# Science, Technology and Innovation for Public Health in Africa

AFRICAN UNION

THE NEW PARTNERSHIP FOR AFRICA'S DEVELOPMENT

NEPAD

A Programme of the African Union

Editors: Fetson Kalua, Abolade Awotedu, Leonard Kamwanja & John Saka

# Science, Technology and Innovation for
# Public Health in Africa

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## About NEPAD Science and Technology Programme

The New Partnership for Africa's Development (NEPAD) is a socio-economic development programme of the African Union (AU) whose express objective is to stimulate Africa's development by bridging existing gaps in Infrastructure (Energy, Water and Sanitation, Transport and ICT); Agriculture and Food Security; Human Resource Development, especially Health/Education, Youth and Training, Social Affairs; Science, Technology and Innovation; Trade, Industry/Market Access and Private Sector Development; Environment/Climate Change and Tourism; Governance/Public Administration, Peace and Security; Capacity Development, and Gender Development. The implementation of these programmes is based on the AU/NEPAD principles of African leadership and the ownership of the continent's development agenda and process, as well as a commitment to good political, economic and corporate governance.

African leaders have explicitly recognized that socio-economic transformation of the continent cannot be achieved without increased investments in science, technology, and innovation. To that end, the leaders have initiated a number of concrete actions geared towards promoting the continent's scientific and technological development. The actions include the creation of the African Ministerial Council on Science and Technology (AMCOST) and its subsidiary bodies -- the NEPAD Office of Science and Technology, and the AU Commission for Human Development, Science and Technology. These institutions have collectively developed a comprehensive strategy and action plan -- Africa's Science and Technology Consolidated Plan of Action -- adopted at the second African Ministerial Conference on Science and Technology in Dakar, Senegal, in September 2005.

The main goals of Africa's Science and Technology Consolidated Plan of Action (CPA) are to strengthen Africa's capacities to develop, harness and apply science, technology, and innovation to achieve millennium development goals (MDGs), as well as mobilizing the continent's expertise and institutions to contribute to the global pool of science and technological innovations. Key to these goals is the promotion of transnational Research and Development (R&D) programmes.

## Preface and Acknowledgements

In 2006, the Bill and Melinda Gates Foundation provided NEPAD OST with a grant to undertake several studies with the objective of contributing to the building of health innovation systems in Africa. The findings of the research were ultimately discussed during an international workshop convened by NEPAD OST in Entebbe, Uganda, from 23-24th July 2007, focusing on harnessing Science, Technology and Innovation for the improvement of health in Africa. The reports were subjected to a review process by an independent team of reviewers and the accepted reports have been compiled in this monograph.

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CHAPTER 1

# Building the Case for Systems of Health Innovation in Africa

***J. Chataway, K. Chaturvedi, R. Hanlin, J. Mugwagwa, J. Smith & D.Wield***

## Abstract

Science, technology and innovation are vital to poverty alleviation and improved health. Improving immediate access to health care and existing health technologies is essential but simply importing technologies and products is not enough to create sustainable health care systems. Countries also need to build the capacities and institutions to develop their own innovations which are tailored to local needs. For innovation to meet local needs, countries need urgently to develop dynamic and integrated health innovation systems. This would enhance understanding between those in the world of healthcare and those who work in health innovation and production of pharmaceuticals, as well as promoting networking between researchers and producers with local users and consumers.

Secondly, improved innovation capacity that responds to the needs of users does not occur in isolation – it is not the product of one-off scientific inventions, heavy investment in science or one-off policies. Rather it is dependent on networks through government institutions, private companies and a wide variety of end-user groupings at national, international and sectoral levels. Finally, knowledge is not accumulated and built up in one set of institutions and transferred to another set – it results instead from the interplay between different organisations and institutions.

There is now an unparalleled opportunity both to address the issues of neglected diseases and to develop such integrated health innovation systems. Huge investments are currently being made in global health programmes which seek to improve health services and health innovation systems. The challenge for African policymakers, as we discuss in this chapter, is to adopt strategies for integrating global programmes with local and regional health innovation systems.

## Introduction

Science, technology and innovation (STI) are crucial to economic and social development. Simply importing new technologies is not a solution for building the expertise and capacity needed to put science and technology to productive use and make it work in the interests of developing country populations. The premise of this paper is that improving immediate access to health care and health technologies is essential but not sufficient for sustainable health improvement and poverty alleviation. The use, adaptation and creation of health technologies and innovation are fundamental to Africa's ability to deliver better health care to its people. One essential challenge for policymakers is to harness technologies and innovation to the needs of Africa's diverse populations. Health innovation systems perspectives can help in meeting that challenge.

Innovation systems thinking tells us that success in innovation is not a product of one-off scientific inventions, heavy investment in science or particular organisations and policies. Rather, sustained success in promoting and delivering productive innovation depends on linkages and networks running through government institutions, private companies and a wide variety of end-user groupings at national, regional and sectoral levels. Since innovation does not occur in isolation, the pattern of particular innovation systems will depend on political, economic and cultural factors. This has major implications for national policy makers and points to the importance of creating 'innovation friendly' national institutional environments.

The emphasis of innovation systems thinking is on the continuous incremental build up of innovation capacities across different actors and institutions rather than on one-off inventions. It points in the direction of a focus on building up 'absorptive capacity'[1] and learning rather than the acquisition of discrete technologies or highly specialised scientific and technical skills. The key point is that economic and social development requires improved institutional capacity in innovation so that consumer and user needs are articulated to producers and researchers who can respond. This means that there is no need for each African country to undertake all the health related production and research; rather Africa should increase its commitment to health provision by getting countries to focus not only on access to medicine but also to increase their role in research and development (R&D), production and learning in relation to user needs. This means that capacity building, training and policy formulation must be rooted in outward looking institutions and must focus on dynamic linkages and interactions that result in innovation.

There is currently an unparalleled effort by global health partnerships, the United Nations, public private partnerships and bilateral agencies to address the issues of neglected diseases and endemic health problems in Africa. The challenge is to grasp the opportunity and build functioning health systems and health innovation systems that will enable African populations to benefit from quality health products and services on a more sustainable basis.

Thus innovation systems stress the interaction between knowledge and linkages amongst

researchers and organisations. This chapter covers a more in-depth overview of the relationship between these different aspects of innovation systems. We use a wider definition than was originally conceived and one which acknowledges multiple levels of action that create connections, reinforcing and strengthening what can be termed the wider 'ecosystem'. We then discuss what such a definition means for the way a health innovation system is perceived. This builds on previous definitions of a health innovation system (Mugabe 2005; Mahoney and Morel 2006). More specifically, the definition acknowledges the need to deal with policy disconnects between social policies and industrial and innovation policies together with the way that systems develop – evolve – according their goals and needs. Thus there is no single health innovation system formula. Instead, as we discuss in Section 3, there are different dimensions around which a system is developed. To these six we add a seventh: the importance of 'system-making' initiatives or the organisational and learning capacity within and between different actors. The emphasis here is placed on the involvement of local stakeholders in order to build on and strengthen existing capacities.

In order to highlight how important these seven dimensions are, we provide examples from a number of different developing countries and cross-country networks. Each example provides a descriptive account of how different countries and networks have built up one or more of the seven determinants in ways that create different but always relevant forms of a health innovation system. We conclude the chapter with a number of policy recommendations. The result is an integrated policy making which links health with innovation system activities and ensures that relevant capacity building takes place. Second, we recommend increased recognition of innovation's cross-border activities and therefore the need to work with global health programmes.

## 1. Definition of Innovation Systems

An essential feature of thinking about innovation systems is the focus on the interaction between public and private sectors and the complex interactions and feedback mechanisms that exist between different elements of the value chain and users. Alternative strands of the analysis highlight various characteristics and different system 'boundaries'. One summary of systems perspectives is as follows:

> *"The systems of interacting private and public firms (either large or small), universities and government agencies, aiming at the production of science and technology within national borders. Interaction among those units may be technical, commercial, legal, social and financial, in as much as the goal of the interaction is the development, protection, financing or regulation of new science and technology."* (Niosi et al. 1993, p.212)

A large section of the literature on innovation studies deals with nationally bounded innovation systems (Lundvall 1992; Nelson 1993). These studies describe how national institutions

(both structures such as hospitals, government ministries, finance institutions and also rules and regulations) influence the ways in which innovation does and does not occur. Whilst national perspectives are key to policy thinking, there is clearly a problem in drawing analytical boundaries around national systems only. The boundaries which identify exact systems are clearly imprecise. Metcalfe and Ramlogan (2005) write:

> *"With increasing evidence in the literature that innovation processes are distributed across national boundaries an analytical focus on a national system seems something of a conundrum. The national perspective underlying national innovation systems has been predominantly adopted on the basis that many institutions, culture, language, common norms, technology policy, and education influencing innovation had a national character... But proponents of the approach admit that these systems are open and heterogenous and that there can be other levels (local, sectoral) at which they can be analysed..."* (Metcalfe and Ramlogan 2005).

Whilst it is vital to understand social and economic institutions in terms of national boundaries, scientific and technical knowledge works within a range of other geographical and non-geographical boundaries. Some authors emphasise the importance of systems properties, and in particular learning characteristics (Lundvall 1992; Edquist 1997) that go beyond national boundaries. So, for example, a major concern is how knowledge is transferred from domestic and international universities or companies to local organisations and institutions. Again, whilst not denying the centrality of national systems, other authors focus on sectors as the primary lens through which to examine systems (Malerba 2004; Mugabe 2005). The focus here is on how different sectors such as pharmaceuticals or engineering evolve and what sorts of institutions, organisations and linkages characterise different sectors. Yet another approach considers how innovation takes place within clusters and industries or technologies (Carlsson 1995; Kiggundu 2004; Oyelaran-Oyeyinka and Rasiah 2005).

Cutting across these different notions of non-geographically bounded systems, Metcalfe et al. (2004) talk about 'micro-innovation systems'. This concept indicates that innovation systems at the national level co-evolve with many 'micro-innovation systems' or innovation based initiatives, projects and enterprises. An example of the relevance of the concept to this chapter are global health partnerships such as the International AIDS Vaccine Initiative (IAVI) which can be thought of as micro innovation systems connecting across national and regional boundaries and assisting in some cases with the building of capabilities in relatively weak national environments. In this chapter conceptual tools are adopted from a variety of systems perspectives to look at the development of health innovation systems within national and regional contexts.

At the centre of innovation systems analysis is a concern with knowledge accumulation and how knowledge and research pertain to economic and social development which has enormous implications for policy. For example, what sort of education would a country want

for its citizens, one may ask. Some people might feel that theoretical physics is essential for a healthy intellectual environment and yet Nobel Prize winners in this field are of limited use in improving hospitals. A theoretical physicist will probably not understand how to engineer a laser machine for use in hospitals even though they may understand the principles on which such a machine should operate. Research biochemists can build an understanding of how certain chemicals change biological states, but they cannot alone design new drugs. In any innovation process a mix of skills and perspectives are required. Yet, in Africa, experiments in mixing more vocational or problem-based learning with more theoretical and academic perspectives are few and far between. Mytelka and Oyelaran Oyeyinka (2003) identify higher education institutions as one of the barriers to innovation in the African context, saying that Africa is unable to adapt to the inherited colonial pure scientific model of tertiary education to serve current innovation needs. Many national and regional initiatives have proved unsuccessful in creating flexible institutions that can respond to pressing social and economic problems.

These more conceptual issues translate into immediate and pressing realities. Health systems and health innovation policymakers need to grapple with issues of whether new initiatives should be regional, national or local. Should they be grounded in a traditional understanding of 'academic excellence' or should they be rooted in practical activities and applications of knowledge? These issues are at the heart of the challenge involved in creating 'systems' and networks that will facilitate innovation in health and other sectors. Identifying a conceptual apparatus to help construct useful institutions is key. If we cannot be precise about geography (national, regional or local) and about which 'systems' or 'models' that we can deploy, how do we use systems concepts to help in the process of creating useful institutions and networks in health innovation? It is therefore needed to distinguish between 'innovation ecologies' representing the sets of individuals, organisations and knowledge repositories in any national context and the *"'system making' connections that ensure the flow of information..."* (Metcalfe and Ramlogan 2005).

**Table 1: (National) Health Innovation Systems**

| | MACRO LEVEL SYSTEM | SECTORAL LEVEL SYSTEM | MICRO LEVEL SYSTEM | |
|---|---|---|---|---|
| **Defined as:** | National Innovation System | Sectoral / Cluster / Technological Innovation System | Micro Innovation System | |
| **ACTORS / ACTANTS** | World Trade Organisation (WTO) Trade Related Intellectual Property Rights (TRIPs) framework | Institutions, rules and norms of National Health Systems | Individual firms and organisations working in health research, care, financing and delivery | **SYSTEM MAKING CONNECTIONS** |
| | National government policy on innovation | Health and health innovation policies | Initiatives around the production of e.g. ARVs | |

## 2. Health Innovation Systems

'Health innovation system' is an overarching term that includes relevant aspects of the macro environment of institutions, pertinent rules and procedures within a national system of innovation, the activities of health institutions within a national health system and the micro level innovation activities of individual companies and organisations involved in the health care value chain including production, delivery, financing and research.

The report of the Millennium Project Task Force on Science and Technology Indicators highlights the importance of technology and innovation to health:

> *"A broad number of health interventions require the development of new treatments and vaccines through improved science (e.g. anti-malarials, HIV treatments and prevention, drug-resistant tuberculosis, vitamin and other micro-nutrient deficiencies in children and mothers, etc). In addition, the production of generic medicines holds the promise of improving the poor's access to essential medicines. A particularly important contribution of science and technology in this area lies in improved monitoring systems for pharmaceutical quality."* (2005:36)

The report also considers that the challenge of improved technology and innovation lies in the capacity of policymakers to tackle issues systemically, building innovation systems that facilitate, promote and respond to developments. A special *Nature Biotechnology* supplement in 2004 made a powerful case for building up health innovation systems in developing countries as part of the effort to develop innovation appropriate to the needs of the world's poor (Thorsteinsdottir et al. 2004). Developing innovation and manufacturing capacity in Brazil, India, Cuba, South Africa, South Korea and China, for instance, has led to significantly increased research and product development for diseases afflicting countries in Latin America, Asia and Africa.

In thinking about health innovation systems, an analytical and policy focus is required that is informed by the more general 'systems' framework set out in the previous section. The way that national innovation systems impact on health care and innovation needs consideration. A wide range of institutions that impact on health will have varying relevance in different national contexts: educational and policy infrastructure, intellectual property frameworks, financial facilities, social welfare and insurance provision, broad economic policy etc. We need to consider sectoral institutions such as hospitals and drug distribution networks because without the basic health systems, the effectiveness of any other interventions including global health partnerships will be limited. The whole value chain associated with health provision is thus extremely complex, including science labs, many highly industrialised, to health services, over the counter and private providers of all kinds, including top hospitals where much incremental innovation takes place.

Figure 1 outlines the different elements of a health innovation system that influence the rate and direction of change and which are influenced by the numerous 'micro systems' in development at any one time. The linkages between users and producers of health care should be considered. For example, policy changes relating to financial restructuring or intellectual property (IP) rights management might have profound impacts on people's access to medicines and also on domestic capacities. One important aspect of systemic perspectives is the attention paid to mismatches and gaps and the potentially contradictory effects of policies. For example what is good for domestic industrial policy (such as the promotion of domestic pharmaceutical industry) does not always match with health policy which emphasises access to medicines via generics available from elsewhere in the world (Kaplan and Laing 2005).

This highlights the fact that in policy terms there is a worrying, endemic gap between social policies on the one hand and industrial and innovation policies on the other. Dealing with such disconnects[2] is vital. Development and the eradication of mass poverty and disease requires a massive increase in productive capabilities and production in developing countries. Some countries, notably in Asia, are achieving this. Yet 'pro-poor' aid policies, especially for the least developed countries, focus strongly on social sector distributional mechanisms and operate almost entirely without reference to policy thinking on promoting innovation and productivity. Conversely, researchers on innovation and industrial policies tend to know little about the potential for social protection to support innovation and productivity improvement. Thus, there tends to be a profound lack of understanding between those who research and make policy in the world of health care and provision of health services and goods and those whose interest is in health innovation and production of pharmaceuticals. Several authors have begun to tackle this divide (Gore 2007; Mackintosh et al. 2007; Mkandawire 2007).

If health innovation systems that directly serve the needs of local populations are to be created this gap needs bridging. Industrial and innovation policies designed to increase productive capacity need aligning with social and health policy designed to address distribution. Social policy can in turn enhance innovative capacities. Mkandawire (2007) and Gore (2007) from UNCTAD urge policymakers to adopt policy frameworks which view social policy and distributive mechanisms as development opportunities.

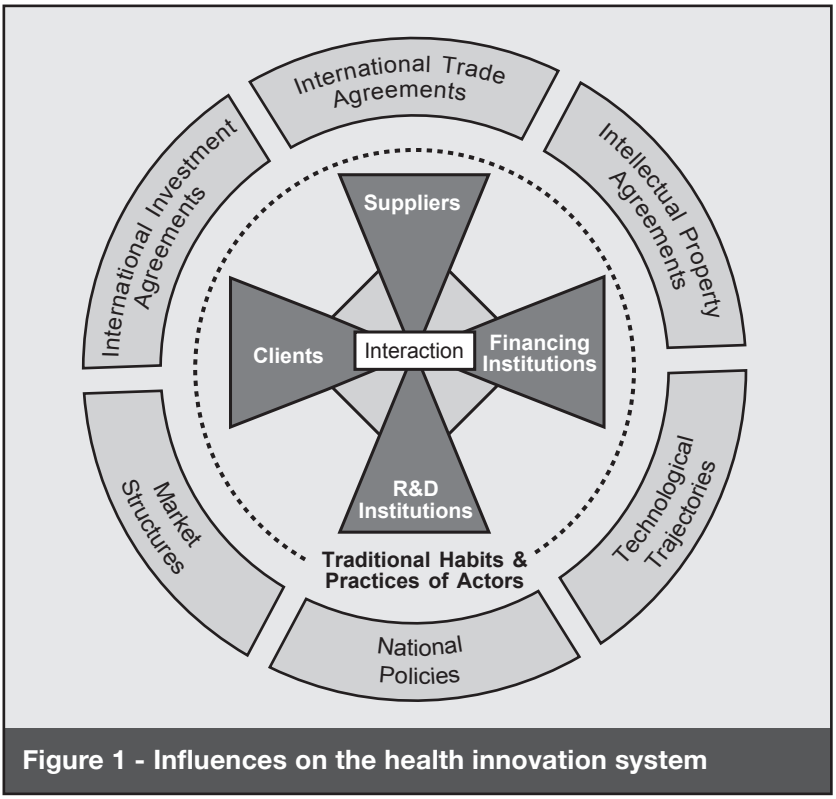


**Figure 1 - Influences on the health innovation system**

*Source: Mytelka (2007)*

Mackintosh and Tibandebage (2007) considered care markets and providers in Tanzania and concluded that informalisation and market liberalisation had created incentives for perverse provider behaviour; associated with heavy reliance on private providers this was inhibiting innovation and efficient and effective provision of health care. The market incentives encouraged rather than discouraged poor quality provision and illegal activities. The authors point out that while there are now high demands for investment in health systems and innovation systems, policy in the Tanzanian and other contexts undermine system capabilities.

> *"Active support for health system integration and organisational sustainability and probity is essential for poverty-focused care and innovation, and will require major investment and deliberate structural change after many years of deregulation and fee-based finance. Policy should aim to constrain perverse market dynamics and move towards system integration"* (Mackintosh and Tibandebage 2007:23)

Thus, thinking about health innovation systems requires some revision of the traditional demarcations between production and provision in creative ways. This view is endorsed

by both NEPAD's health and science and technology (S&T) strategies. Mugabe (2005) says:

> *"The notion of a health innovation systems, is… more than just the sum of the R&D institutions, health care organisations and medical scientists and practitioners, but includes also the policy regime that determines how well there are mutual interactions among various actors. It is a system with changing actors, connections and interactions."*

The main features of health innovation systems in Africa is now briefly discussed.

## 3. Health Innovation Systems in Africa

The NEPAD health strategy paints a daunting picture of the situation in Africa.

> *"The HIV/AIDS epidemic poses an unprecedented challenge for Africa, reversing the gains made in life expectancy over the past half a century. Life expectancy in the most severely affected countries has been reduced by almost a third, from 60 years to 43 years. About 2.4 million people died from AIDS in 2002 and around 3.5 million infections occurred… 1 million deaths [are] caused by malaria each year and 600,000 deaths caused by tuberculosis. Malaria has slowed economic growth by 1.3% per annum at a $12 billion economic cost. Countries have a tuberculosis burden exceeding the 300 per 100,000 population benchmark for severe disease, with 1.6 million new active cases occurring annually. Sleeping sickness is resurging, affecting between 300,000 and 500,000 people annually."* (NEPAD 2003)

These challenges, to different degrees, impact on all African countries, which have extremely diverse health systems and innovation capacities differ greatly. However, health systems in many contexts are impoverished and fragmented because there are very low capacities to undertake scientific and technological development relevant to local diseases and local needs.

### 3.1 Dimensions of Health Innovation Systems

Six major areas influence innovation systems in different countries: R&D; manufacturing; domestic markets; international markets; IP and regulation. It is critical to build capacities in each of these areas in systematic ways that help to link healthcare delivery issues and concerns with innovation policies and issues so that both might meet local needs for new approaches and initiatives. This section provides a schematic overview of the existing state of affairs in each of these six areas and then points towards some of the new approaches that are being developed and how systemic approaches can be built when attention is given to these six determinants.

### 3.1.1 R&D

Determining scientific capacity and levels of research and development is not straightforward. A 2001 Rand report provided an assessment of scientific capacity and indicators of levels of R&D in developing countries based not only on the usual patent and citation data. Rather the report attempted a more sophisticated and accurate measurement based on a comprehensive index of capabilities. These included: the per capita gross national product (GNP) as proxy for general infrastructure; the number of scientists and engineers per million people to capture the human resources available for S&T activities; the number of S&T journal articles and patents produced by citizens of that nation to characterise scientific outputs; the percentage of GNP spent on R&D to measure the society's level of input into S&T; the number of universities and research institutions in the nation per million people to characterise the infrastructure for S&T; a measure of the number of the nation's students studying in the United States adjusted for those who chose not to return home at the conclusion of their studies to characterise the country's contact with external knowledge sources; and the number of patents filed through the U.S. Patent and Trademark Office and the European Patent Office (Wagner et al. 2001).

Countries were categorised into four groups. There are no African countries listed in the 22 countries that made up the 'Scientifically advanced countries' group. Only four countries in Africa are grouped as having built, or as being in the process of building, their scientific capability; South Africa was placed in the 'Scientifically proficient group' while Egypt, Benin and Mauritius where seen as 'Scientifically developing countries' (Wagner et al. 2001).

Mugabe (2005) notes that only a few developing countries possess the necessary capability to engage in scientific research and in the development of medicines or manufacture of pharmaceuticals: "in Africa it is South Africa, Egypt and Kenya that possess capability to conduct drugs research" (Mugabe 2005:7). Nevertheless as Mugabe points out and as other sections in this chapter will show, there are R&D initiatives taking root in Africa and there is a base to build upon.

### 3.1.2 Manufacturing

Industrial competitiveness in much of Africa is poor. Manufacturing value added per capita is not only lower than most developing country regions of the world, but contrary to global trends, it is not growing. Table 2 shows this.

Mugabe (2005) notes that in Africa, only South Africa and Egypt have local companies engaged in some pharmaceutical manufacturing activities. Algeria had reported capability to produce pharmaceutical products such as oral liquids, tablets, capsules and ointments. This potential has not yet translated into capacity because of the absence of a strong industrial production base.

In an overall assessment of constraints on health innovation capabilities in Africa, Mugabe notes the following as important factors: lack of any policy focus on health R&D; low levels of investment in R&D in health with most developing countries spending less that 0.5% of their GDP on health R&D and weak links between public health R&D institutions and private industry (Mugabe 2003:9).

**Table 2: Manufacturing values**

| | ***Manufacturing value added per capita*** *(in US$ adjusted to 1995 values)* | |
|---|---|---|
| | **1990** | **2002** |
| Industrialised economies | 5,161 | 5,839 |
| Transition economies | 863 | 596 |
| Developing economies | 221 | 356 |
| East and South-East Asia | 247 | 576 |
| South Asia | 48 | 75 |
| Latin America and the Caribbean | 670 | 674 |
| Middle East and North Africa | 273 | 365 |
| Sub-Saharan Africa | 99 | 89 |
| Excluding South Africa | 33 | 33 |

*Source: Pietrobelli (2006)*

### *3.1.3 Domestic Markets*

Markets in Africa are dominated by both public and private institutions, involving both state dominated provision of goods and services and increasingly also involving the private sector operating on the basis of commercial rules. The large scale of private funding and provision of healthcare in Africa also involves an important role for non-governmental providers (Bloom 2004; Bennett et al. 2005). Markets also include actors like Non-governmental Organisations (NGOs), donors and multilaterals.

On a global scale the Africa market is very small. In pharmaceuticals the global market is worth over $406 billion, 77% of which is in the US, Europe and Japan. Only 1% of total spending occurs in Africa, which accounts for 25% of the disease burden in the world (Scheffler and Pathania 2005). There is little large-scale regional production of pharmaceuticals in Africa due to a lack of capacity and expertise to produce not only the drugs needed but also vaccines and diagnostics. These figures lead to the coining of the phrase 10/90 gap to illustrate how only 10% of all health research and development is spent on issues affecting 90% of the world's population. What spending there is in Africa on health related R&D is increasingly funded by public sector institutions and through new organisational forms called

'public-private partnerships' (Moran 2005). This is because the private sector pharmaceutical companies find it too costly and risky to invest in development of drugs for diseases affecting those in the developing world, so-called 'neglected diseases', where demand is high but ability to purchase drugs is low (Trouiller et al. 2002).

A wide diversity of policies exists to encourage positive private sector engagement in African health. Policies include: promotion of private corporate investment in African health systems, as in the 2006 International Finance Corporation initiative; support and regulation initiatives to change small providers' behaviour, such as the Tanzanian Food and Drugs Authority initiative to train staff, accredit and locally monitor a network of rural drug shops; and numerous small scale insurance initiatives. Mackintosh and Tibandebage (2007) however note that although all of these schemes depend on good market information, the "field research-based and analytical literature on the operation of the private health sector in developing countries remains thin". They go on to talk about two negative features of the way liberalised markets operate drawing also on a broader cross-country study of health care commercialisation (Mackintosh and Koivusalo 2005). There has been an increase, firstly, in the money spent on out of pocket payments for health care and secondly, related to this healthcare has increasingly undergone 'informalisation' where to varying degrees there is a "lack of enforcement" of regulations and quality (ibid.).

What Mackintosh and Tibandebage highlight is the need to think through the implications of sets of policy that cover access to medicines with those that promote production of medicines. Clearly, you need innovation in delivery systems at low income levels, as well as technological innovation. If access policies are serving people poorly, it is impossible to get new technological developments and innovations to those people. Where scientific and technological innovations could contribute enormously to testing and quality supervision, 'informalisation' of systems may hinder efforts to put technology to use. There is a need to consider factors influencing both supply and demand within healthcare.

### *3.1.4 International Markets*

International markets in generic drugs are of vital importance to Africa. For example with the bulk of HIV/AIDS infection in African countries, the production of cheap anti-retroviral (ARVs) drugs is vital. The production of generic or non-patented drugs for controlling HIV/AIDS by Indian companies has reduced the cost of these antiretroviral drugs by 97% (Henry and Lexchin 2002) making them more affordable for HIV positive populations in African countries. The cheapest regimen, a fixed dose combination of stavudine, lamivudine, and nevirapine, decreased in price from US$350 annually in 2001 to $168 in 2004, and was selling at between $132 and $148 in 2005/6. The price of combinations of zidovudine-lamivudine and efavirenz decreased more slowly and is currently around $400. Second-line drugs remain even more expensive, with an average price of $900 in least developed countries and $1600 in middle-income countries in 2005 (Schwartländer et al. 2006).

The production of generic ARVs made in Africa is small – limited to Kenya and South Africa with Tanzania starting in 2006. The wider branded drug market is also small. A number of countries (particularly, South Africa, Kenya and Nigeria) have local production capacity and some international pharmaceutical companies have licensing agreements with African companies to produce their products in Africa. However, local drug markets are dominated by imported drugs from India.

Although African pharmaceutical companies are expanding and partnering with larger international firms, there are still numerous access issues. The factors impacting international and Northern based pharmaceutical companies' activity in producing essential medicines for African countries also affects companies in Africa e.g. price, quality assurance and IP rights. As such pharmaceutical companies in Africa may follow in the footsteps of their Northern hemisphere and Indian colleagues and increase production of drugs where they can make a profit and which respond to the changing epidemiological transition away from 'diseases of poverty' to more lucrative products targeting heart disease and obesity or as South Africa is doing and move into 'health tourism'. Particularly of note is the fact that IP agreements inhibit sales. As the ongoing disputes over IP and HIV/AIDS drugs show, there is a struggle over Africa's access to IP protected drugs definitions of what constitutes national emergencies and when compulsory licensing might be called for and so on.

### *3.1.5 Regulatory Capacity in Africa*

Regulation is fundamental to the provision of good quality pharmaceuticals and healthcare. Failure to regulate and monitor presents obstacles both in contexts where new treatments and drugs are being developed and in ensuring consumers' rights. Building capacity in regulatory and monitoring mechanisms is fundamentally important as African countries attempt to supply appropriate treatments to its people. Most countries in Africa have a drug regulatory authority as Table 3 shows.

The World Health Organisation (WHO) is concerned that while all countries in Africa have national drug regulatory agencies, the majority of them have limited capacity (SAIIA 2005). For example, Dr Jean-Marie Prapsida of the WHO Regional Office for Africa noted that even the South African Medicines Control Council, touted as the reference point for other African agencies, still has limited capacity, especially for monitoring and evaluating clinical trials. Limited capacity has resulted in countries being unable to enforce proper drug regulations, putting at risk the health of millions from improper drug use, all this happening in the backdrop of mounting complexities from killer diseases such as malaria, tuberculosis and HIV/AIDS. Additionally, some multinational corporations conducting clinical trials in Africa have bemoaned the weak drug regulatory capacity in Africa, with Boehringer Ingelheim, for example, failing to register its single-dose nevirapine in the USA after some clinical trials in Uganda. Some irregularities with data recording and improper reporting were highlighted, and the company had to withdraw its registration application (SAIIA 2005).

The WHO notes that part of the solution to these challenges lies in strengthening medical control councils and regulatory bodies to enable them to offer adequate support and to monitor trials effectively. In 2003, the WHO started a programme to assess the weaknesses of drug regulatory agencies in Africa in order to come up with the best measures for assisting them. The WHO also offers on-going capacity building through universities, especially aimed at human resource-capacity building, but they have no direct authority, as according to Tim Farley of the WHO, they 'do not want to undermine the work that goes on at national level'. The WHO also provides the latest available information to countries to assist them in their decision-making processes. In their programme on Strengthening Drug Regulatory Authorities (DRAs)[3], the WHO provides the following: assessment of National Regulatory Systems; Practical manuals; Training Courses, Model websites for DRAs; Model system for computer-aided drug registration; Certification scheme for the quality of drugs moving on the international market and; the biennial WHO international conference for drug regulatory authorities. For example, Kenya (www.pharmacyboardkenya.org), Tanzania (www.tfda.or.tz), Uganda (www.health.go.ug/national_drug) and Ethiopia (www.daca.gov.et) have benefited immensely from the activity on developing model websites for drug regulatory agencies. The available capacity in each country also determines to what extent they can tap into and benefit from these initiatives.

**Table 3: African Drug Regulatory Authorities**

| Country | DRA |
|---|---|
| Angola | National Medicines Directorate |
| Benin | Direction Des Pharmacies |
| Botswana | Drug Advisory Board / Drug Regulatory Unit |
| Burkina Faso | Directorate of Pharmacy and Medicine |
| Cameroon | Pharmacy & Medicines Department, Pharmacy & Drug Directorate |
| Central African Republic | Inspecteur des Services Pharmaceutiques |
| Congo | Direction des Service Sanitaires |
| Cote d'Ivoire | Directorate of Pharmacy and Medicine |
| Djibouti | Ministry of Health |
| Egypt | Drug Policy & Planning Centre |
| Equatorial Guinea | Aprovisionamiento de Medicamentos |
| Eritrea | Medicines Control & Regulatory Services |
| Ethiopia | Drug Administration & Control Authority |
| Gambia | Medicines Board |
| Ghana | Food and Drugs Board; Pharmacy Council of Ghana |
| Guinea | Direction Nationale de la Pharmacie et du la Laboratoire |

| Country | DRA |
|---|---|
| Kenya | Pharmacy Board Kenya |
| Lesotho | Medicines Control Authority |
| Liberia | Pharmacy Board of Liberia |
| Libya | Drug Regulatory Authority |
| Madagascar | Agence du Medicament |
| Malawi | Pharmacy, Medicines & Poisons Board |
| Mali | Direction Pharmacie et Medicament |
| Mauritius | Pharmacy & Drug Regulation Dept, Ministry of Health |
| Morocco | National Laboratory for Drug Control |
| Mozambique | Pharmaceutical Dept, Ministry of Health |
| Namibia | Drug Control Unit, Ministry of Health |
| Niger | Direction Générale de la Pharmacie |
| Nigeria | National Agency for Food & Drug Administration and Control |
| Papua New Guinea | Medical Supplies Branch, Ministry of Health |
| Rwanda | Pharmacy Services, Ministry of Health |
| Senegal | Direction de la Pharmacie et des Laboratoires |
| Sierra Leone | Pharmacy Board of Sierra Leone |
| Somalia | Ministry of Health |
| South Africa | Medicines Control Council |
| Sudan | General Directorate of Pharmacy |
| Swaziland | Pharmacy Services, Ministry of Health |
| Tanzania | Pharmacy Board Tanzania Food & Drug Administration |
| Togo | Direction Generale de la Sante Publique |
| Tunisia | Directorate of Pharmacy & Medicine |
| Uganda | National Drug Authority |
| Zimbabwe | Medicines Control Authority |

*Source: Table generated from data in proceedings of the WHO International Conference for Drug Regulatory Authorities (1996, 1999, 2002 and 2004)*

Thus, the WHO provides extensive advice on how regulatory authorities should be constructed, making it clear that it is national Ministries of Health who are charged with formulating and implementing regulatory provision.

However, the requirements for drug regulation as set by the WHO are not being met by many African countries. The problem relates to inadequate human, financial and infrastructural resources. This scenario makes it difficult for the drug regulatory authorities to cope with

demand especially in light of increasing pressures of technological developments which mean that new products are being placed on the market at an increasing rate. The challenge to ensure quality, safety and efficacy is not one that most African regulatory authorities are meeting effectively. Recent studies have highlighted the importance of regulation in health innovation and have differentiated between regulatory approaches that constrain on the one hand and enable innovation on the other (Tait et al. 2005; Chataway et al. 2006).

## 3.2 From Separate Determinants to Building Integrated African 'Health Innovation Systems'

Systems of innovation frameworks revolve around the importance of collaborative networking between actors/actants at different levels of innovative activity and learning capabilities. Linked to this are the 'system making' connection components or the purposeful activity around the six determinants outlined above that create linkages between the actors within the health innovation system. We now examine a case example of Niprisan (NICOSAN™) to highlight the interplay of these six determinants with the different actors within a health innovation system. It also demonstrates that productive 'system-making' initiatives are possible even in difficult circumstances and that the challenge is to maximise the potential of these successes.

### *3.2.1 Niprisan for Sickle Cell Anemia*

Sickle Cell Disease (SCD) is an inherited blood disorder caused by an abnormality in the hemoglobin molecule. The disease changes the shape of red blood cells carrying oxygen through the body resulting in pain and anemia. Those with the disease suffer a higher than average frequency of illness and premature death, especially in infancy.

Nigeria probably has the highest sickle cell disease population in the world (four to six million, roughly three to five percent of the population). More than 100,000 Nigerian children are born each year with the ailment. As a result, since the early 1990s, SCD topped the list of priority research projects of Nigeria's National Institute for Pharmaceutical Research and Development (NIPRD). In 1993 NIPRD established collaboration (contractual agreement) with a traditional health practitioner and commissioned a clinical study (1993-2001) using plant abstracts. From the findings of the study, 'Niprisan' was developed by NIPRD.

Niprisan is a drug cocktail, with phyto-pharmaceutical composition of four traditional plants extracted in a proprietary process. It has been patented in 46 countries and is jointly owned by NIPRD and the traditional health practitioner. The funds for patenting and conducting R&D of the drug were provided by the UNDP. In July 2002, Niprisan was licensed to XECHEM Inc., an Indian pharmaceutical company based in the USA, by the Nigerian Federal Ministry of Health. Xechem Nig. Ltd (a subsidiary of Xechem Inc.) commenced local production of Niprisan in 2003. Further pharmacological studies have resulted in standardization of Niprisan into capsule dosage form. In this new form, the drug has been approved, under

the name NICOSAN™/Hemoxin, by Nigerian drug regulators, the National Agency for Food and Drug Administration and Control and launched in Nigeria for sale on July 6th, 2006. Nicosan/Hemoxin has received orphan drug status from the US Food and Drug Administration (2003) and by its European equivalent (2005).

Despite recent setbacks[4], the journey of Niprisan, from plant extract to medicine in capsule dosage form, and from a traditional health practitioner in Nigeria to global markets demonstrates success in developing a range of systems-building capabilities. This example of a micro level innovation system has addressed a number of the six determinants: ensuring R&D and manufacturing capabilities are in place; developing markets for the product and; dealing with IP issues. Nigerian institutions have effectively used the intellectual property system to leverage financial and social benefits from the country's natural resources. National R&D expertise customized to address a specific domestic problem has also lead to some global success. Technology transfer links have been made with national public research institutions in the process of the production of Niprisan in Nigeria by Xechem creating a potential income stream in the form of royalties and other revenue flowing from the agreement with Xechem as well as building local R&D infrastructure.

Systems-making connections have been made between NIPRD, traditional health practitioners, local community members (during trial activities), UNDP which provided a sizeable grant, hospitals and clinicians, patent agents who facilitated the patenting of the product in multiple markets, and a private firm.

While it offers potential as a case to learn from and build on, it has been argued (Oyelaran-Oyeyinka and Sampath 2007) that many public research institutions like NIPRD still suffer from poor funding and subsequent lack of facilities for biotechnology-based research as well as weak institutional mechanisms. For example, until recently, the Nigerian government showed little interest in funding R&D providing only 10% of NIPRD's research funds. Many public research institutions suffer from weak institutional and regulatory infrastructure to conduct meaningful partnerships with, for example, holders of traditional medicinal knowledge or to test for efficacy and safety of traditional preparations. Similarly, at times, there is still weak private sector interest in drug development and few spin-off companies created from public research institutions.

### 3.3 The Missing Determinant: Organizational Capacity?

The Niprisan case study highlights a need to look beyond the market. It illustrates the need to focus on building and maintaining organizational and learning capacity within and between the different actors. International partnerships afford opportunities for this but maximum impact requires that national and regional institutions are built and improved. Several large international networks (in which African countries participate) place emphasis on building capacity within health innovation systems, albeit in different ways. For example, networks such as IAVI, Medicines for Malaria Venture (MMV), Drugs for Neglected Diseases initiative

(DNDi) and the South African AIDS Vaccine Initiative (SAAVI) are involved in the production and clinical testing of new drugs and vaccines for diseases affecting African countries. The R&D capacity in many African countries is, at present, insufficient to perform such studies. Thus one pressing challenge for both government and private sectors is to construct funding and institutional mechanisms that effectively facilitate enhancing capacity. Activities that focus on creating local capacities would involve building physical capacity, training staff, developing lab-infrastructure, improving microbiological and immuno-diagnostics, promoting good clinical practice and ethics infrastructure, and will involve north-south as well as south-south capacity building activities.

For example, SAAVI is a national level public private partnership (PPP) that was set up in 2000 to develop an effective and affordable HIV vaccine for Southern Africa and the surrounding region. The partnership is made up of the South African government, public sector research organisations, private sector companies and financiers. SAAVI has worked on more than just developing a vaccine. With an emphasis on collaboration and strengthening knowledge capacities, SAAVI has built scientific research capacities in skills, knowledge and products in the laboratories, academia and in clinical trials. It has also built stronger health systems mainly through its trial sites operations by creating advanced infrastructure, facilities and trained staff. A combination of capacity building and collaboration between different sectors has produced important knowledge flows between disparate and discrete sectors. These flows occur within and across S&T, policy, community and health actors.

Another interesting project from a systemic capacity building viewpoint is the Tanzanian Essential Health Interventions Project (TEHIP). The project essentially aims to link S&T and other forms of capacity building into broader health systems through the creation of computer based data collection and analysis of burden of disease statistics to aid policy making at the district level. TEHIP demonstrates the importance of integrating research and capacity building and of working in an interdisciplinary fashion that brings together varied skills (social, scientific, economic) together with management knowledge.

A recent initiative that promotes south-south linkages for capacity building is the African Poverty Related Infection Oriented Research Initiative (APRIORI). APRIORI aims at establishing a state-of-the art clinical research centre in Tanzania by involving African Centres of Excellence in Mali and Ethiopia with assistance from a number of Northern based institutions. Strengthening south-south collaboration, the programme aims to build capacities and establishments for malaria, tuberculosis and HIV/AIDS. Streamlining of activities on these three diseases to obtain internal cohesion, collaboration and cross-fertilisation, the programme aims to utilize existing knowledge and innovative research (new tools and strategies). The strong links between centres of excellence from Africa (through south-south initiatives) and Europe (through north-south initiatives) which merges into research and capacity building besides facilitating knowledge flows is very innovative.

The Global Health Research Initiative - HIV/AIDS Prevention Trials Capacity Building grant recently instituted also aims to build capacity in African institutions to conduct HIV/AIDS prevention trials by supporting the development of both new and existing partnerships between African and Canadian research teams. The focus of the grants is to build and enhance individual and institutional competencies required to conduct high quality research, and to build site capacity to conduct planned and anticipated trials in Africa, in particular related to research on, and development of, prophylactic vaccines, microbicides and other preventive interventions. The programme has the specific objective to promote and support partnerships between interdisciplinary teams of Canadian and African researchers. Grants under this initiative are intended to be complementary to other global investments (e.g. Gates Foundation, National Institutes of Health and European Union initiatives) and therefore will not fund prevention trials themselves, but rather capacity building related to conducting such trials.

As these cases illustrate, there is no just one model for building capacities but rather a diversity of approaches that can be pursued. These approaches point to the importance of local stakeholder involvement. International efforts are important but they cannot substitute for local efforts and, in this context, local capacity building is a serious concern. The key issues that need to be addressed to develop successful and meaningful capacity-building programs include: understanding the local context and facilitating local operations; strategising a mix of short-, medium-, and long-term interventions; and thinking and encouraging the development of systems of innovation. Local strengths must be built on, and efforts must be tightly related to, local problems and infrastructure. But building on existing capabilities in local contexts involves a range of time scales and time-bound planning (short-medium-long term) that progresses and builds the local innovation capacities (skills, capabilities, and institutional infrastructure) in a systematic way.

It is evident from the literature that Africa has made progress in S&T. Many countries have shown positive action by creating ministries for S&T, and these ministries have produced policies for implementation. However, in many cases such policies are not integrated with other sectoral policies, and therefore, involve separate strategies that have no link to national (health) development. Also many of these actions are still designed or greatly influenced by international financial institutions and donor countries and they are not always appropriate in the local context. Lack of functioning institutions is one of the main factors restraining Africa's technological development.

## 4. Learning from Others

A number of developing countries, notably Brazil, China, Cuba, India and South Africa, have advanced in health innovation, following different paths to create selective capacities and capabilities in the pharmaceutical and health sectors. They have created a number of ‘system making’ connections linking the institutions and individuals working within the

macro, sectoral and micro levels of innovative activity. By so doing they have addressed the seven determinants as needed to overcome specific obstacles to innovation. The initiatives taken by these countries show some homogeneity such as building of education and health systems, investing and creating large reservoirs of specialised scientific skills within health sectors, long term planning of R&D activities; and creating research networks within the country. They are not meant to be uncritically followed. Indeed, their relatively high resource levels for developing countries make that impossible. Our case studies and analysis of some of the system making connections and capacities below provides better understanding of the successes and failures of these countries and from which valuable insights can be learnt.

### 4.1 Brazil

Brazil has invested in health related biotechnology since the early 1970s and has emphasized the importance of health research since 1900 with the establishment of a federal institute, the Oswaldo Cruz Foundation (known as Fiocruz). In the 1970s the government's National Research Council launched two biotech programmes which were followed in the 1980s by the National Biotechnology Programme that integrated all those working on biotechnology in a programme dedicated to capacity building. The result is a strong public sector dominated biotechnology and health research base, predominantly based out of the main universities of San Paulo, Rio de Janeiro and the Federal University of Minas Gerais. The dominant independent public research institutes are Fiocruz and the Institute Butantan based in San Paulo (Ferrer et al. 2002).

Private sector investment in health research and particularly biotechnology has risen rapidly since the 1990s. During the 1990s the number of biotechnology firms in Brazil increased more than four-fold from 76 firms in 1993 to over 350 in 2001 (ibid.). However, although Brazil has a large pharmaceutical market as well as a growing private biotechnology sector, interaction between these and the public sector has only recently been encouraged with the passing of an Innovation Law (see Box 1). This reversed a previous law that made illegal public sector researcher employment by industry firms.

**Box 1 - The Brazilian Innovation Law**

Following consultation the Brazilian Innovation Law was introduced in October 2005. The law reverses a situation that made illegal public sector research staff employment by private sector firms thus incentivising partnerships between public and private research institutes. The law also aims to encourage participation of public sector research institutes within the innovation process more generally, as well as innovation between private companies particularly through intellectual property rights and licensing agreements. For example, the Innovation Law created the opportunity for product development, as with

Acheflan, an anti-inflamatory cream developed by a private sector Brazilian drug company, Ache, through collaboration with a university research base. Acheflan was Ache's first patent-protected bio-medical innovative product. Ache has gone on to develop other partnerships with Brazilian universities.

*Sources: Ryan (2006); www.scidev.net; www.wipo.net*

One strength of Brazil's strong public sector health research based around universities and other academic institutes is strong human resource capacity. Fiocruz creates not only a large number of highly trained personnel with skills to produce world-class innovation but also accumulates scientific knowledge and absorptive capacity that strengthens and builds the Brazilian innovation system. However, the lack until recently of opportunities for knowledge exchange between the public and private sectors limited the degree to which knowledge exchange took place. Although the introduction in 1994 of National Conferences on STI in Health created national dialogue on the issue, bringing together not only the Ministries of Health, Education and Science and Technology but also involving representatives from research institutes and the general public. These Conferences have been used to set the agenda for research around health related STI in Brazil and the base for which government funds and calls for research proposals are based.

The STI Conferences and the new Innovation Law exemplify the importance of links between different actors within the Brazilian health innovation system, providing a good example of the creation of links between the welfare system and the innovation system (da Motta et al. 2001). Brazil appears to have recognised that the health innovation system is not simply made up of those organizations, institutions, rule and norms influencing the purely scientific innovative process of R&D and product development. It emphasizes the importance of a systemic approach that works to build systems making connections at every, and between, all levels of the innovative process.

Brazil's commitment to health innovation and provision of health services to its population has enabled it to play a policy role internationally. Along with India, South Africa and others, Brazil has argued strongly on behalf of developing countries in the context of WTO discussions. Brazil is a leading member of south-south networks dedicated to producing and distributing better products and treatments for neglected diseases. These include the South to South HIV/AIDS Technological Cooperation Network and the (India, Brazil, South Africa) IBSA dialogue forum which considers issues of trade and intellectual property.

## 4.2 Cuba

Particularly since the 1985 publication of 'Good Health at Low Cost' by The Rockefeller Foundation, Cuba's health system has been championed for its cost-effective performance. Part of its success is due to the building up and integration of its health research sector

into the healthcare system, particularly in the area of biotechnology. In the last two and a half decades, Cuba developed significant national capacity in biotechnological knowledge and infrastructure. In focusing on developing national research capacity with Cuban scientists and professionals, the first priority of biotech research is the domestic market, meaning that the Cuban people themselves directly benefit from the country's medico-scientific expertise. This concern with the well being of the local population goes hand in hand with developing new medical products for export. For example, in the early 1980s, Cuban R&D programmes led to the first and only vaccine for a particular strain of meningitis which was used to stem a local outbreak in the mid 1980s. Further research into meningitis vaccines resulted in Cuba becoming in the 1990s the first country to develop and market a vaccine for meningitis B. It is currently delivered to 30 countries, including China, India, Russia, Pakistan and many Latin American countries (Thorsteinsdottir et al. 2004). More recently, Cuba produced the world's first human vaccine with a synthetic antigen that protects against *Haemophilus influenzae* type B infection, which often leads to pneumonia and meningitis in children under the age of five.

New biotechnologies were expected to facilitate product diversification and import substitution at a time when the collapse of the Soviet Union and the U.S. trade embargo forced it to develop home-grown solutions to local health problems. The development of a national capacity of biotechnology was also seen as a strategy to increase sovereignty and independence from transnational companies of the industrialized countries. This is not to say that Cuba has not collaborated with international companies. One of Cuba's premier research centres, the Carlos Finlay Institute collaborates with GlaxoSmithKline (GSK) to develop and distribute the meningitis B vaccine. Future examples of such efforts could encompass the development and dissemination of vaccines for AIDS, cholera, dengue and other diseases. Researchers at Cuba's Center for Genetic Engineering and Biotechnology (CIGB) and the Finlay Institute are making substantial progress in these and other areas. New partnerships with Latin American and other countries including China and industrialized countries mean that Cuba is at the forefront of developing drugs for international users and markets.

The Finlay Institute (see Box 2) is an example of how Cuba's development model is based on harnessing the nation's wealth in human resources and science to create a knowledge-based economy focused around health. Since the 1959 revolution, the cornerstone of the country's social development has been education and health care. Beginning in the early 1960s, biotechnology and medical research became a top priority of the Cuban government, with over one billion dollars invested in biotech R&D in the 1990s alone. Today, Cuba boasts a ratio of 1.8 scientists per 1000 inhabitants, a level comparable to the European Union (though with a far smaller Gross Domestic Product) (Hurlich 2003). There are 38 biotech centres, grouped together in a science park to the west of Havana, which integrate research, development, production and marketing. Cuban students and specialists are educated and trained in the most technologically advanced countries like USA, France, Japan, Switzerland, Canada, Mexico, England, Germany, and Finland contributing to the impressive knowledge base that exists today in Cuba.

**Box 2: The Finlay Institute**

The Finlay Institute has become an essential component to Cuba's vaccine research and production efforts. Its most successful and best-known product is the vaccine against meningitis B and its current meningitis B and C combination vaccine. As part of the Cuban National Immunization Program, 10 of 27 vaccines currently in the research phase in Cuba are being developed at the Finlay Institute. Previous successes in coordination with institutes such as CIGB have included development of vaccines against tetanus toxoid, leptospira, and hepatitis B. In 2002, the Finlay Institute developed a new vaccine against typhoid fever, similar to one produced by Belgian and French pharmaceutical companies. The Finlay Institute is currently working with GSK on clinical trials of its meningitis B vaccine in both Europe and Latin America, with hopes of extending trials to the United States. Along with the financial benefits received by the Finlay Institute, there is also the political and symbolic importance of a developing country vaccine being used in the north. The VA-Mengoc-BC vaccine is a good example of the need to step beyond narrow international constraints to work for a higher purpose and the benefit of humanity. Finlay Institute researchers are currently involved in applied microbiology, molecular biology, fermentation processes, vaccine development, and immunology.

### 4.3 China

Extensive government reforms in the late 1970s and early 1980s - including policies that began to shift the nation from a centralized, planned economy towards a market-based one - identified the science system as central for the country's modernisation and economic development (Zhenzhen et al. 2004). China has created giant industrial districts in distinctive entrepreneurial enclaves. Niche cities (Beijing, Shanghai, GuanZhong) reflect China's ability to form 'lump' economies, where clusters or networks of businesses feed off each other, building technologies and enjoying the benefits of concentrated support centres. The Chinese government has played a central role in promoting capacity building and innovation in the health and biotechnology sector. In 2002 China established its pharmaceutical S&T policy covering the period 2002 to 2010.

Like Cuba, an emphasis has been placed on building up the capacity of China's health biotechnology innovation system. The origins of modern biotechnology research in the country can be traced to the late 1950s policy of the 'great leap forward'. Health biotechnology industrialization was not widespread until after the mid 1980s, but expanded rapidly when some public research institutes were transformed into enterprises for manufacturing medicines. Under the ninth Five Year-Plan in 1997 the health biotechnology research system received increased financing and support to build up institutions and research capacities as an effort

to establish a National System of Innovation (MIHR 2005). At present there are about 500 Chinese public and private sector biotechnology firms. Emphasis is placed on building up human resource development not only through higher education facilities but also through the public research institutes. A central role is given to the Chinese Academy of Science which conducts research, education and training activities. China's strong public education and research programmes are driving innovation in both state owned enterprises and the burgeoning number of private enterprises.

Parallel to this has been the growth of the Chinese pharmaceutical market. This is one of the world's largest markets, second only to Japan in Asia and is expected to become the world's fifth largest by 2010. The growth of the pharmaceutical output has been phenomenal in China in the last decade with an annual average growth rate of about 20% over the past 15 years. The domestic pharmaceutical industry has been a key contributor to the country's staggering economic growth. There are approximately 6,800 Chinese pharmaceutical firms, of which, 5,000 produce medicines and the remainder are involved in packaging and equipment supply. However, due to an emphasis placed on public sector investment in biomedical science and research, the Chinese private pharmaceutical sector has remained highly fragmented and has suffered from substantial shortages of investment capital to undertake high risk product R&D. Public Sector focus has been strongly on research rather than development. Recently, the Ministry of Commerce announced plans to build 100 export-oriented "innovation bases" for the pharmaceutical sector by 2010. By offering financial and technical support and facilitating the entry of Chinese firms into international markets, the strategy aims to bolster Chinese exports of high-tech products while fostering domestic innovation in the pharmaceuticals.

Special attention has been given to traditional knowledge and mechanisms to use this resource as a base for the biotechnology and pharmaceutical sectors. The protection and domestic commercial exploitation of traditional knowledge is an important issue in China. Traditional medicines are used by large portions of the population and have a significant role in public health. One such medicine is Artemisinin - the frontline treatment for malaria (see Box 3). Used for centuries as a traditional medicine to treat malaria a Chinese pharmaceutical firm is collaborating with Novartis to produce modern malaria drugs. However, weak patent policies and regulations as regards to these have led to a loss of materials to foreign research. Increasingly China is acknowledging the importance of robust and inclusive IP policies in this area to ensure protection of its indigenous knowledge and often return of rewards to its communities sometimes in the form of trust funds that have nurtured this area.

**Box 3 - Artemisinin**

The herb *Artemisia annua* has been used for many centuries in Chinese traditional medicine as a treatment for fever and malaria. In 1971, Chinese chemists isolated from the leafy portions of the plant the substance responsible for its reputed medicinal action. This compound, called qinghaosu (QHS, artemisinin), has been used successfully in several thousand malaria patients in China, including those with both chloroquine-sensitive and chloroquine-resistant strains of *Plasmodium falciparum* malaria. Derivatives of QHS, such as dihydroqinghaosu, artemether, and the water-soluble sodium artesunate, appear to be more potent than QHS itself. Sodium artesunate acts rapidly in restoring to consciousness comatose patients with cerebral malaria. Thus QHS and its derivatives offer a totally new class of antimalarials.

In 1991, Novartis (then Ciba-Geigy) began collaborating with Kunming Pharmaceuticals on Coartem (derivative) production and obtained marketing approval in 1998. Novartis partnered with WHO in 2001 to make Coartem available in malaria-endemic countries on a not-for-profit basis. According to WHO, since the Global Fund for HIV/AIDS Tuberculosis and Malaria (GFATM) began disbursing funds in 2003, the demand for combination therapies based on artemisinin has increased rapidly and led to a drug shortage in late 2004. Since 2001, Novartis has supplied more than 10 million treatments. "The original 2001 agreement forecast demand for Coartem at just over 2 million treatments in 2005… Since then, nonbinding demand forecasts provided by WHO have continuously increased, including a sixfold jump between December 2003 and March 2004, when the 2005 forecast surged from 10 million to 60 million treatments." (Hans Rietveld, global marketing manager for tropical medicine with Novartis)

## 4.4 India

The Indian pharmaceutical industry produces a wide range of complex pharmaceutical formulations and over 400 active pharmaceutical ingredients. The industry ranked fourth globally in terms of volume and thirteenth in terms of value at an estimated US$6.0 billion in 2004 (IMS Health 2004). But until the 1970s, India had virtually no domestic pharmaceutical industry producing drugs from basic raw materials, relying heavily on imports. The 'access to medicines for all' perspective that ruled Indian thinking in the 1950s and 1960s (Amsden and Cho 2003) and the need to build self-sufficiency in local antibiotic production provided the starting point for change.

Liberalization in the 1990s further facilitated a shift from an import-substitution economy to an export-oriented one, enabling the emergence of a competitive domestic industry and set the foundation for world-class generic drug production capabilities in India. Private firms

gradually advanced to creative imitation stage (chiral synthesis) during the early 1990s and started to enter and establish themselves in regulated markets (mainly USA and Europe). Signing of the TRIPs agreement and transition to product patent regimes since 1995 has facilitated research in the Indian pharmaceutical firms to enhance their R&D focus and spend on new drug delivery systems and new chemical entities.

In 2006 there were 5,877 pharmaceutical private companies operating in India. The organized sector consisting of 250-300 companies accounts for 70 percent of products in the market with the top ten companies (out of which 9 are Indian) representing 30 percent. Approximately 75 percent of India's demand for medicines is met by local manufacturing (KPMG 2006). Over the years, the co-evolution of policy and innovation in the public and private sector have contributed to India's rapid development of pharmaceutical and biotechnology (Chaturvedi and Chataway 2006) with the development of industry-institute linkages and private investments for biotechnology ventures. Indian institutes and public research labs not only provide the scientists and technicians for the sector's workforce, but also contribute research discoveries of relevance to pharmaceutical and biotechnology firms. Traditionally, the role of universities was in education and training, whereas laboratories, both public and private, focused on research. Today, the lines are blurring, as universities incorporate research activities and national laboratories provide training for students to join industry later on. A good example of such blurring is seen in the Indian Institute of Science (IISc), Bangalore. Its department of biochemistry is working on immunology, reproductive biology and plant development as part of the study of diseases such as malaria, rabies and tuberculosis, as well as carrying out applied research on drug targets and vaccines. The 1990s saw a flourishing of numerous institutes and laboratories dedicated to biotechnology. Some of the most active in health biotechnology include the National Institute of Immunology and the Institute of Microbial Technology and the IISc. All these Institutes have multiple joint projects and collaborations with domestic as well as international drug giants. Market pull and government push for innovation in health research has enhanced PPPs tremendously in the recent past and the cumulative impact of these factors on knowledge creation and knowledge diffusion is unquestionable.

**Box 4: Shantha Biotech**

Shantha Biotechnics, an Indian biotechnology start-up, began research for an affordable indigenous vaccine in 1993. A western company had earlier denied the technology assuming that India did not have the resources to pay the high technology fee for buying the vaccine nor the ability to absorb the technology. Initiated as an R&D exercise at Osmania University, under the industry-university interaction programme the research was subsequently conducted at the Centre for Cellular and Molecular Biology. Since biotechnology was a relatively unknown segment and there were no venture capitalists around at that time, funding proved difficult. The project finally received funding

from the Sultanate of Oman of 50 per cent equity. It also received a long-term loan from Oman International Bank. Later, a loan was organized for technology development and commercialisation. Shantha Biotechnics launched India's first recombinant hepatitis-B vaccine, Shanvac-B, in 1997 followed by Shankinase (recombinant Streptokinase). Apart from supplying the product all over India, Shantha Biotechnics supplies it to various other countries directly and also through UNICEF agencies after Shanvac-B received the WHO-Geneva pre-qualification. The indigenous development of recombinant hepatitis-B vaccine enabled India to join the select club of five countries in the world to have the know-how to produce hepatitis-B vaccine. Shanvac-B was a huge national success since it developed a vaccine for local health needs, bringing down the prices of imported vaccine from Rs780 to Rs50 in 1997 and to Rs25 in 2003.

Scientific achievements in the field of biotechnology have been very encouraging and of direct relevance for the specific challenges of India's needs. For instance, the Hepatitis B vaccine was first developed by a small biotech firm, Shantha Biotechnics, in 1993, (see Box 4) with government aid and since more than 300 biopharmaceutical products have been put on the world market (STI 2006). According to a recent survey there are 96 exclusive biotechnology enterprises operating in India, making the Indian sector the third largest in Asia. The sector is a diverse mix of private domestic small and medium sized enterprises, such as Shantha Biotech and Bharat Biotech; larger firms like Biocon and Dr. Reddy's, Ranbaxy and Wockhardt; and some public enterprises including Haffkine Bio-pharmaceutical and Indian Immunologicals (Kumar et al. 2004). The result of public and private efforts has been the creation of a large pool of highly qualified personnel and world class biotech and pharmaceutical infrastructure.

## 4.5 South Africa

South Africa has explicitly incorporated systems thinking into its innovation strategy. The strategy was implemented following the adoption of a White Paper on Science and Technology in 1996 and the setting up of the Department of Science and Technology (DST) (see Box 5). The White Paper placed science and technology innovation within the broader macro-economic context within which South Africa was operating, emphasizing competitiveness; job creation and human resources; quality of life; environmental sustainability; the information society and knowledge embedded products and services. Thus an integrative approach was taken. As mentioned in the section on Brazil, South Africa has been a leading member of policy oriented efforts to create global policy mechanisms to support national innovation efforts in developing countries.

The DST has encouraged working with stakeholders to develop health research priorities through a National Research and Technology Foresight Project and National Science and Technology Forum as well as collaborative research programmes such as the South African

Malaria Initiative and SAAVI (discussed in Section 2) together with numerous efforts to encourage dialogue with and between academic, industry and policymakers.

Significant and creative efforts have been made to link science funding into innovation and to support more systemic approaches and initiatives. Recently the DST has supported the creation of a Biotechnology and Health Working Group which is a non-governmental 'trouble-shooting' group dedicated to taking "a leadership role to advance efforts designed to make South Africa a more significant participant in the global biotechnology and biomedicines industry, to address the country's public health requirements and to stimulate innovation in biotechnology"[5].

Two DST activities of particular note have been the efforts to promote competitiveness through the introduction of an Innovation Fund and the emphasis placed on incubators and regional innovation centres within the 2001 National Biotechnology Strategy. The Innovation Fund was designed to encourage innovation at the later stages of the product development pipeline. As such to act as a venture capitalist investing in projects which due to the high risk of later stage development costs may not otherwise have been taken forward. There have been questions raised at the idea of using public funds for venture capitalist type activities. A mechanism to encourage innovation in biotechnology has been the development of regional innovation centres and biotech incubator hubs. These centres have not yet received the tenants that they require to be sustainable. Problems in encouraging start-ups are thought to be partly related to a shortage of venture capital funds.

Although South Africa is clearly committed to investing in science and technology, expenditure on R&D is still less than 1%. Private sector investment in health related biotechnology is low. South Africa's regulatory system has also been widely criticized for slow response times and inefficiency. Siyabulela Ntutela outlines a number of challenges:

> *"… the cost of patenting, the sale of intellectual property rights outside of South Africa, the quality of licensing agreements and the professional management of intellectual property protection in universities"* (Ntutela 2006).

**Box 5: South Africa's Department of Science and Technology (DST)**

Scientific discoveries and the associated development of new technologies are key long-term drivers of economic growth and development. Innovation, technology mastery and the diffusion of knowledge and new products and services into markets are key elements in this growth and result in sustainable improvements in the quality of life of all South Africans. The White Paper on Science and Technology (1996) created the policy framework for the then Department of Arts, Culture, Science and Technology (DACST) to establish key enabling policies and strategies to inform the strategic development of S&T in South Africa.

In 2002 Cabinet approved the National Research and Development Strategy. The National R&D Strategy requires performance and responses in three key areas: 1) enhanced innovation; 2) providing science, engineering and technology human resources and transformation; and, 3) creating an effective government S&T system.

It is in this context that the DST has been established as a separate department to ensure that there is greater coordination, integration as well as better understanding and management of all government funded science and technology institutions and to provide a holistic overview of public expenditure on science and technology.

## 4.6 Building African Health Innovation Capacities

Clearly these countries are at different stages of development, have public and private sectors of varying degrees of maturity and hence are diverse in their approaches. They are also some of the most advanced developing countries, and we should be wary of simplistic calls for 'imitation' and knowledge transfer. But, African countries can surely learn a great deal from the ways in which China, Brazil and India have built industrial and R&D capacity. Cuba provides fascinating insight into policy approaches aimed at developing S&T and health innovation for domestic health improvement. South Africa is experimenting with systems innovation based policy and more integrated policy development. However, it is important to highlight that most of these countries have been only partially successful in meeting their overall development goals in health and health innovation.

Each country has undertaken activities that have built system-making connections along the determinants identified in Section 2 in attempts to strengthen its health innovation system. What emerges from an analysis of the strengthening of their health innovation systems is that the six determinants of the framework are linked in a dynamic manner. Progress in one requires progress in most, if not all other determinants. It is difficult to progress in R&D capability without first increasing manufacturing capability or without having a domestic or export market to generate resources for investment in production facilities (Mahoney 2005). One of the ways in which developing countries can access new technologies for strengthening health innovation is to enter into joint ventures with technology savvy firms in developed countries as India and China are aggressively pursuing. South-south collaborations could be an important vehicle to facilitate knowledge flows within developing countries as we discussed in Section 2. But, as Lall (2003) points out, sophisticated foreign firms will gauge their level of willingness to form joint ventures based on the value of the domestic market in the developing country, the capability of local R&D centres, and the expected level to which IP will be protected.

While the pharmaceutical and health biotech industries in India and China have shown

spectacular growth health provision for the majority in those countries has not improved so dramatically. Thus, in some cases industrial and innovation policies designed to increase productive capacity have not been aligned with social development despite promising policy visions such as “Health For All” and “Access and Affordability of Medicines”. There are serious gaps in putting knowledge and policy into practice. The case study of Cuba is perhaps the best example of an attempt where policy coherence has, on one hand, supported research infrastructure and strong health and education system and on the other hand, has promoted strong linkages between the research system and its health delivery system. The major hospitals are partners in the health biotechnology cluster and the cluster has therefore both users and producers of health biotechnology. Thus the delivery system is by default an integral part of the health innovation system, and distribution and health care services are well integrated into health innovation.

The challenge of improved technology and innovation, as we discussed in Section 1, lies in the capacity of policymakers to tackle issues systemically, building health innovation systems that facilitate, promote and respond to the local health care primarily and possibly global market needs through research and development, manufacturing, distribution and services. Reconfiguration of macro frameworks and integration of multiple technology micro initiatives like genomics, stem cell research or new products like microbicides and vaccines or even new knowledge fields like bioinformatics in health innovation is crucial.

The country cases outlined here have provided strong indicators for the policy, process and practice with examples of how system-making connections can build the determinants of an innovation system. It is useful to build local R&D and manufacturing capabilities – not just in terms of infrastructure provision through the national innovation system but also institutional level organizational capacity to innovate. This needs to take place within the context of the wider international arena in which both the national and international (healthcare) markets and economy play out. Regulation and intellectual property need to be strongly developed and made relevant to local knowledge and situations.

However the case studies also demonstrate the disconnect between thinking about innovation and industrial policy on the one hand and social development policy on the other. In India, China and Brazil policies in these two areas are often disarticulated. Huge increases in scientific and manufacturing capacity have not been pursued with reference to changes in social development policies so that R&D could serve the immediate needs of populations. In Africa, of course, this disconnect is also present but has different dynamics with access issues being dealt with completely separately from industrial or innovation policy. It is obvious and relevant also, to note the fact that African countries suffer from huge difficulties of weak resources of all kinds and extremely fragile relevant institutions, which will require massive focus on core problems, with internal clarity and external support. We return to these issues in Section 6. Before that we will consider some initiatives currently trying to match R&D to African needs.

# 5. Health Innovation Networks

Innovation does not occur within strict geographical boundaries. It is influenced by international markets and regulatory frameworks, as well as cross-national trading and capacity related opportunities and constraints. Successful innovation requires collaborative activity not only at a national level but between countries and increasingly at a regional African level and at a sub-regional (e.g. West African) level as well. The form that such collaborative activity takes is also important. As such regional and sub-regional, together with international initiatives, are taking shape and gaining in strength forming 'health innovation networks' providing the catalyst for successful research, development and access to drugs, vaccines, diagnostics and health services in Africa.

## 5.1 The Globalisation of Knowledge

In acknowledging the fluidity of interactions related to innovative activity it can be argued (Carlsson, 2006) that there has been an 'internationalisation of systems'. Innovation often takes place within a 'national system of innovation' being influenced by a network of national structures. However regulations and frameworks, and knowledge spillovers are increasingly 'international'. Knowledge is now retransferred across organizations and absorbed from and exported to international corporations and other foreign entities (ibid.). This is not only due to the advances in communications but also changes in the way healthcare and innovation are taking place. Health issues are seen as increasingly complex, ignoring territorial boundaries and requiring solutions that take account of spatial, temporal and cognitive changes (Lee et al. 2002) while firms are often multi-national or trans-national. At a smaller scale, advances in communication and the rise of internet technologies, have enabled less sizable companies and business individuals to access information and markets throughout the world. The relationship between local and global is changing leading not only to 'globalisation' (bringing the global to the local) but also the local influencing the global. The result is multiple, varying forms of knowledge and information flow.

## 5.2 Learning from Current Health Innovation Networks

Health innovation networks take no specific form but are the result of interactions with external groups by individual entities or industry clusters operating at various levels within national systems of innovation. As such they operate within and across national, sectoral and micro levels of systems of innovation. International partnerships, bilateral south-south initiatives or regional clusters can all constitute networks. Health innovation networks can also have different objectives focusing either on strengthening one determinant of an innovation system specific to their own activity (e.g. capacity for R&D) or multiple determinants of a health innovation system as illustrated by the work of a number of international health partnerships such as MMV. By looking at how a number of health innovation networks operate – how they transfer knowledge, build their organizational structures and network

between members – it is possible to highlight how building initiatives across national, sub-regional and regional institutions can facilitate and support innovation through establishing solid relationships that are vital for sustainability.

### *5.2.1 Mode 2 forms of networking*

At the heart of these networks is collaborative activity. Innovation requires a strong knowledge base, for example, good research institutes and universities but this on its own is insufficient as there is no pre-determined linear movement of this knowledge upstream to the creation of products. As we have pointed out at the beginning of the chapter, innovation is the result of the dynamic interplay of users and producers of knowledge at different stages of the innovation cycle. As such traditional 'mode 1' or linear based structures of innovation are evolving into more complex loose, 'mode 2', structures containing numerous stakeholders each with their own skills base in which innovation takes place within the wider social, economic and political context (Nowotny et al 2001). An emphasis in 'mode 2' is placed on practice based learning oriented towards specific and practical outcomes. An example of a 'mode 2' health innovation network is the KEMRI-Wellcome Trust Research Programme in Kenya (www.kemri-wellcome.org) which is seen as being:

> *"… fully integrated into the Kenyan research infrastructure, through its close relationship with KEMRI, in Kilifi, the Programme is embedded within Kilifi District Hospital, building its research programmes around local medical infrastructure and contributing to healthcare delivery. Researchers are also committed to engaging with the local community, to discuss their research and why it is being carried out".*

As outlined in Box 6 further this Programme has numerous stakeholders involved and actively participating at various stages of the research process placing its innovation activities within the wider context of the local community healthcare needs as well as wider national and international health issues. Here the Programme is just one node within a much larger network of institutions working towards the creation of an atlas of malaria and its impacts in Africa.

The non-institutionally based collaboration with numerous other stakeholders throughout Africa on the MARA/AMRA Project, and beyond, has not only created useful 'risk' maps of malarial illness to inform malaria control policy in the region but also built the capacity of researchers within KEMRI-Wellcome and others in the region in geographical information systems (GIS) technology and statistical mapping methods. Such activities see knowledge transferred across geographical boundaries strengthening the loose organisational structure of the MARA/AMRA Project around the production and application of its innovation activities. Here capacity building is not confined – nor is it within KEMRI-Wellcome's other work – to being a linear process of those with the knowledge training those without the knowledge.

The focus is on the creation of stronger links between researchers and users to ensure that the maps created are used effectively and adequately within malaria control policy.

The KEMRI-Wellcome Trust is a nationally based initiative rooted in functioning and linked institutions. This solid base however enables it to operate regionally. Thus, even where institutions and organisations are initially set up on a national basis they can offer regional benefits and offer an alternative to new institutions which have weak or non-existent links to a wide range of other R&D and user organisations.

**Box 6: KEMRI and MARA**

**KEMRI-Wellcome Trust Research Programme**
The link between the UK's Wellcome Trust and Kenya's medical research community dates back to 1949 when the Wellcome Trust established a research laboratory in Nairobi's Kenyatta Hospital. KEMRI was established in 1979 as the country's main medical research institute. From the late 1980s formal joint work began between the two groups focusing on malaria research. The joint KEMRI-Wellcome Trust Research Programme has three main principles underlying its activities: internationally competitive research, strong clinical research focus and local applicability. Linked to this is a strong emphasis placed on capacity building. The Programme is built around partnerships with numerous actors including other international research institutes e.g. at Universities of Oxford and Liverpool, the hospitals of Kilifi District and Kenyatta National, the Kenyan Ministry of Health and the local communities in which its research centres are based.

**The MARA/AMRA Project**
The KEMRI-Wellcome Trust Research Programme is a member of a pan-African research project to map malaria risk and endemicity. The MARA/AMRA Project started in 1996. The KEMRI-Wellcome Trust Research Programme became a formal node within the Project in 1997 looking at malarial disease burden with a specific data centre. In the 10 years the project has been running, numerous other data centres have been set up within Africa providing a rich source of malaria data contributing to the development of 'risk' maps used in malaria control policy activities and the geographical modelling of malaria. It has allowed the first accurate assessment of the burden of malaria to occur for Africa. The project has set up a number of national centres, undertaken capacity building of researchers in GIS technology, climate change methods, databases and conducted end-user training workshops.

### *5.2.2 Networked health innovation partnerships*

MMV is a health product development partnership that actively networks to strengthen

health innovation activities (see Box 7). The partnership actively attempts to develop R&D capacity (resolving difficult IP issues and building manufacturing capacity) to create useful malaria medicines particularly for developing countries. MMV places an emphasis on building up the regulatory environment for clinical trials of potential drug and vaccine candidates and works on access issues to ensure the market will be there once drugs and vaccines are developed. Like the IAVI partnership (Chataway and Smith 2006), MMV as an entity works as a broker of innovation across existing systems. It works beyond national boundaries bringing together disparate groups who share a common interest in advancing malaria medicine innovation but who before now had few avenues for interaction. Its focused activities could well result in more general R&D capacity building which will enable those involved to contribute to developments in other disease areas. Thus while capacity building is not the explicit objective of MMV, its activities do seem to result to some extent in capacity development for local partners.

**Box 7: Medicines for Malaria Venture (MMV)**

Set up in 1999 as a not-for-profit Foundation MMV works to "discovery, develop and deliver new antimalarial drugs" by bringing together the public, private and philanthropic sectors in partnerships to conduct research, produce and register drugs for the treatment of malaria in disease-endemic countries. It has activities that span the drug product development pipeline from basic research to delivery through public-private partnerships with groups from around the world. MMV has an in-house team, supplemented by contract research organizations, that manages its drug portfolio of over 20 projects. MMV has held 5 rounds of calls for proposals to identify new projects to add to its portfolio. It has projects that focus on different species of malaria and requirements for different patient groups and therapeutic pathways. Since 2003 MMV has closely collaborated with GSK, a major pharmaceutical company.

In contrast, the European and Developing Countries Clinical Trials Partnership Programme (EDCTP) was set up to consider the specific issue of building R&D capacity within developing countries through linkages with European researchers working on HIV/AIDS, tuberculosis and malarial drugs, vaccines and diagnostics. Although it has an explicit capacity building remit the EDCTP has experienced problems, unlike international partnerships such as MMV resulting in difficulties dispersing funds (see Box 8).

**Box 8: The European and Developing Countries Clinical Trials Partnership (EDCTP)**

Set up in 2003 this is a partnership between 14 European Union countries, Switzerland, Norway and African countries with the aim to develop new drugs and vaccines to fight HIV/AIDS, tuberculosis and malaria through joint research

programmes that would share information and resources. An example of north-south and south-south collaboration and networking to build scientific capacity to conduct clinical trials in developing countries, the EDCTP was developed with developing country scientists involved at every step (Binka, 2004). However, despite this, and perhaps because of the size of the initiative – the EDCTP has been criticised for not processing trial grants quickly enough; some researchers who submitted trial proposals two years ago still have not received a reply (www.scidev.net, Sept 2006). A recent report (IAVI, 2006) highlights that of the €200million committed to the EDCTP published data suggests less than 5% of this money (only €8.3million) has been disbursed.

### *5.2.3 Southern-led African based health innovation networks*

A number of health innovation networks extend beyond geographical boundaries linking groups at a sub-regional, regional level and at times even international level through the function of 'globalisation' so networks originating from within a like-minded group of individuals, within or between countries, can create links to form a sub-regional, regional or international group that takes its national or regional origins as a base. An example of such a group would be AMANET, the African Malaria Network Trust and the AAVP, the African AIDS Vaccine Programme (see Box 9). These groups work in different ways and have different goals but they were both conceived as 'African' initiatives with the goal of building African capacity and opportunity for health innovation.

A similar focus pervades South-South initiatives such as Brazil's work with Mozambique and Angola to build stronger clinical research capacity. Brazil is to help strengthen Portuguese speaking African countries' public health research activities through educational linkages. Fiocruz is to coordinate a project which sees Brazilian researchers support a Masters course in public health research to be run at the Angola National School of Public Health. If successful the project will be rolled out to Mozambique and other countries. The project, supported by the Angolan government and Capes, Brazil's federal research funding agency, allows Brazilian researchers to teach on the two year Master's course in Angola and for Angolan students to spend three months of their second year in Brazil doing research and writing their dissertations at Fiocruz. The course will begin in October 2006. Distance learning branches will be set up in Cape Green, Guinea Bissau and Sao Tome and Principe. The project will also provide the Masters students with free access to 10,000 online journals. Future plans for the project include renovating Angola's technical schools and libraries. The project builds on a programme at Fiocruz which during the 1980s and 1990s saw Fiocruz receive 30 students from Portuguese-Speaking African Countries and East Timor, supported by the Japanese International Cooperation Agency (JICA).

### Box 9: AMANET & AAVP

**The African Malaria Network Trust (AMANET)**
AMANET started life in 1995 as the African Malaria Vaccine Testing Network and is a network of African organisations with external assistance aiming to develop African capacity to conduct malaria vaccine clinical trial work. The change to AMANET occurred in 2002 with recognition of a need for capacity to be built in other areas of malaria research activities with a more integrated approach to malaria research activities. AMANET's mission is to "Promote Capacity Strengthening and Networking of Malaria Research and Development in Africa". AMANET builds both human capacity through conducting training workshops and infrastructural capacity through provision of equipment and facilities. AMANET also funds clinical and field trials themselves. AMANET has a permanent secretariat based in Tanzania coordinating activities through scientific and trial site committees. The governance of AMANET occurs through a General Assembly and Board of Trustees format made up of representatives working in malaria research focusing on Africa.

**African AIDS Vaccine Programme (AAVP)**
A WHO-UNAIDS supported programme, the AAVP was initiated by a group of African scientists in 2000 who "adopted *"The Nairobi Declaration: An African Appeal for an AIDS Vaccine"*, pledging to use their personal and collective commitment and expertise in the development and implementation of *an African Strategy for AIDS Vaccines*." (www.who.int). The secretariat is housed within the WHO-UNAIDS HIV Vaccine Initiative in Geneva providing technical, financial and secretarial support to the AAVP. Working around thematic working groups, overseen by a steering committee made up of 8 African scientists, the AAVP aims to accelerate HIV vaccine work to ensure development of effective HIV vaccines for Africa.

## 5.3 Making the Most of Health Innovation Networks

The value of health innovation networks can be found in their network activities, the emphasis placed on collaboration between groups with common purpose. The development of 'mode 2', which links academics, applied and product development researchers and user groups in health innovation efforts ensures more is achieved together than by going it alone. The need to integrate has become common within a number of industries particularly for health innovation in pharmaceuticals (Henderson et al. 1999) and with 'partnerships' seen as solutions to development problems (Crewe and Harrison 1998). We have moved into a 'shared power world' (Bryson and Crosby 2002) where actors are better served when better connected (Burt 2002) in an increasingly networked society (Castells 1996). The value of networks in health innovation can be found, as highlighted above, at all levels. Health innovation networks such as MMV prove useful at brokering knowledge between entities

across national boundaries at the international level. At the same time, the power and value of local networks on international activities is evidenced by the work of the AAVP. The examples highlight how important such networked relations are at providing a brokering mechanism for groups with common interests.

Many of the networks not only emphasise capacity building and strengthening of a wider health innovation system in which they are a part but create opportunities for this to occur as a result of the networked arrangements in which activities take place. The KEMRI-Wellcome Trust Research Programme and AMANET both build local capacity to conduct research and embed their activities within the communities and health sectors in which they work. The work of MMV places an immediate emphasis on networking to ensure successful development of anti-malarials. In order for this to occur training and other capacity building activities take place. Again, the benefits of linking research to innovation efforts are clear.

Health innovation networks are evolving across the continent on an international, sub-regional and regional basis. Using case studies we can look at the ways in which national structures and sub-regional and regional institutions can support and facilitate each other. Establishing solid relationships between national institutions and sub-regional and regional initiatives is vital to sustainability.

## 6. The International Community

The international community has a vital role in building health innovation systems in Africa. In an increasingly globalised world no one part of the world can operate in isolation. In building financial, human and institutional resource multiple international connections need constructing and sustaining. International policy needs to take into account the importance of building health innovation systems in Africa and international funds need to be targeted to the challenges of meeting related immediate and longer term goals.

In funding research and innovation the international community, particularly donors are often committed to supporting ‘excellence’. However, what constitutes excellence is a thorny and contentious issue. To what extent should funding be directed to exciting basic science that will score highly on traditional indicators of excellence, i.e. highly cited peer reviewed publications and perhaps patents, and to what extent should efforts be directed at more applied work addressing pressing social, health and economic targets? What are the measures that can be used to measure excellence for this type of work? Should international donors support regional centres of excellence or is this a model that inevitably leads to ‘ivory tower’ establishments that are unable to forge the networks and connections needed to address the problems of African countries? The perspective we have adopted in this chapter is that there is scope for coordinating and integration efforts to build scientific and research capacity and building innovation capacity. There is no model that will yield results

in all contexts and support of high quality dynamic initiatives is crucial.

Another set of issues relate to how global 'vertical' or dedicated initiatives, which receive very significant amounts of donor funding, such as the GFATM, the Global Alliance for Vaccines and Immunisation (GAVI), and IAVI can be used to support the larger and broader health innovation system and health system goals of African countries. Whilst the impact of these initiatives has not always been judged to have a positive impact on national health structures and operations (Buse and Harmer 2007) there is good evidence to suggest that in some cases these initiatives have had a positive impact on capacity building in some areas.

IAVI presents an important capacity building example of the relationship between research 'for' developing countries and research 'with' developing country partners, not just research 'in' developing countries. The need for a preventative vaccine against HIV/AIDS is overwhelmingly evident as is the emphasis on the fastest and most effective way of achieving that target. However, a close look at the main PPP working on a preventative vaccine, IAVI, suggests that even here the distinction between 'for' and 'with' need not be so clear cut — IAVI has in fact had very positive impacts in terms of capacity building. In this case (see Box 10), political and ethical sensitivities around vaccine development and clinical trials are powerful arguments in favour of local engagement and voice at all levels (Chataway and Smith 2006).

Overall, this product-based approach to capacity building seems to have important lessons for those thinking about S&T capacity building policy. Capacity building can result from initiatives that focus on product development rather than on broader and more diffuse initiatives aimed at formal training. The tacit knowledge exchange around the vaccine and vaccine preparedness that has taken place as part of the IAVI work is particularly important as a lesson of experience for other S&T capacity-building initiatives.

The IAVI experience shows that some of the global initiatives do see that building capacity in developing countries is important because support and involvement is essential. At a meeting in 2006 at Wilton Park in the UK two other global health initiatives, the GFATM and GAVI also called for more 'systems' building in developing countries. The reasoning here is different. GAVI and the GFATM both consider that their operations have had very significant success. However, their future and the sustained success of their operations depend on better health services and systems in developing countries. Investment at this level of national and regional systems is now essential. Thus, there does now seem to an opportunity to build momentum for investment in systems building in developing countries. There is considerable scope for creative policy aimed at fostering capacity in health innovation and health systems.

**Box 10: The International AIDS Vaccine Initiative (IAVI)**

IAVI was set up in 1996 with the aim of promoting the creation and distribution of an effective preventative AIDS vaccine. IAVI acts as a sort of venture capitalist, investing in promising vaccine candidates and offering support for the expensive clinical-trial stage of drug development. IAVI also engages in high-profile public relations and grassroots advocacy work, particularly vaccine preparedness work, to promote the need for a vaccine and to provide insight into technological possibilities. A crucial part of IAVI's work is developing strong links – partnerships – with developing country institutions to run clinical trials and vaccine preparedness work or planning for vaccine manufacturing and distribution.

IAVI has achieved significant capacity building through its partnerships. IAVI's role in capacity building is paradoxical but successful. Capacity building is not a core priority but it is strategically important. Capacity building has been essential to IAVI for three principal reasons. First, for scientific reasons it is essential that clinical trials be conducted among those populations for whom the drug is intended. Second, building support for a vaccine requires local political support and this is built through active engagement. Third, the majority of IAVI's funding now comes from bilateral and multilateral funding agencies and these agencies clearly favour a capacity-building approach wherever possible.

IAVI partners in Kenya, Uganda, and Rwanda have all received very significant investment in training and infrastructure, and have benefited in particular from close and constant communication via telephone, Internet, and face-to-face meetings with leading scientists and managers. IAVI's African partners say it is the constantly focused activity around a set of tasks associated with vaccine development that has been particularly valuable. For partner organizations in Uganda, Kenya and Rwanda, new prospects have opened up as a result of this engagement and hey can now aim realistically to be centres of excellence for the development of vaccine clinical trials.

## 7. Conclusion and Policy Recommendations

At present, as we have shown earlier, the institutional set-up and range of policy perspectives in health innovation has a number of 'disconnects'. These disconnects exist everywhere and not only in Africa, but they are bigger in countries with weaker resource bases. In Section 2 we summarised the issue as a worrying and endemic gap between social policies on the one hand and industrial and innovation policies on the other. To put it bluntly, health policy and national health 'systems' tend, if at all, to treat innovation as irrelevant – for health product procurers, health products can be obtained just as easily or with just as

much difficulty anywhere in the world. This leads, not only to importation of most drugs, but often importation of the most basic hospital and clinic equipment and instrumentation.

We write in Section 2 of the lack of understanding between those who research and make policy in the world of health care and those whose interest is in health innovation and production of pharmaceuticals. Obviously then, institutions reflect this gap, and policies so far have not integrated social policy and the production policy. In fact health policy tends to deal with partial analysis of healthcare systems (Mackintosh and Koivusalo 2005) with little acknowledgement of wider areas of activity such as S&T research. At the same time S&T policy has not generally focused on health related matters because health has not been strategically important to national growth in many countries (Freeman and Miller 2001).

Increasingly, however, there is recognition that S&T, particularly biotechnology related research and development (R&D), is an important part of the health system and that developing countries must develop their own R&D capacity if they are to achieve sustainable health systems and the Millennium Development Goals are to be reached (Csaszar and Lal 2004; Mugabe 2005). Mahoney and colleagues have developed the idea of a 'health innovation system' around the six determinants of health innovation, summarised in Section 2 of R&D; manufacturing; internal markets; export markets; IP; and regulation. The large health product development projects (like IAVI and MMV) have, in some respects, kick-started integration through doing it, focused on the big killers. Other studies, like the Rockefeller Report on Intellectual Property suggest, just as do the literatures reviewed in Section 1 that working on all fronts at once is key. For example, the ability to build capabilities in partnership working and managing large projects or sub-projects depends on existing or developing the systems-making connections in R&D, regulation, IP etc are necessary. But what matters most is pulling them together. Developing them separately without dialogue or connection, is not only slower, but will not work if the idea is to link the satisfaction of health needs with the capacity to deliver them.

In the following section we focus on some key policy recommendations that are relevant for better integration of the social and technical aspects of health innovation systems.

## 7.1 Linking Health Policy and Health Innovation Systems

Overall, we would still argue that countries with strong health innovation foundations, if they choose to, are well placed to succeed in developing and sustaining good health systems, and vice versa. Countries with better health innovation systems can participate in south-south efforts to improve conditions in weaker countries and regions. Recent academic analysis is focusing on ways in which innovation and industrial policy and social provision impact on one another and can be constructed in ways that are mutually supportive.

One policy action that the African Union and NEPAD might consider is initiating an expert group to develop analysis and promote policy initiatives and mechanisms to integrate health

related industrial and innovation policy on the one hand and healthcare policy on the other hand. The expert group would formulate policy plans and stimulate activities. The group would include policy makers, private sector actors and academics.

Another suggestion is linked to a capacity building action already outlined in the African Union and NEPAD Africa's Science and Technology Consolidated Plan of Action. As part of its science and technology capacity building the Consolidated Plan suggests Short-term Executive Workshops for Senior Government Officials. We suggest that some of these workshops be designed around building health innovation systems and specifically around the need to bridge the gap between different areas of policy.

### 7.2 The Importance of Building on and Integrating Global Programmes

From Africa's side, local institutions could be encouraged to explicitly work to build better conditions for learning from these huge global initiatives and global partnerships and construct a myriad of global connections – avoiding passive sub-contracting and actively learning in order to imitate and innovate.

One policy recommendation is for NEPAD and the African Union to pursue further discussion with international Global Health Programmes such as GAVI and the GFATM about how these initiatives could best support health innovation capacity building in African countries. Discussions along the same lines might also be pursued with some of the large public private partnerships such as IAVI and MMV.

### 7.3 The Importance of Balancing Innovation and its Regulation

Another policy challenge is to ensure that the pressures for innovation are in balance with those for regulation and governance. The High-Level Panel on Modern Biotechnology of the African Union and NEPAD in their report Biotechnology in Africa's Development which was focused on biotechnology but may well have more general import, pinpointed one danger: "The evolution of [Africa's biotechnology] regulatory systems has been largely influenced by international debates that are often not directly associated with the technological needs of the continent. The continent, through its regional economic communities, needs to adopt an evolutionary approach where regulatory systems develop hand in hand with technological opportunities and applications". It goes on to advocate risk taking and care at the same time, not to allow the risk to stop innovation happening.

The balancing act will require great policy finesse, and also significant resources. Regional initiatives will be needed to support local efforts. Efforts should build on WHO initiatives. Concerted efforts should be made to develop systems that are enabling rather than constraining and should be consistent with the detailed policy recommendations developed in the report on Biotechnology in Africa's Development.

## 7.4 Capacity Building for More Integrated Innovation Systems

We have argued that national institutions and organizations can use networks and partnerships to develop health innovation and provision. This analysis of capacity building possibilities builds on work that NEPAD has already carried out on thinking related to centres of excellence in Africa and we would endorse the policy perspectives and actions outlined in the document 'Centers of Excellence in Science and Technology for Africa's Sustainable Development'.[6]

We have also emphasized the importance of building on dynamic initiatives and trying to maximize national and regional capacity from initiatives which show promise. This thinking around building regional networks of excellence and grounding them where appropriate in national and regional institutions needs further development. Universities can clearly play a key role in interacting with and supporting networks and a clear policy recommendation is that Africa's academies of science consider ways to promote and extend health innovation networks in conjunction with African universities. By adopting more 'mode 2' approaches and by prioritizing links with other researchers, with users groups and with policymakers, African universities could make a fundamental contribution to the development of more sustainable health innovation systems.

Universities can also clearly play a key role in providing training in innovation policy and practice that could improve health innovation over the medium and longer term. The Consolidated Plan of Action outlines plans for postgraduate training in innovation and one policy recommendation would be to offer a modular strand of training on health innovation systems and integration with health systems.

## 7.5 Integrated Policy Making

There is need to identify and back 'micro-systems of innovation' whilst concurrently reforming national institutions and policy to provide facilitative innovation environments. This approach requires rethinking the way in which much policy is made. Policy formulation itself needs to become a more dynamic and interactive process. One policy recommendation, then, is for the African Union and NEPAD to support exercises such as Foresight which might help identify promising initiatives and technologies. Foresight exercises tend to work best when based on the involvement of substantial numbers of researchers, scientists and policy makers and it may well be that regional Foresight initiatives might be appropriate.

## Notes

1. Absorptive capacity refers to the ability to search and make use of new knowledge and new technology.
2. For example where industrial and innovation capacity is being created but does not address local health and social needs.
3. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/en/.
4. See http://www.scidev.net/en/news/sickle-cell-drug-mired-in-controversy.html. Accessed 18 August 2008.
5. Meeting at Africa Genome Education Institute, October 2006
6. Prepared by John Mugabe for AMCOST in November 2003

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