmaceutical Pricing Authority (NPPA) to bring essential medicines (captured in the National List of Essential Medicines or NLEM) under price control (i.e. price fixing or price monitoring) and uses a market-based pricing approach (rather than cost-based pricing as was practices under the earlier Orders). While the NPPA has the discretion to fix prices for non-essential medicines, and thus also patented medicines, in 'extra-ordinary' circumstances and in public interest, the exercise of this power has been subject to controversy in the past.[48]

While widely used across the globe, price control has long been recognised as a risky tool with the potential of perverse effects for producers and consumers. When numerous well-informed consumers are purchasing from multiple competitive sellers, the constant dynamic interaction between supply and demand ensures a 'fair' market price. Price control is used when the market fails to provide this dynamic due to entry barriers or information asymmetry, or when people are simply too poor. However, static government decisions can never pursue a similar equilibrium price and risks to set the price either too high or too low.

When set too low, price caps risk eroding profit margins, leading companies to cut back on production of drugs or quality and discouraging market resources and investor capital, ultimately incentivising companies to look abroad for growth. That will lead to less R&D and innovation undermining availability of new drugs to consumers.[49]

Past formulas have been said to adversely affect availability and innovation as the ceiling price has undermined manufacturer's incentives to supply the market. For meeting the domestic demand,

this situation increases reliance on importation and risks the creation of shortages. The high import-dependency today for API is said to be a direct consequence of inadequate price control. One example put forward has been the decline of India's production of penicillin and its dependency on China for supply today. With strong pharmerging markets, most of India's largest drug makers already have plants outside India, particularly in the US and Europe, and they are increasingly expanding to Africa, Southeast Asia and China where – like in India – labour is cheap and the cost of running a plant is low.[50]

When set too high, price caps render generic competition ineffective and even counterproductive. The present regime has been claimed to set the price of some drugs (e.g. for antihypertensive, anti-vomiting, anti-diabetic and cholesterol) much higher than the competitive price.[51]

Mixed signals are being sent with regard to the government's plans. To what extent the present market segmentation between price regulation of essential medicines and price competition for all other medicines will be reviewed remains to be seen. While the Union Minister Chemicals and Fertilizers Ananth Kumar ensured that there were no plans to change the policy of drug pricing of essential drugs, the government's premier policy-formulating institution NITI Aayog recommended the deregulation by delinking of drug price control from the NLEM.[52] This seems to lean towards a more 'market-driven' or 'economic criteria' approach rather than the present principle of 'essentiality of drugs'.

One thing is sure – deregulation is not the solution. In fact it would undermine the whole idea of having price control in the first place – to broaden access to essential medicines.

It could well be that the present price control mechanism is suboptimal in obtaining its goals and that the concept should be reformed. In fact, some evidence suggests that price-regulated industries have seen higher price rises than industries which are not due to the lack of competition and the assurance of a certain return on capital and of market share for firms in such industries.[53] Whichever mechanism is opted for, to ensure affordable access of essential medicines while at the same industry growth and innovation, the policy needs to understand and elaborate the market context.

As such, the ways in which firms coordinate to weaken price control and push the ceiling price up has been largely overlooked. The Competition Commission of India (CCI) has exposed a strong retail consolidation in the Indian pharmaceutical market. Organisations, such as the All India Organisation of Chemists and Druggists strongly control manufacturer's market access (monopsony or demand side dominance vis-à-vis manufacturers) with immense bargaining power to set prices (monopoly or supply side dominance *vis-à-vis* consumers).

Demand-side consolidation is known to ensure countervailing market power. However, the real issue at stake is the risk of coordinated price increases by manufacturers just before the price regulation to raise the market-based ceiling price and circumvent price control. The strong retail consolidation could easily prevent deviation from coordinating prices by manufacturers through retribution. Both manufacturers and retailers will have enriched at the expense of the consumer. As

a result, the price control regime on non-patented products may have anti-competitive effects. Moreover, this situation is unlikely to be corrected as manufacturers operating under the supra-competitive price ceiling will not be targeted by the competition authority.[54]

Moreover, competition in the pharmaceutical market is distorted by high levels of supplier-induced demand and close nexuses between pharmaceutical sectors and doctors which leads to mis- and over-prescription, both at the expense of the consumer. Mandatory generic prescription has been suggested to ensure price competition. However, considering India's high level of substandard and fake medicines, additional regulatory measures are still needed to guarantee quality and safety.[55] Competition is not an end in itself and policies should consider a range of mechanisms that take into account the market's low demand elasticity, supplier-induced demand, entry barriers and information asymmetry. Examples are mandatory prescription and offering by pharmacists, measures to guarantee quality, well-designed process of API purchases by government, the goods and services tax on essential medicines, consumer protection laws against unethical and unfair drug selling practices, transparency in pharmaceutical budgets and/or patents, disciplining of distribution channels, and creative use of government use compulsory licences.

Health Policy

The Ministry of Health and Family Welfare has recently issued the new National Health Policy (2017).[56] This policy is an important part of understanding India's broader approach to a healthy society – treatment and prevention – for economic growth.

The new policy aims to clarify and strengthen the role of the government in shaping health systems in India's changing health context of shifting health priorities, growing incidences of catastrophic expenditure, rising economic growth and emerging robust healthcare industry.

India ranks 154 among 195 countries on the Healthcare Access and Quality Index 2017, lagging behind countries like Nepal, Bhutan and Bangladesh. Remarkable is India's poor performance in tackling cases of tuberculosis (communicable disease), diabetes, chronic kidney diseases and rheumatic heart diseases (non-communicable diseases).[57]

A vibrant innovative ecosystem? The Policy emphasises the need to boost India's role in new drug discovery and drug innovations including bio-pharmaceuticals and biosimilars for own health priorities. It calls for government policy to stimulate innovation and new discovery. The NHP recognises the importance of public investment in priority research areas and greater collaboration between drug research institutions and drug manufacturers. It also calls for increased international cooperation, especially involving nations of the Global South, to build domestic institutional capacity in green-field innovation and to explore knowledge and skill generation.

A vibrant innovative ecosystem requires a shift in mind-set from traditional paths to encouraging risk-taking and challenging status quo, which the NHP fails to incorporate (i.e. strategies and action points for improving infrastructure for clinical trials, financing, human resources, and legal and regulatory framework).

A drug self-reliant country? The NHP calls for special focus on production of Active Pharmaceutical Ingredient (API) as the backbone of the generic formulations industry and calls for incentivising local manufacturing in consonance with the 'Make in India' national agenda to provide medical technology and customised indigenous products for the Indian population in the long run. About 84 percent of APIs of all drugs manufactured in India are imported, with 60 percent from China and the rest from Europe.[58]

The NHP thereby aims to halt further loss of business and decrease dependency on China for API and intermediates. The policy also emphasises the need to improve public sector capacity for manufacturing essential drugs and medicines as to secure health in the long run and address needs that are not attractive commercially. It emphasises that the timely revision of NLEM and the appropriate price control mechanisms for generic drugs are a key strategy for decreasing costs for patients.

The NHP emphasises various priorities in pharmaceutical manufacturing and innovation. Yet, it does not provide an integrated, consistent and holistic approach to catalyse health sector interventions that are aligned with economic policy interventions in the pharmaceutical sector. It does not provide for strategies or clear action points, nor does it address access to medicines as an integral part of universal access to healthcare. It therefore does not seem to provide any framework for past and future initiatives, e.g. Public Private Partnership (PPP) model, FDI under automatic route, tax incentives for R&D expenditure.

Regulatory Framework – Whole-of-Government Approach

To ensure maximum governance, regulatory reforms are explored on an institutional level as well. The announcement of the phasing out of the Foreign Investment Promotion Board (FIPB) and rumours about the disbandment of the National Pharmaceutical Pricing Authority have been circulating. In the past, divergence of opinions between these institutions as policy implementers on the one hand and respective ministries as policy makers on the other has often led to bad governance outcomes. This has led to mixed signals on Indian pharma market's way forward. Similar arguments have led to discussions on bringing the Department of Pharmaceuticals, currently under the Ministry of Chemicals and Fertilizers, under the Ministry of Health or creating a separate ministry.[59]

The same divergence has been present in policy reform debates, where mixed signals on policy intentions between government ministries and departments as well as with the government's premier policy-formulating institution *NITI Aayog* have been creating turmoil amongst the public.

Moving forward, there should be a synchronised and integrated policy approach across regulatory agencies. The success of reforms in the regulatory framework will depend on the transfer of extensive experience built over the years by these inter-ministerial bodies to the respective ministries and departments taking over, as well as the guarantee of synergies between them as significant involvement across institutions remains important. This would allow agencies to work across portfolio boundaries to achieve the shared goals of innovation, access and growth, as

well as ensure an integrated response to broader economic and health issues. Another important communication channel in this regard is between regulatory agencies and the CCI that allows for direct links between market behaviour and regulatory failures.

The Way Forward?

Governments have long recognised the pharmaceutical industry as strategically important for India's economic growth and its population's wellbeing. The recent wave of policy reforms echoes the ambition to develop and sustain a world-leading and self-reliant pharmaceutical market.

Unfortunately, the policymakers seem to have opted for a traditional 'safe' approach that fails to envision the strong strategic change that could lift the pharmaceutical industry and Indian economy to a new global competitive level.

Policy advisors and makers need to be clear on their desired outcomes as to enable indication of adequate methods to achieve those in consonance with market realities. Against the backdrop of a global and domestic innovation deficiency, more patents, easy market access for investors and the promise of large demand will not necessarily increase incentives to innovate. Unless value of systems, infrastructure, education and ease of doing business (e.g. permission to establish enterprises, acquire land, environmental clearances) is guaranteed, industry whether domestic or foreign will not invest in innovative India.

It has been recently expressed by Arun Maira: "the winning proposition is Make in India, for India". India should be an attractive base for companies' innovative operations enabling them to leverage the country's strengths – whether capability and low cost of innovation or expertise and human capital or both – in a way that serves Indian demand and guarantees growth as a globally competitor.

Thus, if economic growth and creation of jobs are the goals behind becoming a global innovation and manufacturing hub, policies focusing on an adequate innovative ecosystem that allow companies to operate with a globally competitive advantage and measures that envision affordable access for the sake of a healthy population would be more effective than measures that do not lead to long-term investments in the economy.

This requires a delicate balance between benefits of competition, static price reductions and their associated consumer benefits on the one hand, and the important dynamic benefits of continued investment in the development of new drugs on the other hand.

Moving forward, fundamental questions remain to be answered by policymakers.
Enabling government policies:

- Why does India not make use of a rigorous Regulatory Impact Assessment (RIA)[60] approach with inclusive Competition Impact Assessment (CIA)[61] to prevent sub-optimal regulations from having unintended outcomes and ensure efficient and effective regulations that meet the desired outcomes?
- How can an adequate innovation ecosystem be ensured in the pharmaceutical market? How can India's

strengths be identified and leveraged in becoming a global innovation leader?

- How could the regulators and the sector benefit from the adoption of a competition policy?

A well-designed regulatory framework:

- How can regulatory reforms ensure a whole-of-government approach in the future?
- How can *NITI Aayog* contribute to achieve more integrated policy approaches across desired goals and regulatory agencies?
- What is the role of the CCI and how can its expertise be leveraged to address market realities and ensure a level playing field?
- What is the role of firms and industry associations in shaping the industry and achieving desired outcomes?
- How can consumer organisations be leveraged efficiently to ensure effective policy formulation?

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