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Research review paper

Development of health biotechnology in developing countries: Can private-sector players be the prime movers?

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ABSTRACT

Health biotechnology has rapidly become vital in helping healthcare systems meet the needs of the poor in developing countries. This key industry also generates revenue and creates employment opportunities in these countries. To successfully develop biotechnology industries in developing nations, it is critical to understand and improve the system of health innovation, as well as the role of each innovative sector and the linkages between the sectors. Countries' science and technology capacities can be strengthened only if there are non-linear linkages and strong interrelations among players throughout the innovation process; these relationships generate and transfer knowledge related to commercialization of the innovative health products. The private sector is one of the main actors in healthcare innovation, contributing significantly to the development of health biotechnology via knowledge, expertise, resources and relationships to translate basic research and development into new commercial products and innovative processes. The role of the private sector has been increasingly recognized and emphasized by governments, agencies and international organizations. Many partnerships between the public and private sector have been established to leverage the potential of the private sector to produce more affordable healthcare products. Several developing countries that have been actively involved in health biotechnology are becoming the main players in this industry. The aim of this paper is to discuss the role of the private sector in health biotechnology development and to study its impact on health and economic growth through case studies in South Korea, India and Brazil. The paper also discussed the approaches by which the private sector can improve the health and economic status of the poor.

Contents

Abbreviations: AIDS, Acquired Immune Deficiency Syndrome; APEC, The Asia-Pacific Economic Cooperation; DNDi, Drugs for Neglected Diseases Initiative; DCVMN, Developing Countries Vaccine Manufacturers' Network; EMVI, European Malaria Vaccine Initiative; FIND, Foundation for Innovative New Diagnostics; FDA, Food & Drug Administration (USA); GERD, Gross Expenditure on Research and Development; GDP, Gross domestic product; HDI, Human Development Index; HHVI, Human Hookworm Vaccine Initiative; HIV, Human Immunodeficiency Virus; IAVI, International AIDS Vaccine Initiative; IDC, Innovative Developing Countries; IDRI, Infectious Disease Research Institute IP—Intellectual Property; IPM, International Partnership for Microbicides; IMF, International Monetary Fund; iOWH, Institute for One World Health; MIHR, Centre for the Management of Intellectual Property in Health Research and Development; MGDs, Millennium Development Goals; MMV, Medicines for Malaria Venture; MVI, Malaria Vaccine Initiative; NEPAD, New Partnership for Africa's Development; NIS, National Innovation System; OECD, Organization for Economic Co-operation and Development; PID, Integrated Programme on Genetics; PPP, Public Private Partnership; PPP-PDs, Public Private Partnerships for Product Development; PDPs, Product Development Partnerships; PNI, National Immunization Program; PCT, Patent Cooperation Treaty; R&D, Research and Development; S&T, Science and Technology; SME, Small to Medium Enterprise; TRIPS, Trade-Related Aspects of Intellectual Property Rights; UNICEF, United Nations Children's Fund; UNDP, United Nations Development Program; USA, United States of America; MMV, Medicines for Malaria Venture; WTO, World Trade Organization; WIPO, World Intellectual Property Organization; WHO, World Health Organization; WHO/TDR, World Health Organization/Research and Training in Tropical Diseases.

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1. Introduction

Health biotechnology is becoming one of the driving forces behind the economic development of developing countries and a vital tool for improving the efficiency and accessibility of healthcare for the poor. Several developing countries have made remarkable progress by addressing local health needs through intensive research and development and innovative health products (Jason, 2006; Mahoney and Morel, 2006; Thorsteinsdóttir et al., 2004a). For instance, Brazil, China, Cuba, Egypt, India and South Africa are considered innovative developing countries (IDC), as they have made significant gains in research capacity and outcomes by increasing the number of health products, patents and scientific publications that they produce. These developments were supported by significant government investment, as well as by the growth of the private sector, which contributes to economic growth (Jason, 2006; John, 2005; Mahoney and Morel, 2006; Morel et al., 2005a; Thorsteinsdóttir et al., 2004a).

The rapid growth of health biotechnology in developing countries is partially due to a dramatic shift in the focus of health biotechnology in industrialized countries. Previously, research focused on chronic diseases such as cardiovascular disease, diabetes mellitus, respiratory diseases and cancer. Less than 10% of health research worldwide is dedicated to diseases prevalent in developing countries (John, 2005). From 1975 to 1999, out of 1393 new biotechnology products produced in western countries, only 16 (~1%) targeted tropical diseases and tuberculosis, the main health issues in developing countries (Cheri, 2010; Jason, 2006; John, 2005; Troullier et al., 2002). Similar trends were observed in the number of US patents from IDCs from 1990 to 2003; only 10 of 105 drug, vaccine and pharmaceutical products targeted the diseases that mainly affect the poor in developing countries (Morel et al., 2005a). Essential medicines and healthcare are not available or affordable to most people in the developing world (John, 2005).

Thus, innovation in heath biotechnology can be used to meet local health needs in the developing world. The continuous development of science and technologies has made novel health products, such as new vaccines, therapeutics, and drugs available for the prevention and treatment of infectious and non-infectious diseases. Innovative diagnostics and medical devices have significantly improved the accuracy and speed with which the diseases that affect the developing world can be identified, prevented and treated (Daar et al., 2002; John, 2005; Mahoney et al., 2005; Morel et al., 2005a; Sarah et al., 2006; Daar et al., 2007).

In 2002, the top 10 health biotechnologies were identified in a study conducted by the University of Toronto with the participation of scientists from both developed and developing countries. These technologies align with the United Nations Millennium Development Goals (MDGs) by improving the health status of the poor and other economic-development indicators over the next 5–10 years (Sarah et al., 2006; Tara et al., 2004; Thorsteinsdóttir et al., 2004a). These technologies are molecular diagnostics, recombinant vaccines, vaccine and drug delivery, bioremediation, sequencing of pathogen genomes, female-controlled protection against sexually transmitted infections, bioinformatics, enriched genetically modified crops, recombinant therapeutic proteins, and combinatorial chemistry (Daar et al., 2002; Sarah et al., 2006; Tara et al., 2004).

Developing nations, however, could take better advantage of these technologies if they were widely implemented, overcoming the lack of funding and resources, shortage of scientific capacity, and inefficient policies and regulations, as well as the weak linkages between the public and private sector. This latter shortcoming is largely the result of an inadequate national innovation system (NIS) (Jean, 2004; John, 2005; Tara et al., 2004).

Innovation studies have found that a successful health-biotechnology industry requires a relatively strong health-innovation system to assess a nation's science and technology capacity (John, 2005). A country's national system of innovation (NSI) is "*a system which encompasses various institutions that contribute to the creation, diffusion, and use of new economically useful knowledge and the linkages and synergies between the institutions. These institutions not only include formal ones like firms, universities, research centers and government, but also institutions in a wider sense, such as social norms and law*" (Lundvall, 2010; Sarah et al., 2006; Tara et al., 2004; Thorsteinsdóttir et al., 2004a). A national health-innovation system consists of such dynamic networks of public and private sector, connected through nonlinear interactions and activities to generate specific knowledge and use it to produce and supply new technologies to solve health problems (John, 2005; Morel et al., 2005a).

The government has a fundamental role in health-innovation systems, as policymakers establish government agencies and encourage research institutions, universities and private companies to initiate and develop health biotechnology research programs with funding and resources (Jason, 2006; Mahoney and Morel., 2006; Thorsteinsdóttir et al., 2004a). Nevertheless, the private sector is becoming a vital player in biotech industry development in IDCs. Many scholars who study innovation systems have stated that private firms/sectors are the core of health innovation and that they are crucial for the success of IDCs (Lundvall et al., 2002; Mahoney and Morel, 2006; Morel et al., 2005a; Sarah et al., 2006; Thorsteinsdóttir et al., 2004a).

Private sectors contribute significantly to health biotechnology, using knowledge, expertise, resources and relationships to translate basic research and development into new commercial products and innovative processes (Krattiger, 2002; Sarah et al., 2006; Thorsteinsdóttir et al., 2004b; UNDP Commission on the Private Sector and Development, 2004). The contribution of private sector development was stressed in the report by the UNDP Commission on the Private Sector and Development (2004): "*The Commission believes that any approach to private sector development—and the policy and action recommendations that accompany it—should be grounded in the realization that the savings, investment and innovation that lead to development are undertaken largely by private individuals, corporations and communities. The private sector can alleviate poverty by contributing to economic growth, job creation and poor people's incomes. It can also empower poor people by providing a broad range of products and services at lower prices*". Studies have examined the relationship between economic growth and private sector investments and have demonstrated that countries with higher growth had higher private investment (UNDP Commission on the Private Sector and Development, 2004).

In developing countries, however, most of the investment in health research is sponsored by the government and carried out in public institutions, while the private sector is the largest biotechnology investor in developed countries (Krattiger, 2002; Morel et al., 2005a; UNDP Commission on the Private Sector and Development, 2004). The most recent estimate of annual research and development (R&D) investments in medical, agricultural and industrial biotechnology was US$12 billion in both the public and private sectors. Out of the total investment, approximately 60% occurs in the USA, nearly 30% in Europe and less than 10% in Japan. Only 20% of the total is invested by the public sector, with the majority coming from the private sector. Nearly 80% of the total private investment is directed to medical applications.