The role of the domestic private sector in developing countries for addressing local health needs

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Abstract: Developing countries can benefit from conducting innovative research and development in science and technology prioritised to their own specific health and development needs. Here, the role of the domestic private sector in utilising its knowledge, expertise, resources and relationships is critical for translating R&D results into tangible health products and services for individuals. We have recently initiated a study to analyse how the domestic health biotechnology sectors of four developing countries – India, China, Brazil and South Africa – address local health needs. In this paper, we introduce the purpose, design and objectives of the study, describe our rationale for undertaking this research and present preliminary results from our analysis of health biotechnology firms in India.

Keywords: global health; private sector; development; developing countries; science and technology; innovation systems; local health needs; genomics; biotechnology; India; China; Brazil; South Africa.


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1 Introduction

There is a tremendous disparity in global health in the world today. Every year millions of children less than five years of age from the developing world senselessly die from diseases that are preventable by vaccines commonly included in most national vaccination programmes in the developed world (World Health Organization, 2005). Three diseases alone, AIDS, TB and malaria, cause more than six million deaths annually, almost all of them in developing countries (World Health Organization, 2003). The average expected lifespan in developed countries is approaching 80 years, while in developing countries it is less than 40 years and falling (Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, 2003). Better solutions and approaches are needed to address this growing inequity, which is perhaps the greatest ethical challenge of our generation. In recent years, science and technology have been identified as key components of these solutions.

With the turning of the 21st century, a push came among the international community for the implementation of science and technology for development. For example, the 2001 report ‘Making New Technologies Work for Human Development’ (United Nations Development Programme, 2001) from the UN Development Programme and the 2004 report ‘Inventing a better future: a strategy for building worldwide capacities in science and technology’ by the Interacademy Council on Science and Technology Capacity (Interacademy Council, 2004) both promoted science and technology as tools to improve developing countries’ health and economic performance. The 2005 report ‘Innovation: applying knowledge in development’ from the UN Millennium Project Task Force on Science, Technology and Innovation (UN Millennium Project, 2005) also emphasised the need for long-term development strategies that place science, technology and innovation at the centre of efforts to improve human well-being. These findings have been reiterated by those of the WHO Commission on Macroeconomics and Health, which also emphasised the central role of health in securing economic development and called for
developing countries to integrate their development strategies with health priorities (World Health Organization Commission on Macroeconomics and Health et al., 2001).

Genomics and biotechnology in particular have a tremendous potential to improve global health equity (Singer and Daar, 2001; World Health Organization Advisory Committee on Health Research, 2002). However, efforts to encourage research, including capacity strengthening, consensus building, public engagement and investment, are needed to harness the potential of this technology in a decisive and timely manner. To this end, a foresight study was conducted in 2002 to identify and prioritise the appropriate biotechnologies required to address developing countries’ health needs (Daar et al., 2002). An international group of eminent scientists with expertise in global health issues were surveyed to identify the biotechnologies that hold the greatest potential for improving health in the developing world. The specific technologies identified, including molecular diagnostics and recombinant vaccines, offered concrete guidance to those in a position to influence the direction of research and development to address local needs and also to help achieve a number of the Millennium Development Goals (e.g. Goal 4, Reduce child mortality and Goal 6, Combat HIV, malaria and other diseases (Acharya et al., 2004a,b; United Nations Millennium Summit and United Nations Department of Public Information, 2000)). Importantly, these findings challenge some common assumptions regarding the relevancy and affordability of using biotechnology in developing countries and make solid the concept of the application of new technologies to development. They support the argument that the prioritisation of innovative technologies to address developing countries’ health needs will help reduce the gaps in global health that the MDGs aim to close.

Developing countries themselves are key actors in prioritising and implementing new technologies (Acharya et al., 2004a,b). A recent empirical analysis of the health innovation systems of seven developing countries (Cuba, Brazil, South Africa, Egypt, India, China and South Korea) further helped to identify the conditions that encourage successful development of health biotechnologies (Thorsteinsdóttir et al., 2004). A country’s health innovation system includes several key actors, including governments, private sector firms, research institutes, universities, financial institutions and the general public. Each plays an important role in creating, diffusing and using knowledge and thus contributes to the innovative process of developing new health products. Governments, for example, contribute to innovation systems in their role of setting up institutions, developing policies that support innovation and providing regulatory frameworks that can have a considerable influence on sector development. Research and educational institutes are similarly essential for training quality human resources in fundamental scientific inquiry. However, it is often the innovative firms of the private sector that are at the core of innovation systems. These firms must integrate various types of knowledge to translate basic research and development into new commercial products and innovative processes.

Several key factors were found to be critical to the success of health innovation systems in developing countries, including supportive political will and the use of biotechnology to address local health needs (Thorsteinsdóttir et al., 2004). Also critical is the development of a domestic health biotechnology sector with the capacity to harness genomics and biotechnology and commercialise health products relevant to domestic needs. Furthermore, a well-developed and commercially innovative domestic private sector will become increasingly important for addressing national health needs, as developing countries continue to adopt more stringent patenting systems in concordance
with the World Trade Organisation’s Trade Related Aspects of Intellectual Property Rights (TRIPS), for example, as India did earlier this year.

Recently, the UN Commission on Private Sector and Development, co-chaired by Paul Martin and Ernesto Zedillo, emphasised the role of the domestic private sector in developing countries for their development (UNDP Commission on Private Sector and Development, 2004). In their 2004 report ‘Unleashing Entrepreneurship, Making Business Work for the Poor’, the Commission highlighted how the managerial, organisational and technological innovation in the private sector, particularly the small and medium enterprise segment, can improve the lives of the poor by empowering citizens and contributing to economic growth. The main message of the report is clear. Sustained economic growth reduces poverty and strong private investment contributes to economic growth. However, more sustained research and analysis of the best practices for harnessing the capabilities of the private sector in support of development is needed to understand better the determinants of private sector behaviour and performance in developing countries (DFID Health Systems Resource Centre, 2000). Although this report did not specifically address the role of private sector development for health, its findings are consistent with those from the analysis of health innovation systems in developing countries. The expertise and efficiencies that reside in the private sector are essential for the translation of health biotechnology knowledge into products and services for the poor (The Rockefeller Foundation, 2004; Thorsteinsdóttir et al., 2004).

The purpose of this paper is to introduce a study, which we have recently initiated to analyse the role of the domestic health biotechnology sector in developing countries for addressing local health needs. In Section 2, we will describe the study’s design, including its purpose and objectives. In Section 3, we will describe our rationale for undertaking this analysis, including a discussion of the potential audiences who stand to benefit from this work. Finally, in Section 4, we will present some preliminary results from our analysis of health biotechnology firms in India.

2 Description of study design

We have initiated a study of the domestic health biotechnology sector of four developing countries – India, China, Brazil and South Africa. The purpose of this study is to explore how the domestic private sector in developing countries, particularly Small- to Medium-sized Enterprises (SMEs), can contribute to the development of health technologies targeted to address local health needs.

The study objectives are listed in Box 1. In brief, they are:

1. to survey the capacity of health biotechnology firms in developing countries for prioritising the development of health products, which address local health needs
2. to identify the barriers to and incentives for firms to address local health needs
3. to identify how developing country firms form linkages to address local health needs
4. to survey the capabilities of developing country firms along the value chain for developing products targeted to address local health needs and
5. to explore the financial environment for private sector investment in products targeted to address the health needs of developing countries.
Box 1  Study objectives

- To survey the capacity of the private sector, including core platforms, services and products, for prioritising and developing health technologies, which address local health needs in developing countries.
- To identify the incentives for and barriers to investment in local health needs, which shape the business strategies of domestic private sector firms in developing countries.
- To explore how, when and why developing country firms form linkages to push forward the development of new health biotechnology products, including private–private strategic alliances and public–private partnerships with universities, research institutes or international development agencies.
- To assess the capabilities in human and financial R&D resources, manufacturing, intellectual property and regulatory affairs of private sector firms in developing countries for development and integration of health technologies targeted to address local health needs.
- To explore the financial issues surrounding private sector commitment to local health needs, including availability of both publicly and privately offered funds.

We selected India, China, Brazil and South Africa as a representative set of developing countries, which have had some success in their domestic health biotechnology sectors. These countries are leaders in health biotechnology innovation, and as such could provide useful lessons to other countries in the developing world on stimulating the domestic private sector investment to address the local health needs (Thorsteinsdottir et al., 2004). All four countries fall within the UNDP Human Development Index’s ‘medium human development’ category.

This study uses a comparative case study analysis, where the case is defined as a health biotechnology firm from the domestic private sector of a developing country. We have limited the study to companies, which specialise in biotechnology for human health and did not include those involved in agricultural, environmental or industrial biotechnology. We have also included companies specialising in genome-related technologies (such as bioinformatics) and in health biotechnology-related contract services (including R&D, clinical development and manufacturing). We will analyse 15–20 firms per country for this study.

The data will be collected from two primary sources: key documents and interviews with key informants. The documents include annual reports, company brochures and business plans that describe the business practices of each firm. Relevant documentation regarding each country’s domestic biotechnology sector from additional outside sources, including local biotechnology associations, confederations of industry, chambers of commerce and academic literature will also be included in the analysis. Semi-structured and open-ended interviews with key informants will be conducted in face-to-face settings. Key informants will be identified from the background documents and company websites. We will discuss with the key informants, the five major themes to highlight how developing country firms are addressing local health needs: prioritisation of health product commercialisation; incentives and barriers related to government policies; partnerships; company capabilities along the product value chain and financial issues. As is typical in qualitative case studies, the interview guide will be modified during the data analysis to capitalise on emerging themes. The interviews will take place at the
institutions of the informants and last for approximately 60–90 min. Observations from touring firms’ facilities will augment the information collected via interviews.

Our conceptual framework is the innovation systems’ framework (Edquist, 1997; Lundvall, 1992; Nelson, 1993). Innovation systems are made up of institutions that contribute to the creation, diffusion and use of a new knowledge. They are held together by a web of linkages and synergies that involve non-linear, multidirectional knowledge flows among various actors. Interviews will be analysed via open, axial and selective coding by the research team. Open coding is used first to identify and group chunks of data (passages of text) that relate to a common theme or idea. Axial coding is used next to develop further the conceptual categories identified above and compare them with each other. Finally, selective coding is used to identify core concepts as the central themes of the study, and to organise the conceptual categories in relation to the core concepts. The in-depth qualitative analysis of the personal interviews and key documents will be combined with the descriptive quantitative indicators identified from the key documents to maximise the comprehensiveness and diversity of the analysis.

This research was approved by the Ethics Review Office of the University of Toronto Research Services.

3 Description of study rationale

This analysis will expand upon recent key findings regarding the critical role of the private sector for development (Prahalad, 2004) and for health innovation in developing countries. Several key decision makers from both the public and private sectors have the ability to influence international investments in global health. These decision makers include, for example, governments of developed and developing countries, health biotechnology firms in developed and developing countries, global health foundations and the international investment community. We believe that all these key decision makers stand to benefit from the findings of this study (Figure 1). Our goal is to provide them with the knowledge they need to support private sector development in developing countries for the purpose of recruiting domestic firms to the challenge of global health inequity.

Figure 1 Key decision makers to benefit from study’s findings
3.1 Governments and firms in developing countries

It is the responsibility of developing country’s policy makers to act as facilitators of private sector development. This includes the provision of an enabling domestic macroenvironment for business and good governance with policy predictability, transparency and accountability (UNDP Commission on Private Sector and Development, 2004). The findings from this study will identify the best incentives for and worst barriers to health innovation, as identified by the private sector firms themselves. The results will be shared with federal science and technology departments and agencies, such as India’s Council of Scientific and Industrial Research (CSIR), to promote strategies that encourage the domestic private sector to develop health products targeted to address local health needs. In addition, firms in developing countries can learn from each others’ experiences and adapt good practices to their own unique situations. Our findings regarding successful strategies for commercialising products targeted to address local health needs, particularly with respect to prioritisation, financing and partnerships, will provide valuable knowledge to health biotechnology firms in all developing countries.

3.2 Governments and firms in developed countries

Linkages among firms in developing and developed countries provide an effective channel for sharing access to markets, financing, technology, skills and know-how and for discussing issues of common interest. Developing and developed country governments can facilitate strategic linkages among companies by sponsoring trade and research partnerships. Developed country governments in particular can provide incentives to domestic firms to invest in products targeted to developing country health needs and to seek partnerships with developing country firms. We will share the findings from this study with governments and firms of developed countries to promote investment in and partnerships with developing countries. For example, we are currently consulting with International Trade Canada (ITCAN) to develop a pilot partnering programme for Indian and Canadian health biotechnology firms. The purpose of this programme is to facilitate linkages between firms by helping them to identify potential strategic partners and providing them with competitive intelligence. This pilot programme will be tested at the 11th Technology Summit and Technology Platform 2005 in New Delhi, for which Canada is India’s partner country.

3.3 Global health foundations

Long-term success in battling diseases of the poor will require effective, affordable, acceptable and accessible health products that are superior to those that currently exist (The Rockefeller Foundation, 2004). Institutions dedicated to global health efforts, such as the Rockefeller Foundation and Bill and Melinda Gates Foundation, have established public–public partnerships which offer appropriate stimuli and incentives to attract the essential expertise and resources of the private sector to the field of research on neglected diseases (Initiative on Public–Private Partnerships for Health, XXXX). However, the majority of these efforts have sought the expertise of partners from developed countries (Moran, 2005), thus undervaluing the potential contributions of developing country partners. Developing country institutions in both the public and private sectors are
capable of innovation to develop products and services for addressing the local and global health needs, although various hurdles to harnessing these capabilities do exist. In recognition of their capabilities, however, global health foundations and funding agencies need to give developing country firms the opportunity to develop, test and deliver new health technology products for their own local needs and for those of other resource-poor countries (The Rockefeller Foundation, 2004). The in-depth and up-to-date findings from this study regarding the capabilities of developing country health biotechnology firms to address the local health needs will be of a significant value to these global health institutions.

3.4 Venture Capital investment community

Venture Capital (VC) investment is essential for the success of a start-up biotechnology company in a developed country. However, the resounding message from the developing world is that risk capital and the management tools, networks and opportunities that come with it, are nearly non-existent there. Given that the private sector involvement is a crucial ingredient for addressing the local health needs in developing countries, a global health venture fund that provides firms with support to commercialise health innovations would have a significant impact on both the health and economic performance. Therefore, we will share with the VC investment community the findings from this study regarding the financial environment in developing countries for investing in health products targeted to address local needs.

4 Discussion of preliminary findings

In this section, we will present preliminary findings from our analysis of health biotechnology firms in India. After India became an independent country in 1947, the Government of India began to tackle its problems of widespread poverty and under-development by focusing its policies on education and infrastructure. These policies helped to create a strong capacity in science and technology. In particular, when the Government of India changed its patenting policies in the 1970s to emphasis novel process innovation, rather than product innovation, it spurred the domestic pharmaceutical industry to develop strong capabilities in bulk and generic manufacturing, making affordable drugs available even to poor citizens. In the 1980s, the Government of India recognised the scientific advances that were spurring the global biotechnology industry and in 1986 created the Department of Biotechnology. A number of initiatives were taken to promote modern biology and biotechnology at academic and industry levels, including the establishment of national research institutes/centres of excellence and specialised university graduate programmes. As a result of these and other investments in infrastructure and education, India’s national research laboratories today employ over 15,000 scientists and the colleges and universities annually produce nearly 500,000 graduates with diplomas in biological sciences, bioinformatics and biotechnology (Department of Biotechnology, 2005).

Despite these impressive figures, India’s biotechnology sector has nevertheless taken shape over the last two decades through a number of scattered and sporadic academic and industrial initiatives. The Ministry of Science and Technology and Department of
Biotechnology are currently aiming to integrate these efforts, and have recently released a draft of the country’s National Biotechnology Development Strategy (Department of Biotechnology, 2005). The strategy stresses a shift in policy to support cooperation rather than competition among science agencies, research institutions, academia and industry, including initiatives to promote public–private partnerships. By prioritising national health needs and encouraging high-quality scientists to work in small and medium biotechnology firms (a change from Indian traditions), several of the initiatives aim to create a favourable and enabling environment for enterprise creation and private sector development, including financial and problem-solving support for both early stage innovative research and later-stage product development. These and other initiatives of the National Biotechnology Development Strategy clearly demonstrate the Government of India’s recognition of the important contribution that the health biotechnology sector must make in addressing national health needs.

Till date, we have interviewed 21 health biotechnology firms in India (Box 2). Here, we provide a snapshot of how three of these firms, Shantha Biotechnics, Biocon and Bharat Biotech International, have targeted specific products to address local (and global) health needs.

**Box 2** List of Indian firms interviewed

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<th>Bangalore</th>
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<td>Biocon Limited</td>
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<td>Bhat Bio-Tech India (P) Ltd.</td>
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<td>Strand Genomics</td>
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<td>Dr. Reddy’s Laboratories Ltd.</td>
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<td>Shantha Biotechnics Limited</td>
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<td>Bharat Biotech International Limited</td>
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<td>Indian Immunologicals Ltd.</td>
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<td>Wockhardt Limited</td>
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<td>Nicholas Piramal India Limited</td>
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<td>Reliance Life Sciences Pvt. Ltd.</td>
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<td>Bharat Serums and Vaccines Limited</td>
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<td>SIRO Clinpharm Pvt. Ltd.</td>
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<td>Panacea Biotec Ltd.</td>
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<td>Lifecare Innovations Pvt. Ltd.</td>
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<td>Serum Institute of India Ltd.</td>
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Shantha Biotechnics Private Limited (Hyderabad) was the first Indian firm to sell recombinant Hepatitis B vaccine on the domestic market. Indian patients directly benefited from Shantha’s cost-effective and efficient manufacturing process, as Shantha priced their branded Shanvac-B product at $0.50 per dose, a significant reduction from the $15 per dose cost of the rival import. Although Shantha was founded with the purpose of serving domestic unmet health needs, its influence has been felt beyond India’s borders. Shantha’s Executive Director, Khalil Ahmed, explained “we realized that UNICEF also supplies to as similar or less fortunate countries. And I think it’s equally important to actually supply UNICEF at a lower price”. Shantha revamped their manufacturing facility to meet the requirements for WHO prequalification, and is now selling nearly 40% of UNICEF’s requirement of recombinant Hepatitis B vaccine. The relationships with UNICEF and PAHO have allowed Shantha to address unmet global health needs in Asia, Africa and Latin America.

Biocon (Bangalore), the first-ranked biotechnology company in India, was one of the first domestic companies to sell recombinant human insulin in the country. The ability to produce products cost effectively through an efficient proprietary fermentation technology, while also respecting current patent protections, has allowed Biocon to sell the lowest priced insulin product in the country. They launched their branded Insugen product at nearly half the cost of rival imports, which prompted the multinational competitors to reduce the prices of their own branded products by approximately 40%. The price war that followed Biocon’s entry into the domestic market significantly increased the amount of affordable insulin available to India’s burgeoning diabetic population, again illustrating the role of the domestic private sector for addressing local health needs.

Bharat Biotech International Limited (Hyderabad) is partnering with the US-based Malaria Vaccine Initiative (MVI, Bethesda) and Program for Appropriate Technologies for Health (PATH, Seattle) to develop candidate vaccines for malaria and rotavirus, respectively. Bharat has committed to providing the final product (if successful) at a price that is affordable to those in the developing world in return for financial and intellectual contributions from MVI and PATH and other incentives. For example, if a successful malaria vaccine is developed, Bharat must sell the vaccine for less than $1 per dose and in return will receive exclusive manufacturing and marketing rights. Although the projects are quite risky in nature, the majority of the risk is assumed by MVI and PATH while Bharat benefits from the technological knowledge transfer to improve its capacity for innovative research. Bharat’s commitment to producing affordable vaccines for the developing world exemplifies how health biotechnology companies in developing countries are uniquely suited to derive both commercial and humanitarian benefits from addressing global health challenges.

5 Conclusions

Developing countries can benefit from conducting innovative research and development in science and technology prioritised to their own specific health and development needs. Here, we describe our preliminary findings regarding India’s health biotechnology sector, including examples of three domestic firms, which are successfully addressing local and global health needs. We are currently finalising the results of India analysis and have begun to explore the health biotechnology sectors in China and South Africa also.
Underlying the examples cited above is an enabling environment for research and development directly resulting from earlier public sector investment in scientific infrastructure and human resource development. It is clear that a number of different tactics and policy approaches are needed for developing countries to address their burgeoning health needs. Translating the results of scientific R&D into tangible health products and services for individuals is a difficult challenge that requires the active participation of the private sector and a diverse set of policy measures. Like the efforts of India described above, other developing countries should consider enacting measures that improve the environment for research and development, build scientific infrastructure, invest in scientific human resource development and spur entrepreneurial activities (Juma and Yee-Cheong, 2005). Utilising the knowledge, expertise, resources and relationships of the domestic private sector is especially critical to this challenge. The strategies that support the private sector development and facilitate cooperation among the government, academia and firms are needed. Governments from both developing and developed countries can facilitate this and international development and global health institutions can assist them. In return, private firms in developing countries must make their products and services affordable, accessible and available to domestic markets. Working together, all these players can harness biotechnology to bridge the growing global health divide.

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