



# ALIGNING HEALTH AND INDUSTRIAL POLICIES TO ENCOURAGE INNOVATION IN INDIA





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# FOREWORD

Around the world, trends show an increase in R&D investment. Economies such as India, China, South Korea, Singapore and Brazil have all expanded their R&D expenditure. It is widely accepted that this drive in industrial policy must be complemented by an effective innovation ecosystem. This includes policies to strengthen research infrastructures, skilled workforces, and legal and regulatory certainty. However, the innovation ecosystem must also consider aspects associated with health policy – how health systems assess, adopt and use new technologies.

In this paper, we look at the role that aligning health and industrial policy can play in delivering benefits to the economy and society, and how this relates to India's aspiration to grow and develop an industry focused on innovative medicines and become a global pharmaceutical powerhouse and in so doing embrace the so-called fourth industrial revolution. This revolution is predicted to fuse technologies, blurring the lines between physical, digital and biological domains. Undoubtedly, this has the



potential to transform entire systems of production, management, and governance.

In the research-based biopharmaceutical industry we are embracing such new opportunities in meeting diverse and complex health challenges. In the development of immuno-oncology combination therapies we are seeing unique cross-company research cooperation. In R&D, but also in health system capacity building for communicable and non-communicable diseases, we are seeing many more public-private partnerships. In part, this is thanks to alignment around common goals, such as the 2030 Agenda for Sustainable Development (SDGs). To meet the greatest health challenges of our time, and make true headway towards universal health coverage, governments, civil society and the private sector must look for solutions together. There can be challenges to collaboration, but each stakeholder must be able to freely share their unique experience and expertise to maximise our collective impact on the road to success.

This paper provides tangible evidence of how aligning health policy and industrial policy in India will not only develop the country's economic potential, but also improve people's health. The findings show that there are clear benefits in moving up the value chain by enabling innovations and new drug discovery - even greater alignment between health and industrial policy would be highly beneficial. By filling a gap in current research into this area, we hope the paper can support national governments' empirical evidence building and subsequent policy making in order to contribute G20 and OECD discussions.

The research-based biopharmaceutical industry looks forward to engaging in these discussions, sharing our wide-ranging knowledge and expertise on what it takes to achieve medical breakthroughs that benefit patients and society.



in this paper we consider the role that aligning health and industrial policy can play in delivering benefits to the economy and society and the relevance of the argument for India.

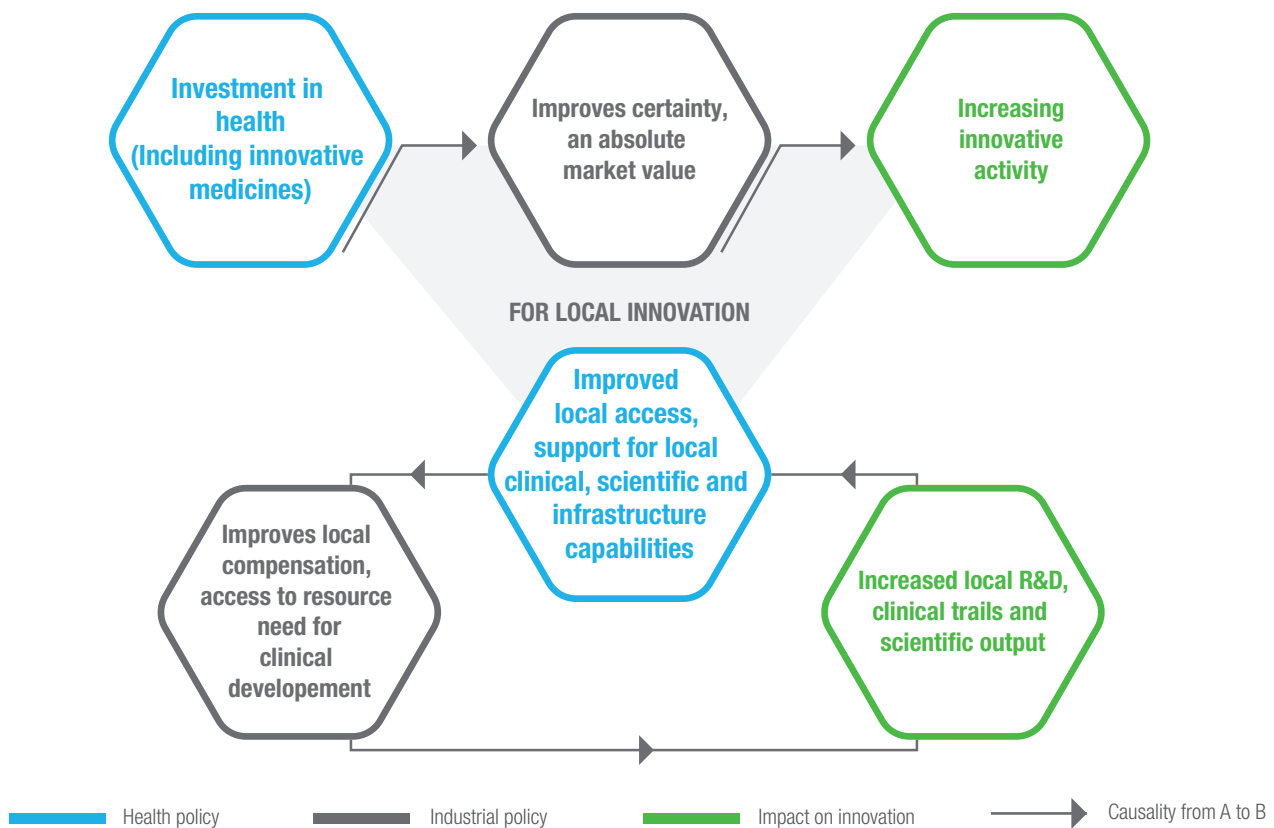
# EXECUTIVE SUMMARY

The need to develop an innovation friendly eco-system to encourage innovative activity is now widely accepted in the development of industrial policy. This often focuses on the alignment of policies associated with improving the research infrastructure, the financing of innovation, the skills of the workforce and the degree of certainty in legal and regulatory aspects. However, the eco-system also includes how the health system assesses, adopts and uses new technologies – policies largely associated with health policy - in this paper we consider the role that aligning health and industrial policy can play in delivering benefits to the economy and society and the relevance of the argument for India.

## Aligning health and industrial policy

At a macrolevel, health policies can improve the value of markets and encourage innovative activity. Turning to the impact at a local level, national health policies can improve the environment for undertaking research and development encouraging local innovative activity. To complete the circle, the reverse holds, as industrial policies that encourage local innovation support local access and infrastructure and expertise, improving local access.

**Figure 1: The interaction between health and industrial policy**



Source: CRA analysis

Turning to the evidence, there is clearly a correlation between investment in healthcare and the amount of innovative activity. This in itself does not provide evidence of causation. However, if we look at the impact of healthcare investment in terms of the clinicians, healthcare infrastructure, information systems and even the value assessment process, each of these acts to improve the innovation environment encouraging innovative activity. Equally, innovative activity helps with the adoption of new innovation, international best practices and improves the infrastructure that is subsequently used to treat patients beyond the clinical trials. At each point in the value chain, healthcare policy and industrial policy have the potential to work together to the benefit of the patient.

## Applying this to the policy debate in India

This debate seems particularly relevant for India. India has an aspiration to grow and develop an industry focused on innovative medicines and become “a global pharmaceutical powerhouse”.<sup>1</sup> To date, activity has focused on the production of generic medicines. It supplies 20% of global generic drugs and is globally important location for generic drug production.



To promote the development of the industry in India, there are a range of initiatives that have been undertaken over the last five years focused on manufacturing in India (Make it in India), encouraging finance for start-ups (Start-up India), the IT infrastructure and education and skills (the New education policy). However, the link between health policy and industrial policy has largely focused on the role of generics. The evidence in this paper suggests health policy and industrial policy focused on innovative medicines should be aligned as well.

There is an argument that India is different. The high level of public provision and the need to invest in raising provision of health means that need for alignment is less. It could be argued that the benefits from industrial policy encouraging local innovative activity would then benefit only those using private facilities. However, there are synergies in place that can be exploited and further enhanced through best practice sharing by private players with public health professionals and use of private facilities, sharing of facilities and staff, public-private partnerships and co-operation between the public and private sectors through strategic purchasing of services from the



**The high level of public provision and the need to invest in raising provision of health means that need for alignment is less.**



private health sector. This link between private and public sector provision means that the benefits in terms of infrastructure, training and access to medicines will apply to all patients.

Indeed, this has been recognised in the National Health Policy (NHP) 2017 which aims to improve population health through the expansion of health coverage, for primary care and essential medicines in particular, change the balance of funding, and ensure improved access to secondary and tertiary services. The NHP 2017 includes a discussion of the role industrial policy can play in helping to deliver health objectives. Our analysis is supportive of this:



Equally, industrial policy can contribute towards the delivery of health outcomes:

- Appropriately regulated clinical trials deliver early access to patients and increase clinical capabilities and knowledge about new procedures and treatments
- An improved environment for clinical trials leads to improvements in healthcare infrastructure and resources for provision of healthcare

If India is to deliver on the opportunity to move up the value chain by enabling innovations and new drug discovery, even greater alignment between health and industrial policy would be beneficial.



There are a range of policies that policymakers use to shape and encourage innovative activity in a way that best contributes to a country's economy and development.

# 1. Introduction

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) commissioned the Charles River Associates (CRA) to investigate the need for mutually re-enforcing industrial and health policy and then consider if these arguments apply in India. This builds on an analysis of the factors that contribute to encouraging innovative activity.<sup>2</sup> The goals of this short analysis are the following:

**Articulate** the arguments why aligning health and industrial policies encourages innovation.



**Document** the evidence of how their alignment can result in increased innovative activity;

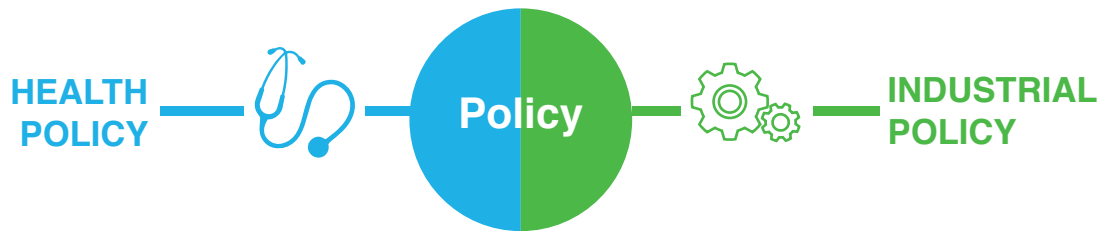


**Set out implications** for innovation policy in India.



## 1.1. The taxonomy of health and industrial policies

There are a range of policies that policymakers use to shape and encourage innovative activity in a way that best contributes to a country's economy and development. These can be grouped into two branches of policy, namely health and industrial policy.



Typically, policies aimed at encouraging innovative activity (whether early stage research, pre-clinical and clinical trials, or on-going studies), are regarded as industrial policy. Industrial policy is a widely debated tool and several definitions are provided in literature, but a commonly used definition has been provided by the OECD:<sup>3</sup>

*Targeted government actions aimed at supporting production transformation that increases productivity, fosters the generation of backward and forward linkages, improves domestic capabilities and creates more and better jobs.*

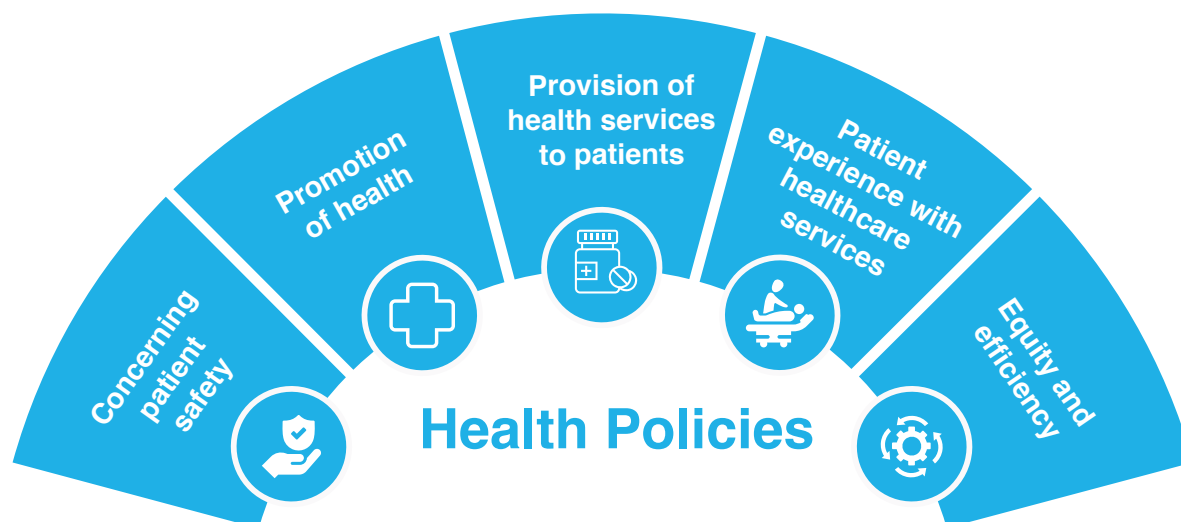


Industrial policy has a very broad remit, however, this normally is focused on policies affecting intellectual property rights, competitiveness, labour and capital markets and trade. There are many reports that focus on the role industry policy plays in encouraging domestic innovative activity in the pharmaceutical sector.<sup>4</sup>

However, in this report, we also wish to investigate the impact of health policy on innovative activity. Health policy has a widely accepted definition provided by the **World Health Organisation**, which states the following:<sup>5</sup>

*“Health policy refers to decisions, plans, and actions that are undertaken to achieve specific healthcare goals within a society. An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people.”*

Health policies typically address issues **patient safety, promotion of health, the provision of health services to patients (including innovative medicines), patient experience with healthcare services, equity and efficiency.**



However, the focus of these policies adapts to reflect the health challenges affecting a particular country. For example, in the past, the focus on policymaking for middle-income markets, has been on the reduction of mortality by infectious diseases and improving equity in access to a reasonable quality healthcare but it is increasingly turning to non-communicable diseases (NCDs).<sup>6</sup> This is the case in India over the last five years.

“The need to have a consistent and aligned industrial and health policy, to encourage innovative activity has commonly been advocated in policy research.

The need to have a consistent and aligned industrial and health policy, to encourage innovative activity has commonly been advocated in policy research. A prior study conducted by CRA on behalf of IFPMA, has set out a set of recommendation for encouraging innovative activity based on a series of case studies. The authors argue that health policy was important because “even for early stage research, the certainty regarding the environment is likely to be higher if the country values the innovative output, and this will benefit their citizens. This is particularly important if public funding is involved in supporting the research. Therefore, a coordinated policy encompassing industrial and health policy is needed to support domestic innovation.” The reverse was also argued, that industrial policy such as the location of clinical trials is important for value assessment of medicines



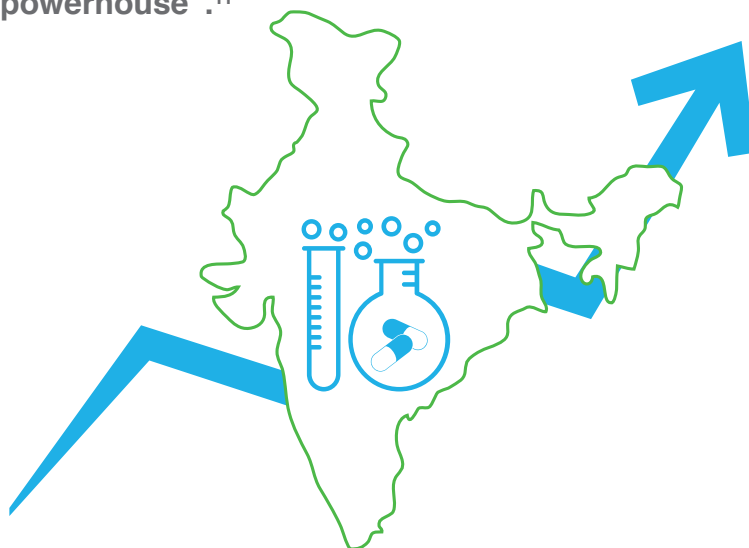
in the market. Therefore, the report suggests that an aligned industrial and health policy is needed to support domestic innovation.<sup>7</sup> Other authors have drawn similar conclusions. In a study by Miraz (2013), it is argued that the role of industrial policy such as intellectual property and trade policy settings can only be assessed holistically, within a wider cluster of interacting policy domains that together determine health outcomes.<sup>8</sup> The same author argues that this is key for local innovation in particular as the framework to encourage local production of pharmaceuticals, requires industrial and health policy coherence (for shared goals).<sup>9</sup> Another report that focuses on African countries and draws lessons from other markets recommends that industrial and innovation policies to be designed to increase productive capacity through aligning with social and health policies drafted to address distribution, which can then in turn enhance innovative capacities.<sup>10</sup>

Despite a broad support for the need for alignment in order to encourage innovation in general and local innovation, there are few papers that document the evidence regarding the interaction between health and industrial policy. Some policymakers argue that industrial policy should focus on encouraging industrial activity, while independently, health policy aims at addressing the healthcare challenges in the country.

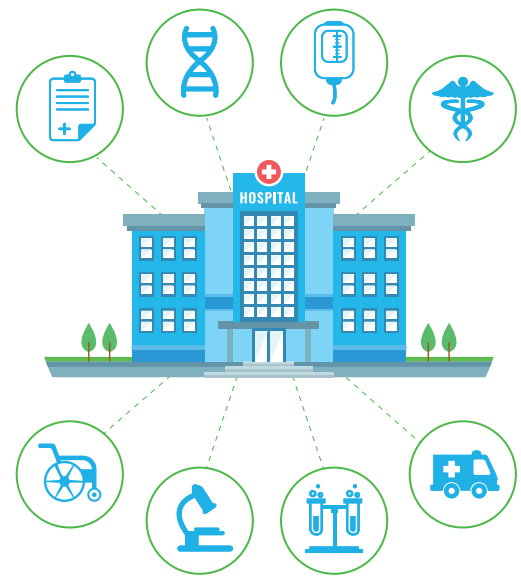
*This report aims to address the question of the need for coherence and consistency directly, drawing conclusions based on evidence from markets that have successfully aligned policies and encouraged local innovation and the implications of these learnings for policymaking in India.*

## 1.2. Innovation and health policy in India

This debate seems particularly relevant for India. **India has an aspiration to grow and develop an industry focused on innovative medicines and become “a global pharmaceutical powerhouse”.**<sup>11</sup>



To date, activity has focused on the production of generic medicines. It supplies 20% of global generic drugs and is globally important location for generic drug production. To promote the development of the industry in India, there are a range of initiatives that have been undertaken over the last five years focused on manufacturing in India (Make it in India), encouraging finance for start-ups (Start-up India), the IT infrastructure and education and skills (the New education policy). At the same time, improving the healthcare infrastructure and provision is a significant priority for the Indian government.




Improving the healthcare infrastructure and provision is a significant priority for the Indian government.

Currently the level of spending on healthcare, the healthcare infrastructure and the resulting health outcomes are behind those of comparable countries.<sup>12</sup> Moving towards universal health coverage, lowering the reliance on out-of-pocket payments and improving the quality of provision are clearly priorities. The National Health Policy 2017, aims to improve population health through the expansion of health coverage, for primary care and essential medicines in particular, change the balance of funding, and ensure improved access to secondary and tertiary services.<sup>13</sup> It aims to improve the performance of health systems. Within this document, there is a clear recognition that the health and economic performance are linked.

The **linkage between health policy and industrial policy** is discussed:

*“India is known as the pharmacy of the developing world. However, its role in new drug discovery and drug innovations including bio-pharmaceuticals and bio-similars for its own health priorities is limited. This needs to be addressed in the context of progress towards universal healthcare. Making available good quality, free essential and generic drugs and diagnostics, at public healthcare facilities is the most effective way for achieving the goal. The free drugs and diagnostics basket would include all that is needed for comprehensive primary care, including care for chronic illnesses, in the assured set of services.”*



... and the implications for drug pricing recognised “The regulatory environment around pricing requires a balance between the patients concern for affordability and industry’s concern for adequate returns on investment for growth and sustainability.”

“Government policy would be to both stimulate innovation and new drug discovery as required, to meet health needs as well as ensure that new drugs discovered and brought into the market are affordable to those who need them most.... Public procurement policies and public investment in priority research areas with greater coordination and convergence between drug research institutions, drug manufacturers and premier medical institutions must also be aligned to drug discovery.’

However, to date the alignment has focused on generic medicines.

*“This needs to be addressed in the context of progress towards universal healthcare. Making available good quality, free essential and generic drugs and diagnostics, at public healthcare facilities is the most effective way for achieving the goal”*

In this paper, we ask whether even greater alignment between health and industrial policy for innovative medicines would be mutually re-enforcing, improving results in terms of economic and public health objectives.

*India is known as the pharmacy of  
the developing world.*



### 1.3. Structure of the report

The report is structured as follows:

- ▶ **Chapter 2** sets out the arguments that could be used to provide the rationale for aligning health and industrial policies to encourage innovative activities and puts these into the Indian context;
- ▶ **Chapter 3** provides evidence related to these arguments drawing from India and other countries that may serve as success stories; and
- ▶ **Chapter 4** discusses implication of these findings for policymaking in India.



Provide the rationale for having mutually reinforcing health and industrial policies to encourage innovative activities.

## 2. Arguments for aligning Health and Industrial policies to encourage innovation

In this chapter we set out the arguments that could provide the rationale for having mutually reinforcing health and industrial policies to encourage innovative activities. **The arguments regarding the interaction between health and industrial policy can be grouped in three main categories as follows:**







## 2.1. The role of health policy in incentivising innovative activity

At a high level, the outputs of innovative activity in the pharmaceutical industry are only valuable if they are used in addressing health challenges. The uptake of innovation is not the only goal of innovative activity, but also the rewards that ensue. Therefore, health policy aimed at ensuring new medicines are available to patients, obviously plays a role in encouraging overall innovative activity. So, policy that affect the speed at which innovative medicines reach the market, the diffusion, and uptake contribute to encouraging innovation. There is an interaction in terms of:

Pricing and reimbursement and funding structures that allow for increased timely access, improve the commercial value of the market and the willingness to invest in developing products in the market.

A predictable Pricing and reimbursement process that allows innovators to anticipate how successful innovations will be. The R&D process for innovative pharmaceutical is often over ten years long and consistent clear signals regarding the value of innovation and how it will be used impact on the incentives to innovate.

There is a large literature that discusses how the costs of incentivising R&D should be shared and the merits of basing this on willingness to pay – this is the argument for differential pricing. Health policy determines the share that countries are willing to pay for innovation.

These arguments suggest that health policy (as it determines the rewards from innovative activity), should be aligned with industrial policy.<sup>14</sup> For example, if health policy does not respect intellectual property rights, this would negate the incentives from the patent and market exclusivity regimes. If health policy focuses on infectious diseases and industry policy focuses on non-communicable diseases, the signal sent to innovative companies is mixed and unlikely to deliver what society wants. As set out in



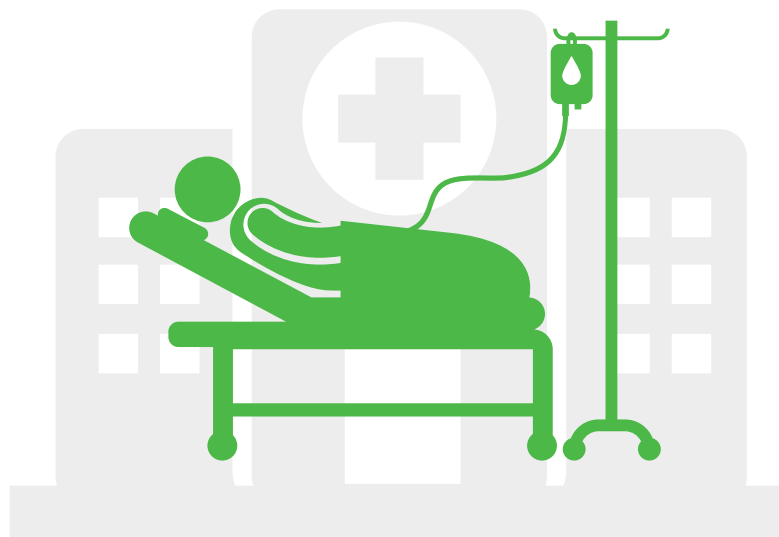
Health policy determines the share that countries are willing to pay for innovation.

the introduction, the National Health Policy recognises this argument.

*However, for this argument, health policy affects the incentive to innovate but is not directly related to the location of innovative activity.<sup>15</sup>*

## 2.2. Health policies that encourage innovative activity by creating an innovation friendly environment

The second group of arguments for aligning industrial and health policies focuses on the impact of health policies on the environment or undertaking innovative activities. Investment in health policy could encourage local innovative activity through:



**The environment for undertaking Local clinical trials:** Investment in healthcare infrastructure directly improves healthcare provision but also the infrastructure to undertake clinical trials. Better availability of approved medicines in the market, the development of clinical guidelines, increase the likelihood that products in development have appropriate international comparators. This will reduce the cost in undertaking local clinical trials and will be able to conduct internationally recognized clinical trials. The number of clinical trials being undertaken in India is low and has been falling. There have been a range of policy initiatives to encourage clinical trial provision including reducing the delay in approving clinical trials.

**Supporting the clinical community:** Investment in sustaining and training the clinical community obviously directly improves health outcomes but could lead to the return of

native scientists in foreign countries due to probability of higher compensation in the local market, but also increases the number of clinicians experienced in participating and running clinical research. Effort to improve primary care infrastructure and the co-ordination between primary and secondary care are clearly important as set out in the national health plan.

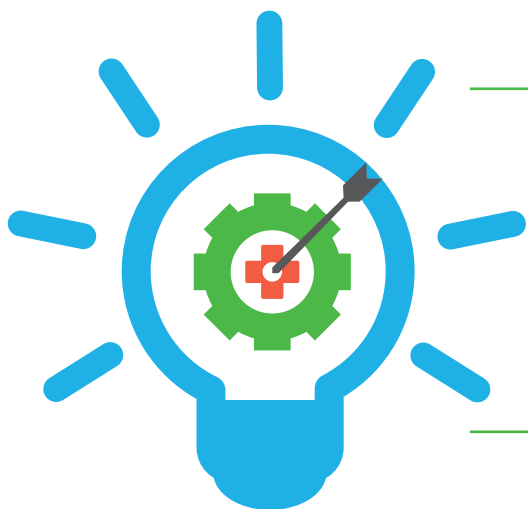
**Patient data availability:** Patient records, registries lead to better understanding of diseases and allow health system to optimise care. It is also a potential resource for undertaking research and development activities. This is relevant in the Indian context, with the debate on establishing the National e-Health Authority (NeHA) and the development of integrated health information system, to promote adoption of standards and facilitate exchange of patients' health records across facilities.

Not only Investment in healthcare infrastructure has a direct impact on patient care but also influences the environment for undertaking innovative activities in a given market.



**Not only Investment in healthcare infrastructure has a direct impact on patient care but also influences the environment for undertaking innovative activities in a given market.**

## 2.3. Innovative activity encouraged by industrial policies contributes to the goals of health policy



*The third argument for aligning industrial and health policies focuses on role that industrial policy plays by encouraging local innovative activity which, in addition to the economic benefits this brings in terms of employment and growth, contributes to the goals of health policy.*

There are several arguments that contribute to this:



#### **Local Clinical trials and access to medicines:**

Undertaking clinical trials leads to access to some patients for novel treatments, where they might otherwise have none. In markets, where access to novel treatments might be limited, such as India, this could bring even larger benefits.



#### **Local clinical trials and value assessment:**

Local clinical trials using local epidemiology and relevant patient populations, facilitate value assessment in the market and as a result lead to increased and faster uptake, which improves the value of the innovation and patent in that market. This is becoming more relevant in India, as the National Health Policy commits to the development of health technology assessment capabilities and the use of this approach for making technology choices that impact public health.



#### **Awareness of physicians:**

Where local clinicians and hospital have been involved in the development process and they are advocates of the value of the technology, uptake and diffusion, will be quicker in benefiting the patients. It is also likely that dosing and formulation will take into account the challenges of the local healthcare system (which is consistent with the aims to improve the quality of medical training and clinical consistency).



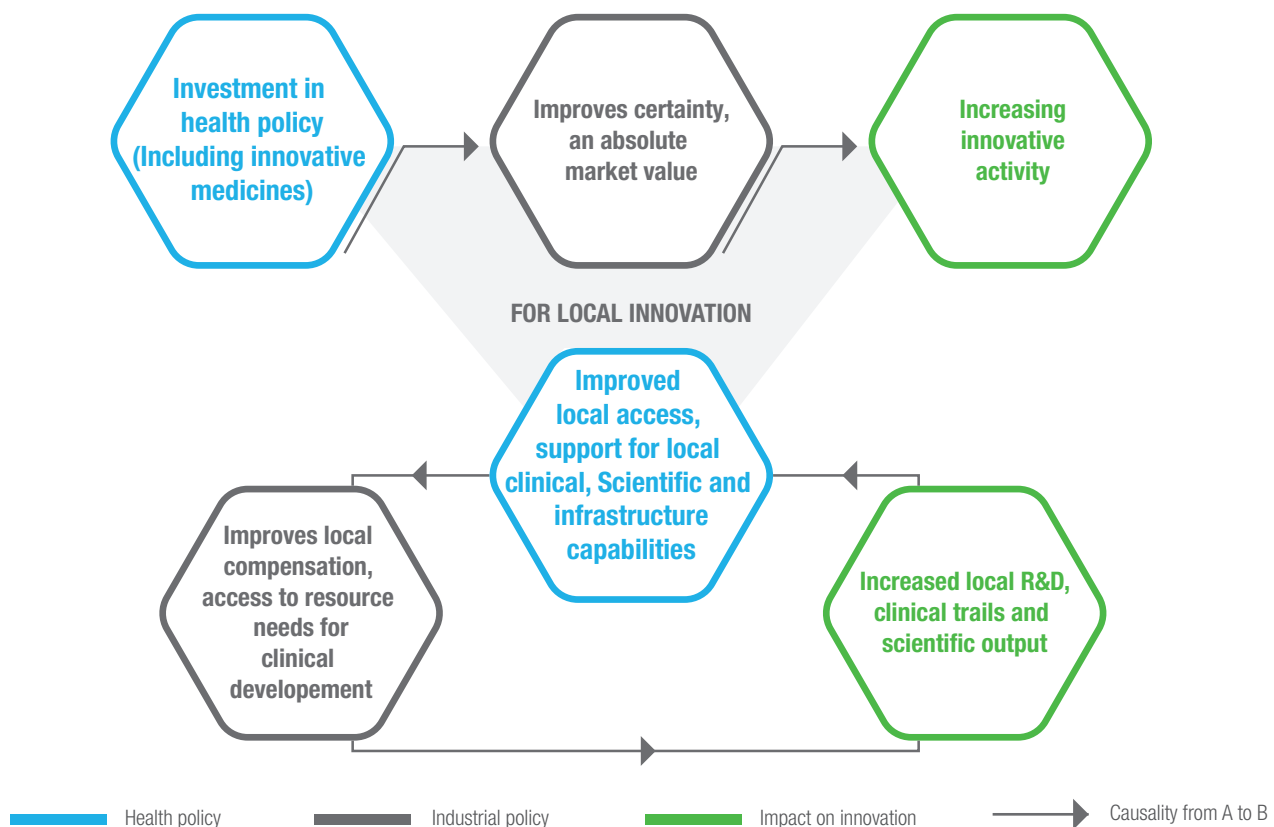
#### **Local clinical trials, investment in infrastructure and healthcare professional education:**

Local clinical trials contribute to physician education, can include investment in healthcare infrastructure (such as scanners or diagnostics) and therefore contribute to disseminating international guidelines and best practice. Although, there is considerable progress, it is recognised that primary care infrastructure and co-ordination to secondary care facilities (for example through limited strategic purchasing), particularly in the public sector remains problematic.

## 2.4. The interaction between health and industrial policies in encouraging (local) innovation

In summary, the arguments above set out a **theoretical link between mutually reinforcing health and industrial policies** and a more innovative environment, as shown in the virtuous circle in Figure 1 which appears relevant to the debate in India. At a high level, health policies can improve the value of markets and encourage innovative activity. Turning to the impact at a local level, national health policies can improve the environment for undertaking research and development encouraging local innovative activity. To complete the circle, the reverse holds, as industrial policies that encourage local innovation support local access and infrastructure and expertise, improving local access.

Figure 1: The interaction between health and industrial policy



Source: CRA analysis

In the next chapter, we focus on the evidence that health policy can create an innovation-friendly environment and that industrial policy can contribute to the goals of health policy.



A positive relationship (although less strong) can be found between spending on patented medicines and clinical trials.

### 3. Evidence regarding the value of mutually reinforcing Health and Industrial policies

In this chapter, we consider the arguments developed in the last chapter and the extent to which they are supported by evidence drawing on experience of a range of different countries (including India), before we turn to the policy recommendations in the next chapter.



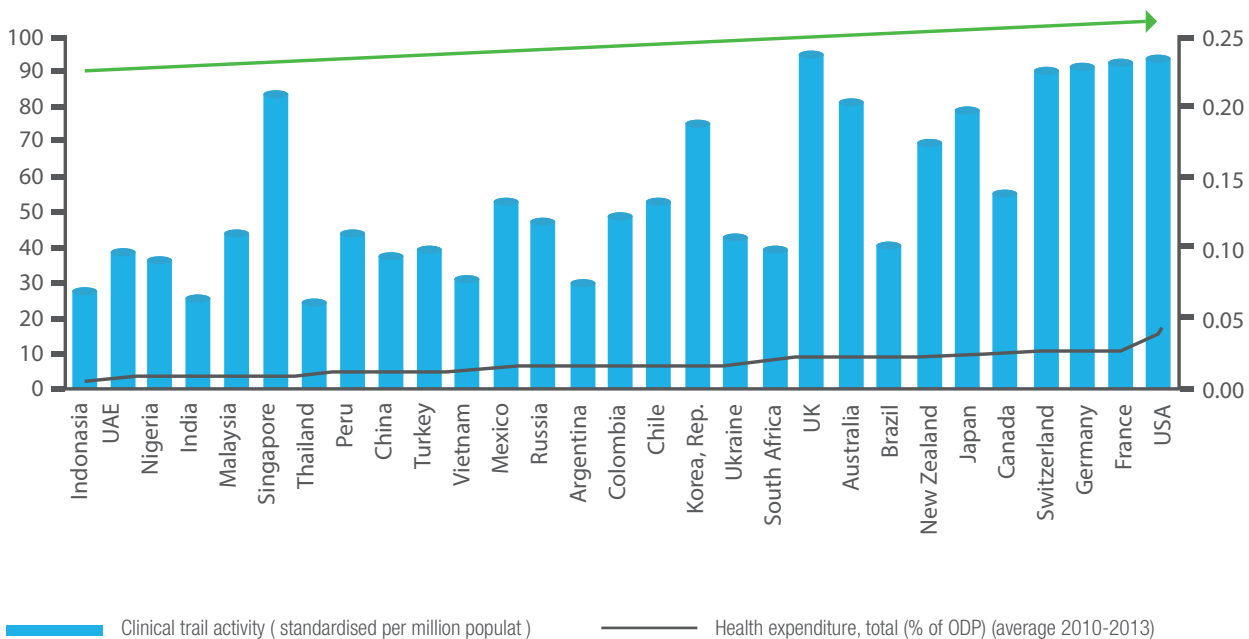
### 3.1. Evidence on the relationship between investment in health and innovative activity

First, we explore the relationship between the level of health spending, the reward for innovation and the level of R&D activity (number of clinical trials is the proxy). As argued in the last chapter, it is possible that where there is a high level of investment in health, there is greater likelihood of better infrastructure to undertake clinical trials. Indeed, when we investigate this relationship, we find supportive evidence across countries. As Figure 2 and Figure 3 illustrate, **there is a positive relationship between the level of spending on healthcare, the level of spending on patented medicines and the amount of clinical activity.**<sup>16</sup>

*India has a low level of healthcare spending and a low level of clinical trial activity per million of the population.*

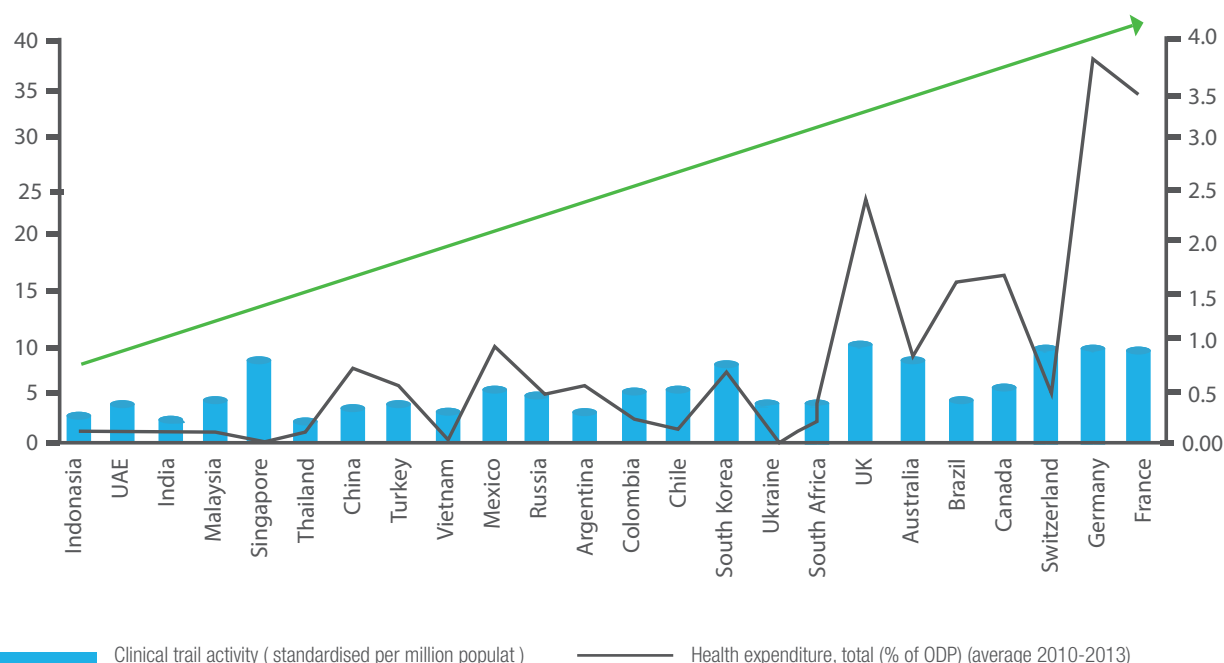


Figure 2: Relationship between healthcare spending and clinical trial activity across countries



Source: World Bank and Pugatch Consilium

**Figure 3: Relationship between spending on patented pharmaceuticals and clinical trial activity across countries**



Source: World Bank and Pugatch Consilium

A similar positive relationship (although less strong) can be found between spending on patented medicines and clinical trials. The causality in this correlation can clearly be debated. It is possible that wealthier countries are able to afford to spend more on healthcare and provide a better environment for clinical trials. However, there is some recognition of this link from policymakers across countries. For example, China has recently lifted price controls on patented medicines and has increased spending on health, explicitly further encourage domestic innovation.<sup>17</sup>

### 3.2. The impact of health policy on the environment for undertaking innovative activity

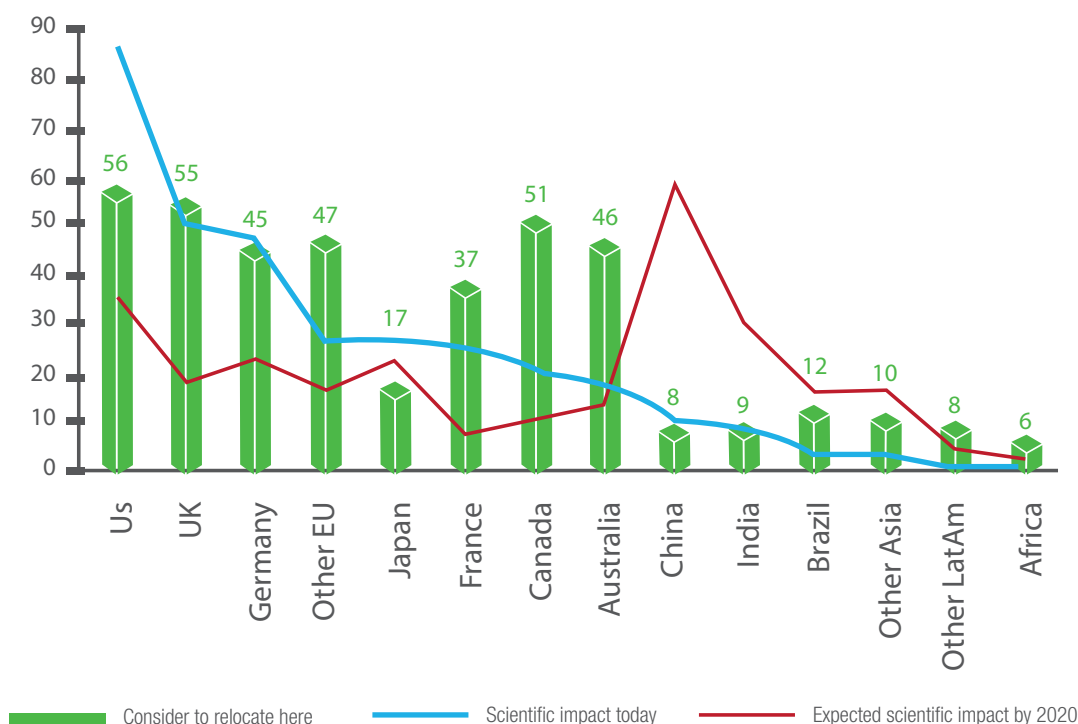
To understand how health policy could impact the incentives to innovate locally, it is useful to consider the different channels by which this could occur. Health policy clearly impacts the clinical and scientific community. An appropriate human skills base is vital for clinical development and multiple studies have argued the key role of human capital in the adoption and introduction of innovation.<sup>18,19</sup> This is consistent with the OECD finding that investment in training and education directly benefits healthcare and industrial policy. It also recognises that in today's mobile world, there should be further incentives to retain



human capital alongside the investment in education for building capacity.<sup>20</sup>

It is also the case that the retention of experienced clinicians and scientists is difficult for developing countries who have limited “attractiveness” when compared to other countries.<sup>21</sup> For example, we find that in one study, India has the largest proportion of scientists overseas.<sup>22</sup> **Another survey, which examined barriers preventing the return of native Indian scientists back to India, provides that key reasons for this are negative expectation the amount of compensation, research environment and infrastructure, ease of accessing reagents and presence of other researchers (clustering).**<sup>23,24</sup> As such, in order to encourage innovation, it is key to ensure that the appropriate human capital base is available.

**Figure 4: Scientists relocation vs markets current and future scientific impact**



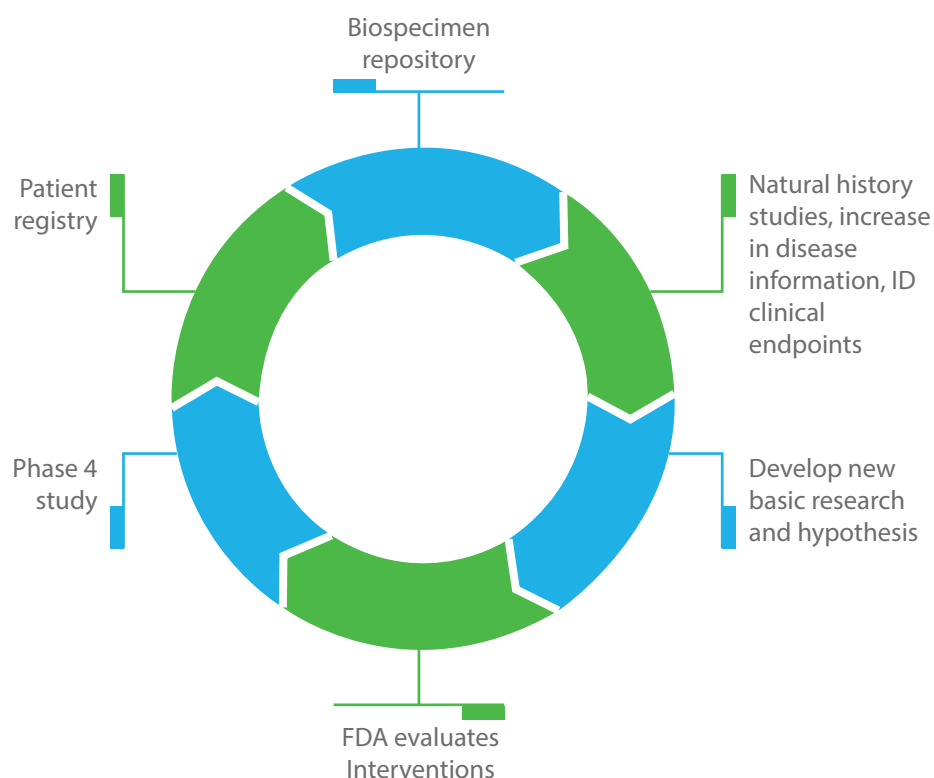
Source: Van Noorden, *Nature* (2012)

The availability of medical expertise is a factor often mentioned as a pre-requisite for the undertaking of clinical research. It is noted, that in order to encourage physician participation countries need to improve two key elements, namely have appropriate organisational and operational health infrastructure in place and offer appropriate opportunities for on-going education and training.<sup>25</sup> These key determinants of participation are embedded in healthcare systems and suggest a close relationship of a strong health structure for health provision and expertise and infrastructure in place that would encourage physician participation and enhance clinical activity. A further

determining factor is the availability and quality of medicines in the market facilitating trials based on international standards of care. A study by Medina et al. (2011), argues that it is important not only to have a comparator medicine in the market, but also that this is a high quality compound that meets regulatory requirements. This is suggested to be important for the clinical validation of research and for diminished support, costs and delays in the examination.<sup>26</sup> However, the evidence established on the latter is scarce and further data on actual impact of greater availability and higher quality comparators on the location of research is required.

In terms of information tools and patients records as a potential factor affecting the location of innovative activity, the evidence on this from emerging markets is relatively weak. However, a US Food and Drug Administration analysis on patient registries and its usefulness, found that patient registries facilitated the identification of patient cohorts for studies and the recruitment of participants in clinical trials. Furthermore, as shown in the cycle presented in Figure 5, the patient data was useful for stimulating new research on a disease's cause, treatments and outcomes and was crucial for scientific advances, particularly in therapies such as those targeting in rare diseases.<sup>27</sup>

**Figure 5: Patient registries developing pathways to interventions through partnerships**

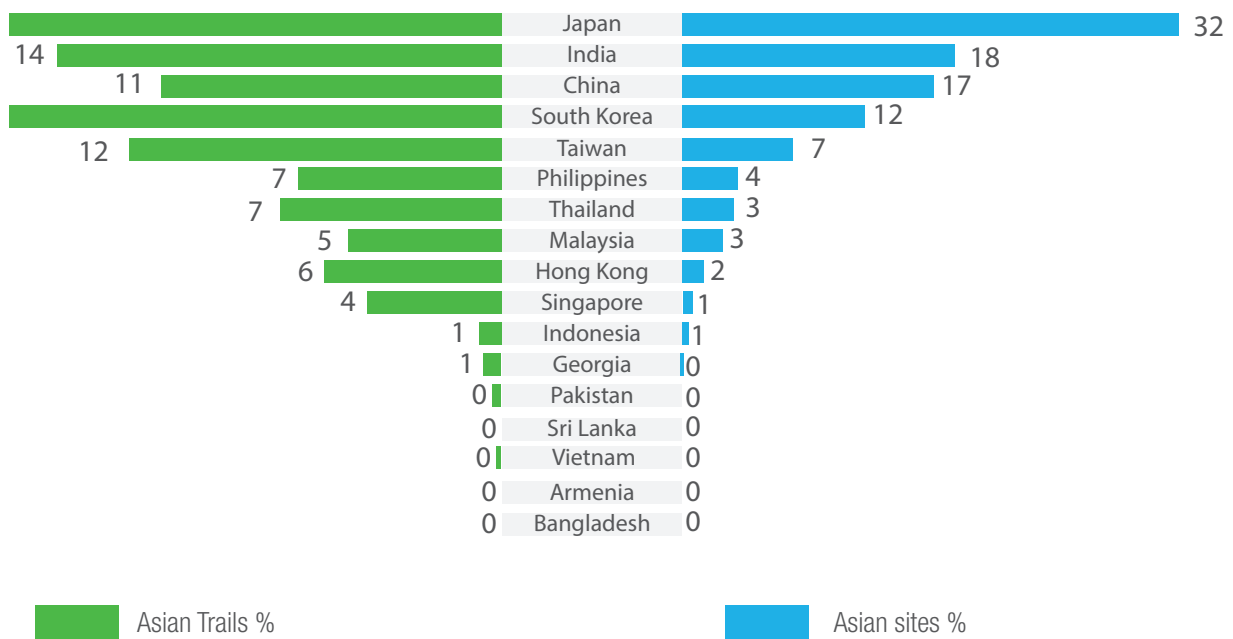


In Europe, information is also seen as key to encouraging local innovative activity. The UK's National Health Services (NHS) sees unified information as an important advantage. The NHS collects data on hundreds of millions of treatments every year. In 2010 alone, it

gathered data on more than 400,000 patients that were involved in clinical trials. It is argued that by “turning every patient into an anonymised research subject”, the NHS has built an important base for medical research as the use of this data could be licensed to the private sector for clinical research use.<sup>28</sup> Indeed, researchers in the UK have found that utilising electronic health records improves understanding of treatment outcomes and makes clinical trials less expensive.<sup>29</sup> Given the length of time required to develop effective patient data resources, this is likely to be an issue that emerging markets should also be considering.

Finally, the process for assessing value of medicines and determining their value in terms of the goals of health policy can affect location on innovation. This is an explicit relationship between new medicine assessment process and incentive to develop medicines locally. This is perfectly illustrated by the case of Taiwan. Since 2008, the health technology assessment process in Taiwan requests and has encouraged local epidemiology data in budget impact analyses.<sup>30</sup> The assessment process also includes a reward for local innovation as all products that have an efficacy and safety clinical trial of reasonable scale in Taiwan, a 10% pricing mark-up is provided.<sup>31</sup> In response, as illustrated in Figure 6, compared to other Asian countries, Taiwan is ranked highly in percentage of clinical trials conducted in the market (particularly given its relative population size).

**Figure 6: Location of clinical trials in Asia**



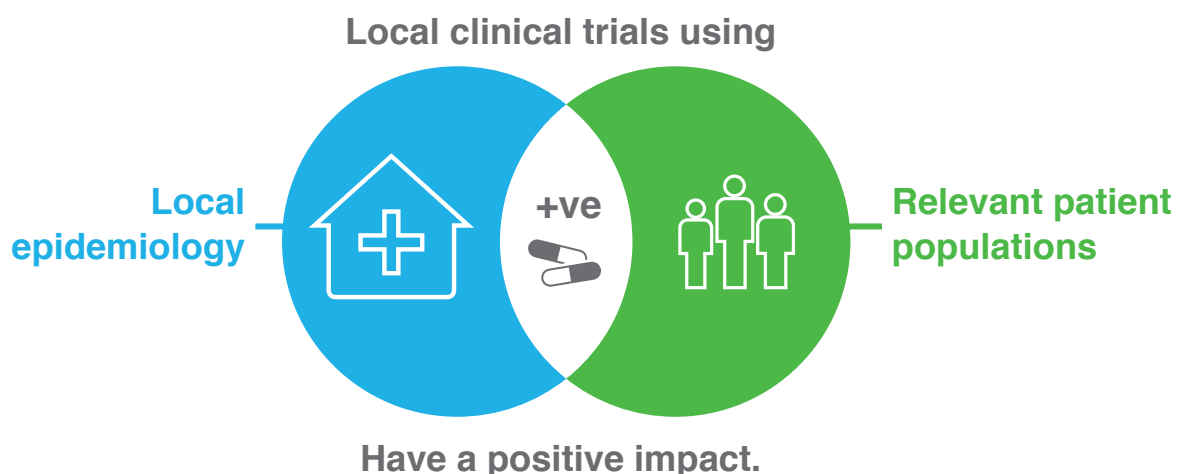
Source: Clinical Trial Magnifier Vol. 4:2 Apr 2011

### 3.3. The contribution that industrial policies can make to the goals of health policy

In this final section, **we consider the evidence that local innovative activities contribute to improving healthcare and health policymaking in countries.** At one level the link is straightforward, clinical research, particularly trials grant patients with immediate and direct access to novel treatments. This is particularly the case for Phase III trials, where safety has been tested, and they represent a large pool of patients with the underlying disease. Indeed, a large number of patient organisations and disease associations encourage participation on these **grounds, particularly for patients in healthcare system with limited coverage of novel medicines.**<sup>32</sup> However, it must be recognized that this does not represent a systemic change or improvement for two key reasons. First, treatments are by their nature experimental and some patients will be on the placebo arm of the trial, and this only involves patients during the trial and is not a sustainable method for providing patient access. It is also argued that local clinical trials using local epidemiology and relevant patient populations have a positive impact on health through a variety of channels.



a large number of patient organisations and disease associations encourage participation on these grounds, particularly for patients in healthcare system with limited coverage of novel medicines.



They can facilitate value assessments of a medicine and lead to faster uptake or contribute to improved health infrastructure, education of physicians and the dissemination of international guidelines and clinical best practice.

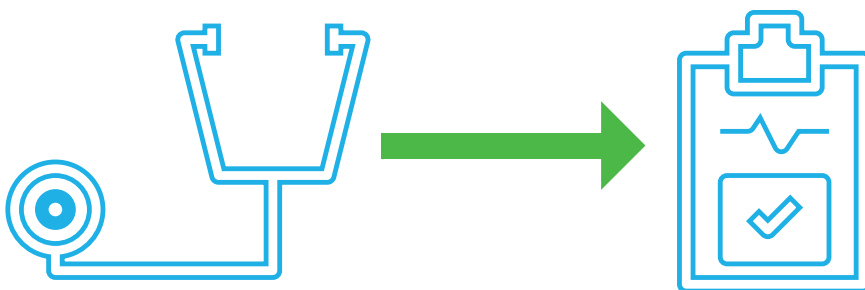
First, we discuss the impact of local clinical trials diffusing knowledge of a medicine and how it should be used in clinical practice.

There is evidence that illustrates that the development of clinical trials is beneficial for these key stakeholders and enables them to offer better quality care. For example, in the Netherlands structural training and quality assurance through clinical trials was found to improve national outcomes.

This study by Van Gijn et al. (2011) observed that surgical training and quality assurance gave rise to lasting positive effects on survival outcomes in colorectal cancer patients.<sup>33</sup> It should be noted that this may also be as a result of physicians' personal characteristics, multi-disciplinary collaboration and any additional training and education provided.

The process of providing care is shaped by a research intensive environment, which leads to a greater likelihood that the institution and/or physician follow clinical guidelines.

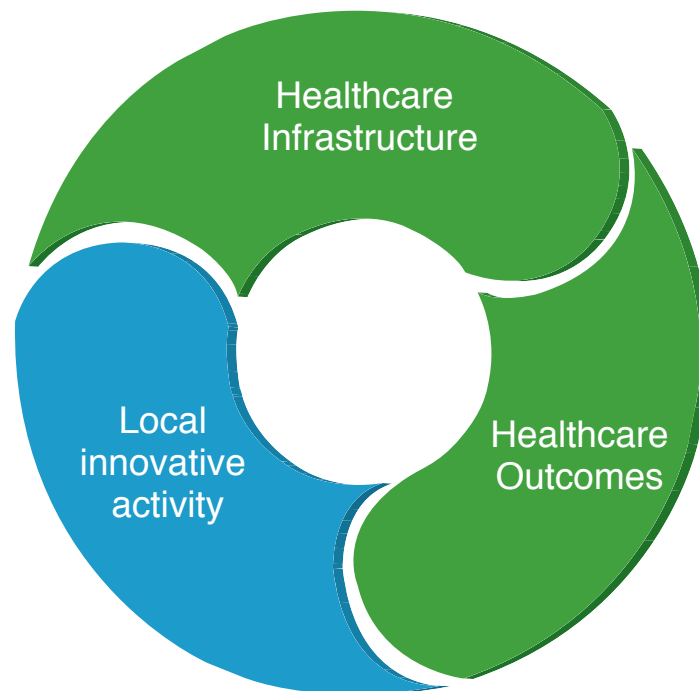
A systematic review of the effect of health practitioner or institution participation in clinical trials shows a “trial effect” where **trial participation led to a greater use of evidence by healthcare professionals, a greater adherence to guidelines and improved health outcomes.**<sup>34</sup>



Another study of patients with acute coronary syndromes showed better compliance with clinical guidelines and lower mortality in patients treated in institutions that participated in clinical trials in acute coronary syndromes.<sup>35</sup> There is further supportive evidence from a European study, which showed that patients treated in institutions that participated in clinical trials had more complete surgical procedures and had better survival rates compared to patients treated in institutions not participating in clinical trials, which suggests improved clinical practice and guideline adherence.<sup>36</sup>

*This is consistent with evidence from India that participation in clinical trial is often the only way that some patients will get access to medicines and this is particularly the case in the public sector.*<sup>37</sup>

In addition, performing local innovative activity can have great implications for healthcare infrastructure and ultimately improve healthcare outcomes.

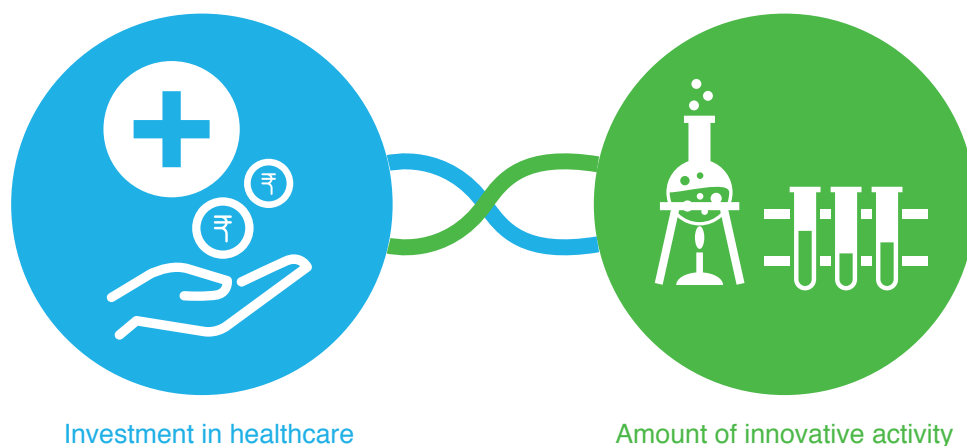


Infrastructure in this context refers to the setting where care is delivered including hospitals, equipment, staff etc. Conducting clinical trials requires the appropriate physical infrastructure and specialised equipment and services to perform research activities. This is often established for the purposes of research or existing infrastructure is improved to the standards required. These facilities are highly likely to remain and be embedded in the healthcare systems when the clinical research ends. Such developments are likely to be even more important in markets concentrating on improving the healthcare infrastructure, such as India.



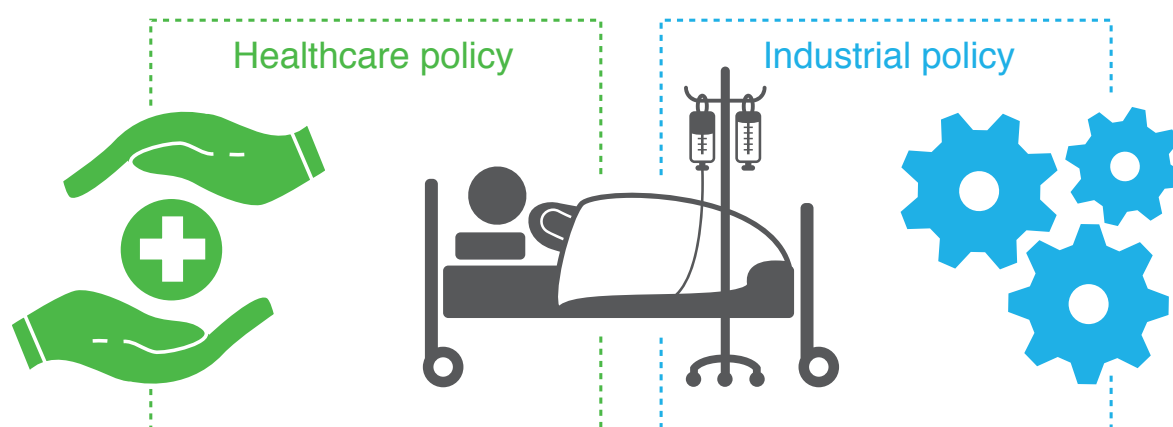
### 3.4. Summary

*There is clearly a correlation between investment in healthcare and the amount of innovative activity. This in itself does not provide evidence of causation.*



However, if we look at the impact of healthcare investment in terms of the clinicians, healthcare infrastructure, information systems and even the value assessment process, each of these acts to improve the innovation environment encouraging innovative activity. Equally, innovative activity helps with the adoption of new innovation, international best practices and improves the infrastructure that is subsequently used to treat patients beyond the clinical trials.

*At each point in the value chain, healthcare policy and industrial policy have the potential to work together to the benefit of the patient.*





There are also many policy initiatives aimed at encouraging innovative activity in India.

## 4. Policies that encourage pharmaceutical innovation in India

As set out in the introduction, India has developed a world-class generic industry and aspires to be a powerhouse more broadly in terms of innovative medicines. There are a number of challenges in terms of encouraging growth in innovative activity in India,

The current level of investment is low, with India hosting 2.7 percent of global R&D spend.<sup>38</sup>

The number of clinical trials started per year in India have decreased.<sup>39</sup>

The 2016 Global Innovation Index suggests that India has risen up almost 15 positions since the last report and ranks at number 66, as compared to 81 in 2015.<sup>40</sup>

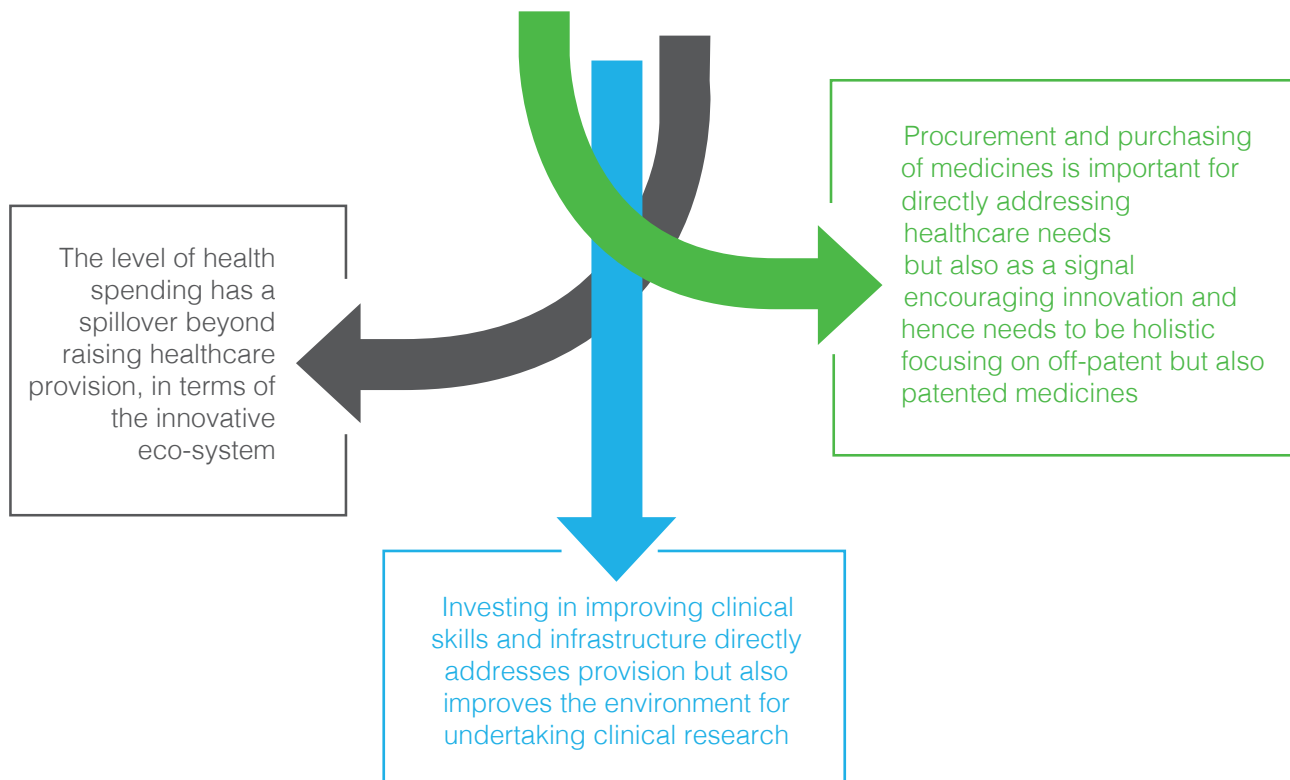




However, there are also many policy initiatives aimed at encouraging innovative activity in India. The need to improve investment in R&D is longstanding. In 2010, the Government of India declared the next 10 years as the “Decade of Innovation”. Since then, the government has issued The Science, Technology and Innovation Policy 2013 (STI) which includes key elements of innovation policy in India. In particular, the policy aims to increase R&D funding to 2% by 2018 and establishes a public-private partnership to increase the attractiveness of undertaking research and development to the private sector.

*More recent initiatives to encourage domestic production, financing and skills also aim to improve the innovation eco-system. The national health policy includes a discussion of the role industrial policy can play in helping to deliver health objectives.*

Our analysis is supportive of this:

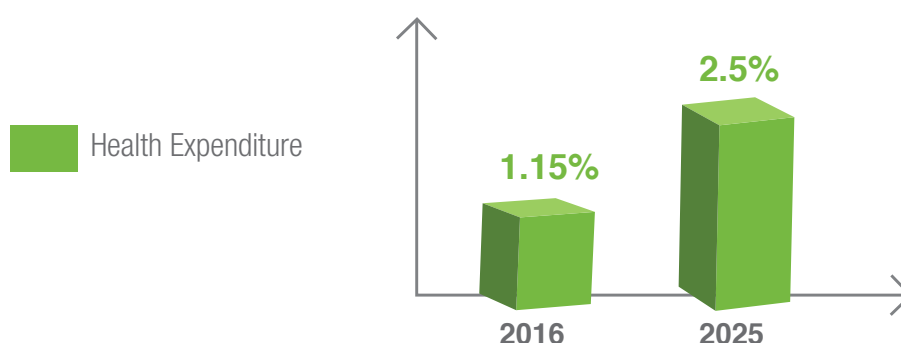


Equally, industrial policy can contribute towards the delivery of health outcomes:

- Appropriately regulated clinical trials deliver early access to patients and increase clinical capabilities and knowledge about new procedures and treatments
- An improved environment for clinical trials leads to improvements in healthcare infrastructure and resources for provision of healthcare

## Adapting the argumentation to the Indian environment

As we have discussed through this report, these arguments appear as relevant or even more relevant to the debate in India. However the evidence-based arguments for investing in and integrating health and industrial policies also needs to be adapted to the Indian environment. The evidence in this paper typically comes from wealthier countries where public healthcare plays a larger role. **India plans to increase health expenditure by government as a percentage of GDP from the existing 1.15% to 2.5 % by 2025.**



India is also a country with one of the largest private healthcare spend in the world. **It is estimated that only 33 percent of healthcare expenditure came from government sources, and only 5-10 percent of the population are covered by private health insurance.**



0.7 trained physicians per 1,000 population

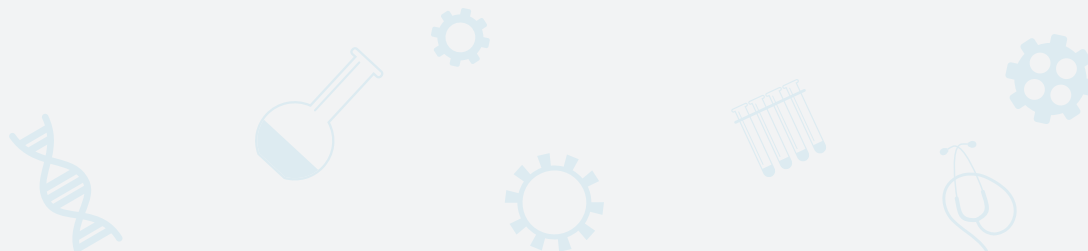


0.67 hospital bed per 1,000 population

These figures show even higher discrepancies in rural areas, where the provision of healthcare is very poor. The system suffers from significant healthcare professional shortages and issues associated with infrastructure.

*There are 0.7 trained physicians per 1,000 population and 0.67 hospital bed per 1,000 population, both significantly below the recommended WHO figures of 2.5/1,000 and 3.5/1,000 respectively.<sup>40,41</sup>*

Given the differences in the India markets it could be argued that the benefits from industrial policy encouraging local innovative activity would then benefit only those using



private facilities (and not the prime objective of the Indian government, raising overall provision). However, there are synergies in place that can be exploited and further enhanced. First, there is best practice sharing by private with public health professionals and use of private facilities.<sup>42</sup> These workers can serve as unregistered staff in both public (mainly rural) and private sectors and help with the spillover of information on clinical practices. A stronger relationship between public and private healthcare professionals is established through public-private partnerships. Such models are highly debated and some pilot programmes are being applied in India.

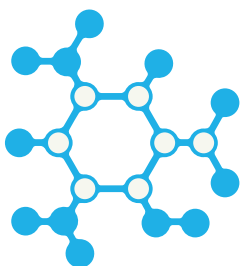
For example, since 2015, primary health centres in Rajasthan are run in a PPP<sup>43</sup> and there is a partnership between SRL (Diagnostic) with the Himachal Pradesh State Government to set up and operate 24 labs in the large state-run hospitals in various districts, thereby bringing superior diagnostics services in remote areas.<sup>44</sup>

This is a common route used by many developed and developing countries to cross-share practices and improve the state of publicly provided services in health. **Equally, within the National Health Policy 2017, there is policy to improve co-operation between the public and private sectors through strategic purchasing of services from the private health sector. This link between private and public sector provision means that the benefits in terms of infrastructure, training and access to medicines will apply to all patients.**

*This link between private and public sector provision means that the benefits in terms of infrastructure, training and access to medicines will apply to all patients.*



In this paper, we have set out how health policy and industrial policy have the potential to reinforce one another. Drawing on international markets, there is compelling evidence that taking into account the spillovers from health and industrial policy will benefit objective of improving the health of patients and the economic potential of the country.



*If India is to deliver on the opportunity to move up the value chain by enabling innovations and new drug discovery, even greater alignment between health and industrial policy would be beneficial.*

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## Arguments for aligning health and industrial policies to encourage innovation

**14.** The argument that innovation requires a reward and hence health policy affects innovative activity is uncontroversial and requires little evidence. However, it is nicely illustrated by the debate on new antibiotics. Policymakers have recognized that in order to address this shortage, in addition to further support for investment in R&D in the area, ‘pull’ mechanisms in the form of more favourable reimbursement processes need to be introduced. Hwang et al. (2015) argued that a new policy for patients in the Medicare programme, which allowed access to breakthrough medicines through the New Technology Add-on Program (NTAP) impacted reward and incentives in antibiotics innovation. In 2012, the Centres for Medicare and Medicaid Services, granted an NTAP payment of \$868 per fidaxomicin, a first-in-class antibiotic for the treatment of Clostridium difficile-associated diarrhoea. The latter allowed the manufacturer of fidaxomicin to partly overcome the market challenge of having to compete with generic alternatives, such as vancomycin, on price alone. The authors suggest that a better alignment of expected returns from antibiotic drug development with reimbursement-based incentive programmes did and could improve the further investments in antibiotic development. Hwang et al. (2015), “Paying for innovation: Reimbursement incentives for antibiotics”, Science Translational Medicines, 7, 276.



**15.** The exception to this is where an innovation will only be valuable in a single market. In this case, that country is the only country that rewards the innovation. It is also likely that innovative activity will focus many activities on that market, as that is where the patients are and clinicians experienced in treating the disease. In this case, rewarding innovation and the location of innovation are clearly directly linked. This is illustrated in the development of a vaccine for the dengue virus. The virus has a particularly high prevalence in Brazil. In response, the Brazilian government and the state of Sao Paulo are dedicated to controlling the dengue virus and to work closely with the Pan American Health Organisation (PAHO) in research activities for a vaccine. This establishes an environment that is useful for developing medicines and vaccines to tackle the dengue virus. As a result, Brazil and the state of Sao Paulo have attracted investment in dengue research. Most recently, the TV003 dengue vaccine, developed by the NIH's National Institute of Allergy and Infectious Diseases in the United States has decided to further test the product in Brazil through collaboration with the Brazilian Butantan Institute due to the infrastructure available in Brazil and the health impact of the research on the local population. Quadros C (2014), "Preparing for a dengue fever vaccine: why Brazil's ahead of the game."

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