Strengthening Pharmaceutical Innovation in Africa

Designing strategies for national pharmaceutical innovation: choices for decision makers and countries

Final Study Report:

revised after review by the Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa

Supporting
- The African Union's Pharmaceutical Manufacturing Plan for Africa
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

African Union
Council on Health Research for Development (COHRED)
The NEPAD Agency of the African Union (New Partnership for Africa's Development)
with contributions from The George Institute for International Health

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Acknowledgments

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Strengthening Pharmaceutical Innovation in Africa

Final report of the study and Pharmaceutical Innovation Tool.

Revised after review by the Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa.

The initiative: *Strengthening Pharmaceutical Innovation Africa*, is endorsed by the African Ministerial Conference on Science and Technology (AMCOST)*

* Political endorsement by Science and Technology Ministers for the NEPAD Agency/African Research for Health Initiative (NARHI)

During its fourth ordinary session held from 7-10th March 2010 in Cairo, the African Ministerial Conference on Science and Technology (AMCOST IV) adopted the following:

- It noted and appreciated the progress made by the AUC and the NEPAD Agency in the implementation of the CPA.
- It commended the NEPAD Agency for its program on pharmaceutical innovation and harmonization of drugs registration in the AU Member States in line with (i) the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the World Health Organization; (ii) the AU Health Strategy and Pharmaceutical Manufacturing Plan for Africa; and (iii) the Africa Science and Technology Consolidated Plan of Action of the African Union.

Foreword

Practical approaches for countries: Africa's perspective on medicines access and pharmaceutical innovation.

This study and the resulting initiative, Strengthening Pharmaceutical Innovation in Africa, come at an important moment in the development of pharmaceutical innovation strategies in Africa and in achieving access to essential medicines for all in Africa.

Two landmark agreements for research and medicines production in Africa have been reached. The *Global Strategy on Public Health*, *Innovation and Intellectual Property* is a mechanism signed by 192 countries that calls for increased investments for research and production of medicines that are needed by countries, to be coordinated by them. The *Pharmaceutical Manufacturing Plan for Africa*, adopted by the Summit of the African Union in 2007 is the basis for a more coordinated approach to local medicines production – based on countries' needs.

These agreements and other developments set the foundation and a long-term political agreement for the planning and financing of medicines research and production on the African continent.

At the same time, much work remains to be done to make national and regional pharmaceutical and health innovation a reality for our countries. Countries need to better understand their current situation, their potential for engaging in local research and medicines production and they need to develop strategies to do this.

This report and tool mark the starting point of an initiative to strengthen pharmaceutical innovation in Africa. It started with a study and practical reflection between countries on what is needed to provide better access and encourage local production of medicines in Africa. It was reviewed and revised by the Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa incorporating the core committee of member state representatives and other experts in health and health policy, science and technology, trade and industry and pharmaceuticals – in Pretoria in February 2010. The initiative, its study and pharmaceutical innovation tool, have been endorsed by the African Ministerial Conference on Science and Technology (AMCOST) at its meeting in Cairo in March 2010.

The regional dimension will have an important place in this process. As an African vision and agenda for pharmaceutical innovation emerge, the Regional Economic Communities will have an important role to play, both as catalysts and 'multipliers' to build consensus, and move the plan forward by coordinating member countries.

The collaborative spirit in which this report was produced fits well with two of NEPAD's core mandates: building capacity of Africa's health research and science and technology sectors; and making knowledge management and sharing a way of working for science, across the continent. The process started by this study serves both of these goals.

These two mandates are also central to the Memorandum of Understanding between NEPAD and the Council on Health Research for Development (COHRED), which provides technical support to NEPAD and countries for this initiative. It was first signed in 2005 and renewed and updated this year for a further five years. Under this strategic partnership, NEPAD calls on COHRED to provide technical input, to conduct studies on questions of health research – especially for system building – and to support NEPAD's long-term investment in creating African centers of excellence in various aspects of health research. In a linked initiative, 'Research for Health Africa', NEPAD and COHRED are working together to build and develop the capacity of managers and health research systems in a number of countries.

Based on the comments and review by the Extended Expert Committee, I encourage my African colleagues working in research for health, science and technology, and trade and industry to make use of the pharmaceutical innovation tool presented here and of the new knowledge generated by the study. In doing this we will start developing a broad-based perspective and consensus on Africa's needs for access to medicines and pharmaceutical innovation for our future.

Dr Ibrahim Assane Mayaki
Chief Executive Officer
New Partnership for Africa's Development - NEPAD
NEPAD Planning and Coordination Agency

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Executive summary

The Initiative for Strengthening Pharmaceutical Innovation in Africa

This publication provides the evidence base and direction for the initiative: *Strengthening Pharmaceutical Innovation in Africa*.

The initiative is based on the study conducted by NEPAD and COHRED in 2008-2009 on the pharmaceutical innovation landscape and current approaches in Africa. From these findings, the first pharmaceutical innovation tool – the Pharmaceutical Innovation Framework and Grid – has been produced.

Strengthening Pharmaceutical Innovation in Africa is a long-term capacity building programme created by African research and political leaders who are active in health research and pharmaceutical innovation. The initiative supports African countries to craft strategies and build skills and to engage in pharmaceutical innovation and access to medicines for the benefit of the continent's population.

The initiative is a partnership between the African Union; the New Partnership for Africa's Development (NEPAD) – ensuring implementation and support to countries; and the Council on Health Research for Development (COHRED) – bringing technical support to NEPAD and countries for research capacity strengthening.

Study and analysis of innovation and medicines access in Africa

The study presented here (Chapters 1-4) is the first of its kind to analyze countries' needs and the obstacles to putting pharmaceutical innovation into action in a low/middle income country context. It presents a map of innovation and access activities in Africa (Strengthening Pharmaceutical Innovation in Africa - NEPAD, COHRED 2009 www.nepad.org - www.cohred.org/African_Innovation).

Tool for countries - pharmaceutical innovation framework and grid

Chapter 5 presents the tool for countries – the Pharmaceutical Innovation Framework and Grid. Developed as part of the study, it is a unique planning tool, that has been reviewed and adapted to countries needs. The tool helps countries do self-assessments, develop strategies, build capacity and partnerships to engage in innovation and improve access to essential medicines.

Validation and expert review

This report reflects the views and needs of African countries. The study, and the Pharmaceutical Innovation Framework and Grid, have been critically reviewed by the Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa it included experts from 11 African countries that are the core of the Committee, national leaders in research and policy making, members of the African pharmaceutical industry, representatives of civil society and members of several international organisations, including the World Health Organization (*see Meeting Final Statement and participants list in Annexes*). Their insights and comments are included in this updated final report.

Endorsed by Africa's ministers of Science and Technology

The initiative: *Strengthening Pharmaceutical Innovation Africa*, was endorsed in March 2010 by the African Ministerial Conference on Science and Technology (AMCOST) as the starting point for African countries to put into action the:

- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the World Health Organization
- African Union Health Strategy and Pharmaceutical Manufacturing Plan for Africa.

Guided by NEPAD the initiative is an effective coordinating mechanism for pharmaceutical innovation, medicines access and research capacity strengthening activities in Africa.

Call for Partners

The Initiative is seeking partners among pharmaceutical and development organisations to support developing of countries' capacity for research and innovation, in areas such as:

- **Work with countries to develop national and regional strategies** for pharmaceutical innovation and access.
- **Targeted capacity building of senior research managers, policy makers and researchers** to better design and manage innovation and access activities.
- **Regional meetings and exchanges to share experience and forge partnerships** – between policy makers, pharmaceutical producers, research organizations and civil society.
- **Further development of useful tools and processes** to help implement the WHO 'Global Strategy', and the AU Health Strategy and the Pharmaceutical Manufacturing Plan for Africa.

Country needs and global health initiatives in Africa

Today there are many initiatives and organisations that do research and develop cures to neglected diseases, that produce and deliver medicines, and improve access to medical products in Africa.

More than 120 have been identified in this study and presented in a map (See page 21).

This diverse field of players is generally shaped by the interests of international programmes and funders and often does not directly engage with countries and their public health needs.

The goal of the initiative, Strengthening Pharmaceutical Innovation In Africa, its study and tools is to provide the perspective and evidence that helps countries to manage their affairs for pharmaceutical innovation and access to medicines.

Moving forward: Strengthening pharmaceutical innovation in Africa. Chapter 6 details comments received from the group[1], and presents their recommendations on how the initiative on Strengthening Pharmaceutical Innovation in Africa can be taken forward to support countries to provide pharmaceutical access and innovation to their populations.

Strengthening Pharmaceutical Innovation in Africa has three broad areas:

- **Preparing an action plan** and proposal to secure funding to provide ongoing support to countries for strategy development and capacity building.
- **Identifying a core of countries interested in becoming 'first adopters' of the Pharmaceutical Innovation Framework and Grid**, supported by NEPAD and COHRED. This will be the first practical approach to putting the GSPOA and AU Pharmaceutical business plan into action at country and regional level.
- **Close monitoring of this work** (for a proof of concept), and sharing this learning with other countries in Africa and beyond as a part of the process.

Summary of recommendations

(Full recommendations are detailed in Chapter 6)

This Pharmaceutical Innovation Tool (Framework and Grid) was reviewed by the AU Technical Committee on the Pharmaceutical Manufacturing Plan for Africa; extended to include a broad group of African leaders in research and policy, pharmaceutical development partners, and members of civil society held in the Pretoria meeting (February, 2010),

The Committee recommended the use of this tool by African countries to design strategies and build their capacity for national and regional innovation.

The study complements previous studies on innovation. The experts confirmed that this study and tool converge with the results of their analysis in 2007. They recommend to use the report findings and tool to support the African Union's business plan for the Pharmaceutical Manufacturing Plan for Africa (PMPA).

Supporting harmonization and evaluation of the 'Global Strategy' and African Pharmaceutical Manufacturing Plan. The experts said that the tool is a useful mechanism for coordinating and harmonising between the various players involved in implementing the Pharmaceutical Manufacturing Plan for Africa (PMPA); and for monitoring and evaluation aspects of the PMPA and WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA).

The group recommended:

- Establishing objectives and milestones for pharmaceutical innovation and manufacturing in Africa.
- Creating mechanisms to stimulate research and development, technology transfer and other conditions needed to facilitate and strengthen manufacturing in Africa.
- Creating a coordination mechanism to ensure better synergy and improved intra and inter-regional support.

Implementing innovation in countries

- Establish a mechanism to manage information on country developments.
- Create a workshop series to ensure governments and regulatory authorities the best available information and share expertise and lessons learned – to include mentoring and partnerships (4.-6 sessions per year over 5 years).

Ensuring Access:

- Strengthen policies and enforce regulations on substandard drugs, dumping of medicines, and donated drugs resulting in mono-therapy and increased resistance.
- Build capacity of agencies to ensure safe, high quality medicines.
- Strengthen drug regulatory capacity, especially for inspection, quality control and laboratory work.
- Increase national capacities to address international intellectual property laws, health insurance.
- Explore regional partnerships to share expertise between countries.
- Build will contribute to sustainable financing and improve access.

Manufacturing:

- Universities to align curricula to produce the skills needed.
- African governments to establish fund to provide low interest loans.
- Country to forge partnerships with agencies (e.g. UNIDO) for WHO prequalification.
- Governments to assist local manufacturers to overcome challenges of prequalification, especially cost of bio-equivalence studies.
- Build capacity in traditional and phyto-medicines, cultivating medicinal plants. Including specific skills of national regulatory authorities in taxonomy, quality control and microbiology, among others.
- Increase competitiveness of local manufacturers.
- Do feasibility studies to provide evidence for financing local manufacturing.

Capacity building for R&D

- Establish an enabling research environment and build human and institutional resources for creating a critical mass of scientific leaders across research institutions in Africa, building up on specific competence already existing in various research institutions and looking for networking opportunities and collaborations, for instance by encouraging the development of regional centres of excellence.
- Promote partnerships between research institutions and private sector to build up capacity in real novel drug discovery.
- Build up specific capacities for dealing with traditional medicines, especially in the areas of developing remedies, pharmacology training, expertise in taxonomy, quality control of medicinal plants and microbiology, among others.
- Encourage African states to allocate 2% of their national budget for research.

"How can my country provide better access to essential medicines?"

The answer to this simple question is a complex one that requires detailed reflection.

To invest in national pharmaceutical innovation, countries can focus on long-term economic benefits by strengthening science and technology and adjacent sectors, such as drug delivery infrastructure. Or they can focus on improving universal access to essential medicines.

Both approaches are viable. And countries often mix the two objectives when considering innovation strategies. In the end, decision makers must be clear on the balance they want to achieve and craft a strategy that meets their short and longer term goals — economic development, improved access, or both.

The expertise needed for local medicines production extends well beyond public health. It also covers research and development, intellectual property, trade and commerce, tax and tariff policies, drug regulatory and registration issues, finance, raw materials procurement, medicines, pharmaceutical manufacturing and marketing.

The capacity to produce should not be viewed independently from the need for building national capacity for innovation.

Chapter 1

Introduction

A 'systems' approach to innovation

This initiative advocates that countries take a systems and evidence-based approach to shaping their pharmaceutical innovation strategies and priorities.

It encourages them to set realistic targets for access and innovation and provides a tool to guide decision makers in the creation of a national innovation system for health – the Pharmaceutical Innovation Framework and Grid.

Successful pharmaceutical innovation is the result of a complex web of interactions between many stakeholders, including multiple government ministries, regulatory authorities, and private and public research, development, teaching and healthcare delivery institutions. Countries have diverse landscapes for health research, innovation and pharmaceutical production.

Each will implement the Global Strategy and Plan of Action (GSPOA) in a different way and needs to better understand where they are situated in terms of health innovation and access to essential medical products, to decide where they want to go and how to get there.

1.1 About this report

Across Africa today there are dozens of activities in the broad area of pharmaceutical innovation – focusing on procurement, development and access to drugs. In contrast, there are no comprehensive descriptions and little evidence on the current status of pharmaceutical innovation[2].

This study aims to fill this information gap. And to equip decision makers to decide where they want to go with pharmaceutical innovation—and reflect on how to get there.

Most current thinking on innovation is based on evidence from developed countries. Apart from some surveys undertaken by the Technical Committee of the AU Pharmaceutical Manufacturing Plan to inform the implementation of the plan, this study is perhaps the first of its kind to offer a critical analysis of the constraints, resources and challenges in the region— from the viewpoint of African decision makers. It focuses on how countries can put innovation into action to support their health needs – in terms of priorities, investment needs – and provides tools for decision makers to design national and regional innovation strategies.

This report also attempts to clarify issues of research and innovation for health and development. These are much-discussed in the 'inner circle' of global health debates and intergovernmental bodies, but less understood by national decision makers who define national policies and strategies in the health, science and technology.

1.2 Background and context

With non-communicable disease on the rise and infectious disease continuing to take a heavy toll on people's health, Africa is confronted with a very high disease burden. Yet, there are well known and sometimes simple solutions that can help African populations address their health problems, especially if they had regular access to safe and effective treatment and care. Access to medicines is a recognised and well-established universal human right; but one that is far from being guaranteed for a majority of Africans.

African governments have taken decisive steps in a series of ministerial declarations[3] to address this problem. The African Union (AU) has adopted a clear policy position *'to pursue, with the support of our partners, the local production of generic medicines on the Continent and make full use of flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration on TRIPS and Public Health*'. To this end, the AU adopted the Pharmaceutical Manufacturing Plan for Africa in 2007 and gave mandate to a technical committee to coordinate the efforts.

The AU and the New Partnership for Africa's Development (NEPAD) are spearheading a number of initiatives to promote knowledge-based economic growth in Africa and to strengthen countries' capacity for policy formulation in the science, technology and innovation sector that includes pharmaceutical innovation.

At the global level, awareness of the need for the international community to improve access to affordable, essential medical products for vulnerable populations has increased over the past decade. Challenged by the burden of HIV/AIDS and pressure from civil society for increased access to antiretroviral medicines, the international community started negotiating new rules and developed new mechanisms for improving access to affordable, good quality, essential drugs and medical products.

While great efforts are being made to provide incentives and support to enhance the accessibility of low and middle countries to life saving drugs – particularly with

the emergence and multiplication of product development public private partnerships – certain diseases and conditions primarily affecting developing countries remain truly neglected[4].

The problem of access to essential medical products – diagnostics and vaccines as well as medicines – persists for reasons that are complex and often interlinked. They have to do with trade agreements, market size, drug pricing, intellectual property and competition within the pharmaceutical industry as well as with a progressively drying R&D pipeline, the financing of R&D and pharmaceutical production, procurement and supply issues, and the failures of health systems in many poor countries and regions. This complex situation calls for a comprehensive approach that will improve coherence among many players across different sectors.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) is probably the most important initiative to date that enables developing countries to access the drugs they need and to support innovation in these regions. Adopted in 2008 by the World Health Assembly, the Global Strategy reached an international consensus on the need to provide long-term support and financial mechanisms for needs-driven research and development on 'diseases that disproportionately affect developing countries'.

Access to medicines is a well-established universal human right; but one that is far from being guaranteed for a majority of Africans.

The GSPOA and the African Union Pharmaceutical Manufacturing Plan (PMPA) are mechanisms that aim to put countries in the driver's seat for access, research and local medicines production. Together, they form the first comprehensive framework and promise of long-term funding to support countries' strategies for pharmaceutical innovation.

The GSPOA and the African Union's PMPA are aspirational statements that need to be translated into practical work plans and action.

With clear political support for the need for access to drugs for low- and middle-income countries, the big challenge now – for global health stakeholders and countries – is how to effectively implement the Plan of Action. Africa faces particularly challenging gaps in access to essential medical products. Countries have very different needs and resources and not all will be able to implement all aspects of the Global Strategy.

This report proposes an overview of pharmaceutical innovation today, analyses its main gaps, challenges and resources and presents a framework for assessing, prioritising and planning pharmaceutical innovation strategies.

1.3 What is 'pharmaceutical innovation'?

Health innovation covers a wide range of scientific, medical, economic and social issues. This study focuses on the concept of pharmaceutical innovation— the discovery, development, production and delivery process that enhance the availability of medical products and people's access to them. In this case, 'medical products' include diagnostics, drugs, vaccines and medical devices.

The industry view of pharmaceutical innovation is largely linear, as illustrated in the drug pipeline that ranges from discovery to registration (Figure 1).

In 2006, the WHO Commission on Intellectual Property Rights, Innovation and Health (CIPIH) described innovation in the developed world as a cycle from discovery of new lead products to development and delivery of new tools and back to discovery through effective demand based on health needs and post marketing research[5]. CIPIH noted that economic constraints in low income countries lead to significant gaps in this cycle. Despite pressing health needs, the demand for pharmaceutical innovation is weak. Figure 2 represents the '3D' Innovation Cycle – of demand, discovery and development.

Research focuses on various problems and results in diverse discoveries: new drugs, new vaccines, and new diagnostics. Beyond all this, existing tools adapted for local application and relevance, new strategies to use these tools, new social or economic policies to reinforce their use or create a supportive environment for their application fall under the umbrella of 'health innovation'.

Just as there is no universally accepted definition of innovation, there is no single definition of what an innovation system is, or what constitutes such a system. Industrialised countries, and some innovative developing countries, may have a structured system to stimulate, support and create innovation, with well-defined actors, established institutions and clear coordinating mechanisms and policies. Many other countries do not have a structured system, only a loose network of players involved in research, industry, or the social aspects of innovation.

1.3.1 Issues for pharmaceutical innovation in Africa

The African population has the world's highest burden of infectious and neglected diseases, and faces a rapidly-rising burden of non-communicable diseases. The hardest hit groups are women and children – half the world's deaths of under-five's are on this continent. This situation is further compounded by a lack of access to essential medicines for many of the affected populations.

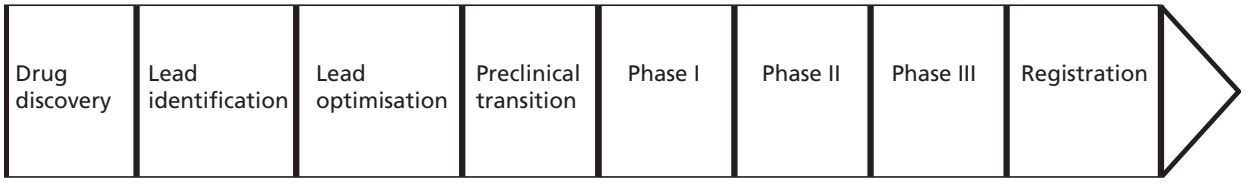
These health needs have been largely overlooked by a predominant focus on drug development for lucrative 'western' markets. The World Health Organization estimates[6] that at least one-third of the world's population lacks access to essential medicines. In poorer areas of Asia and Africa this figure is as high as 50%.

This gap in Africa's access to essential medicines highlights an urgent need to prioritize the public health agenda, in areas such as improving weak health systems, increasing the health workforce in quality and numbers, and more directly addressing the needs of disenfranchised populations. The development of knowledge-based economies, including a thriving pharmaceutical sector, will support the continent's economic development.

Recent international trade rules – requiring that countries comply with World Trade Organization TRIPS regulations[7] – risk jeopardizing access to essential medicines by driving up cost of generic pharmaceuticals, which are affordable today. To mitigate this risk, the *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* confirmed in 2001 that TRIPS should not prevent Members from taking

Figure 1, Drug pipeline, from discovery to registration

The linear approach of the classic pharmaceutical product development pipeline



Adapted from Solomon Nwaka and Robert G. Ridley. Virtual drug discovery and development for neglected diseases through public–private partnerships. Nature Reviews Drug Discovery (2003) 2: 919-928

measures to protect public health, and that countries can use public health safeguards in the TRIPS Agreement.

This was a major achievement that allowed India – one of the major exporters of pharmaceuticals to Africa today – and China, to manufacture and export drugs, making affordable antiretroviral medicines (ARVs) available in developing countries and worldwide.

While TRIPS flexibilities offer a window of opportunity (until 2016) for the least developed countries to locally manufacture pharmaceutical products needed for public health, the practical implementation of this policy could be hampered by countries' lack of capacity to manage legal, scientific, technical and fiscal aspects of pharmaceutical innovation. Very few low and middle-income countries are likely to be in a position to take advantage of this opportunity. In addition, recently-negotiated bilateral trade agreements further limit the ability of some countries to produce generic drugs and may have adverse consequences on the affordability of essential drugs[8].

Nevertheless, developing countries are striving to find alternative solutions. Some seek South-South collaboration to develop production. For example, the Indian company CIPLA is establishing manufacturing plants in Africa. Brazil, too, is providing support to African countries to strengthen their pharmaceutical innovation.

The complex and dynamic trends in the global pharmaceutical market and global trade rules highlight the need for African countries to strengthen their capacity on two fronts: for research, development and local pharmaceutical production; and the ability to engage constructively in debates and deliberations that affect the health of their populations. In this picture, high income countries are well placed to support the capacity development of their lower income counterparts.

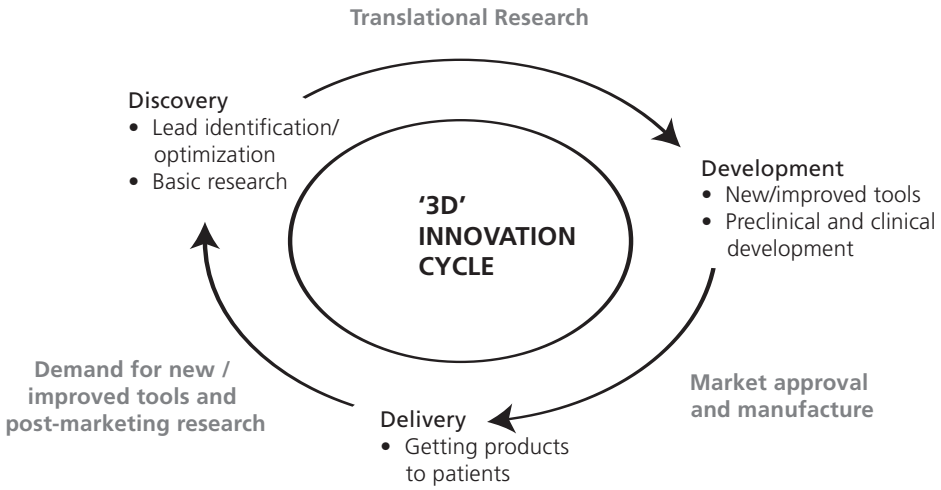
1.4 Scope and method

The geographical scope of the study is Africa. It focuses on diseases that disproportionately affect Africa, including neglected tropical diseases.

The method used was keyword internet searches, key informant interviews and discussions review of literature and documentation[9], participation and consultation in a number of international meetings and consultations on pharmaceutical in several low income countries. The data obtained was analyzed manually along main emerging themes. The draft report was externally peer reviewed.

Figure 2, '3D' Innovation Cycle

The innovation process as a cycle which presents demand and the population's health needs.



Step 1: Identifying and categorising projects and programmes contributing to the improvement of access to medical products in Africa. Global, regional and national examples were considered.

Step 2: examination of a minimum set of conditions, policies; human, structural and financial resources to identify initiatives most likely to be successfully implemented in any African country.

To guide reflection and analysis, several visual tools were used throughout the study process (Annexes 6 and 7) resulting in the development of the framework and grid presented in Chapter 5.

1.4.1 Limitations

Due to limited scope, budget and time, the pharmaceutical innovation initiatives mapped in this paper are not exhaustive. A few illustrative, thought-provoking examples have been chosen, based on their unique contributions to specific components of pharmaceutical innovation in Africa.

The extent to which some of the initiatives listed in this report contribute to pharmaceutical innovation in Africa has yet to be clarified. Evaluating the effectiveness of these initiatives was beyond the scope of the study and will be an important next step.

Finally, the report reflects the predominant situation in a majority of African countries; but it does not fully represent the continent's heterogeneity. It is hoped that subsequent phases of the project – that aim at using the tools developed as a result of this work – will allow for more in depth study of the specifics of disease burden, R&D capacities, production potential and level of development of the countries selected for implementation.

Context analysis

Chapter 2

2.1. Africa's burden of disease

Africa is home to 11% of the world's population. It consumes less than 1% of global health expenditure[10]. Yet it carries 25% of the world's burden of disease.

Major contributors to this disease burden are:

- diseases of poverty, such as malnutrition,
- infectious diseases, such as HIV/AIDS, malaria, diarrhoeal diseases, pneumonia
- neglected tropical diseases (NTDs)
- diseases predominantly affecting African populations, such as sickle cell disease
- non-communicable diseases, which are on the rise.

These problems are further compounded by limited access to safe, effective, quality and affordable medicines, vaccines and diagnostic tools. Africa's disease burden raises concern on many fronts. Unmet health needs result in high morbidity and mortality, creating a vicious cycle of poverty, disease, disability and death.

2/3 of the global value of pharmaceutical products are produced in 5 countries (USA, Japan, France, Germany and UK). Japan and USA contributed to 47% of global production value in 1999.

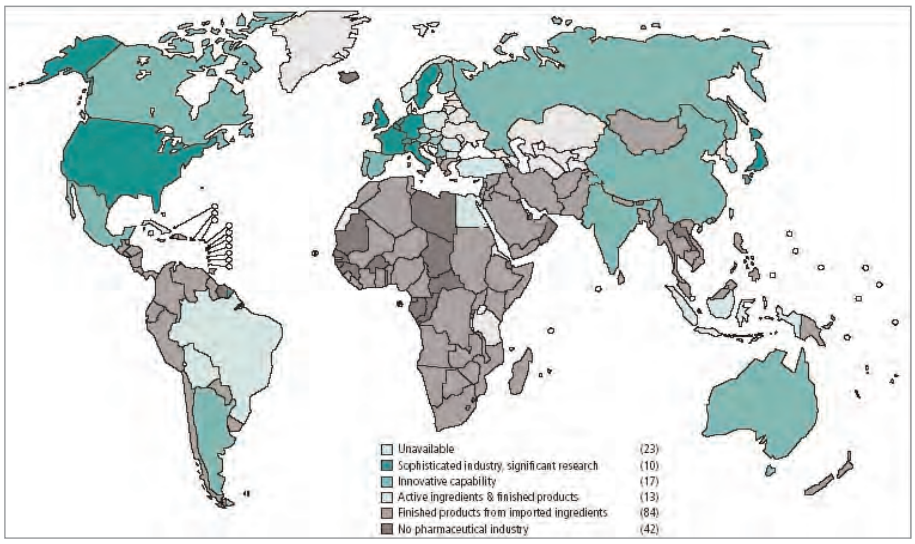
Malaria's economic burden

Africa bears 90% of global malaria deaths. In addition to this, the direct and indirect impact of malaria results in an estimated US $12 billion annual income loss in Africa, which translates to a 1.3 % annual loss in growth domestic product (GDP) in malaria-endemic countries[11]. These significant health and economic losses from malaria and other high-burden diseases are compounded in countries struggling under a heavy debt burden, faced with weak governance, prolonged war and civil conflict, famine and other environmental catastrophes.

2.2 Africa in the global pharmaceutical picture

Two thirds of global value of pharmaceutical products are produced in 5 countries; USA, Japan, France, Germany and UK. Japan and USA jointly contributed to 47% of global production value in 1999[12].

Figure 3,[13] Local pharmaceutical R&D and production (WHO 2004)



In 1998, more than 97 % of research and development activities occurred in developed countries[14]. Africa's capacity for pharmaceutical R&D and local drug production is among the lowest globally. Overall, 37 countries have some pharmaceutical production, and only South Africa has limited primary production of active pharmaceutical ingredient (API) and intermediates[15]. Local production in Africa therefore relies on imported active ingredients. As a result, the sustainability of African pharmaceutical supply remains highly contingent on foreign funding and manufacturing. While national capacity for local production has increased – with, for example, Egypt and Tunisia producing between 60% and 95% of their national requirements for essential medicines[16] – it is still dramatically low in many countries of the continent, and Africa will remain dependent on imports for at least the medium-term.

These disparities are replicated in global R&D for health needs specific to Africa. Though much effort is needed to address the dismal and outdated pool of products available for use in Africa, stimulating interest for R&D is an onerous task in this predominantly market-driven industry. From 1975 to 2004, only 1.3% of the 1556 new chemical entities registered were meant for use in tropical diseases and tuberculosis, even though these diseases account for 12% of the global disease burden[17]. Despite bearing a disproportionately large share of the global disease burden, African markets remain unattractive because most countries have poor public health financing mechanisms and their already disenfranchised populations largely resort to out-of-pocket payments to finance their health care[18].

Prevailing trends in the global pharmaceutical sector bring additional barriers to Africa's access to essential pharmaceutical products.

Prevailing trends in the global pharmaceutical sector pose additional barriers to Africa's access to essential pharmaceutical products. Pharmaceutical R&D pipelines are running dry as 'low hanging fruit' (chemical entities that are easy to develop) have already been picked. In addition to this, there is increased competition from emerging pharmaceutical markets such as Brazil, Russia, India and China (BRIC) which are broadening their drug portfolios beyond generic products to include innovator drugs for western markets.

For Africa, this situation brings a comparative advantage in the area of pharmaceutical innovation, development and production using African Traditional Medicine and the continent's rich biodiversity as raw materials of choice. This presents a unique opportunity for investment in pharmaceutical innovation in Africa. Over 80% of Africa's natural raw materials have not been subjected to standard scientific evaluation.

Furthermore, about 67% of new medicines introduced worldwide from 1981 to 2002 were derived from natural sources. These facts provide compelling justification for investing in biodiversity as basic raw materials for pharmaceutical innovation, development and production.

2.3 The poverty factor

The disparities in global pharmaceutical research, development and production are a reflection of underlying global inequities in health and socioeconomic development. Poverty is a break on the potential of countries, regions and the continent to develop. A poor country has fewer resources to invest in pharmaceutical innovation, especially in the face of competing priorities and limited resources. This is illustrated by the low levels of government commitment to financing health research and development in science and technology in most African countries. With the exception of South Africa, which invests 0.9%.of its GDP in research and development, R&D intensity in the rest of Sub-Saharan Africa is generally less than 0.3% of GDP[19]. Further, the potential for private-sector contributions to bridging financing gaps is hampered by the high business risk posed by unstable political environments, poor governance, and weak or absent legal and regulatory frameworks.

Better health creates more wealth. Health as a driver of economic development.

Some decision makers recognise that the ultimate benefit of stronger pharmaceutical innovation in Africa goes beyond curing disease and delivering medicines; saying that a healthier workforce brings significant economic gains to a country, as people can better contribute to economic development. Evidence also shows that knowledge-based economies are a catalyst for helping countries break the poverty/disease/disability/death cycle. Driving this are interventions that focus on health, equity and development considerations.

Comments on Commission on Macroeconomics and Health 2001[20], WHO Commission on Social Determinants of Health 2005[21]

2.4 Changing landscape, new actors, new funding sources

In the past decade, changes in the environment, demography, patterns of diseases and the global economy have created new challenges for research. Low-income countries are facing an increase in non-communicable diseases, along with the ongoing threat of infectious conditions – some re-emerging as a consequence of HIV/AIDS or drug resistance.

A host of Public Private Partnerships (PPPs) have emerged to address these challenges. Their approach is to stimulate R&D for neglected diseases while minimising business risk. This R&D is typically done as not-for-profit or no-profit-no-loss, by partnerships involving public, multilateral and bilateral agencies, pharmaceutical companies, NGOs and philanthropies.

These partnerships, especially those developing new medical products based on the needs identified by the most disadvantaged countries – known as Product Development Public-Private Partnerships (PDPPPs) – are seen as a positive force. They have raised great expectations for expanding the pool of products available for improving the health status of the most deprived populations. However, some prevalent diseases and conditions— for example, trypanosomiasis, schistosomisasis or filariae — are still truly neglected, partly because of restricted potential markets.

New partners develop medicines for neglected diseases

The Novartis Institute for Tropical Diseases in Singapore is one example of the institutions and projects created specifically by global pharmaceutical companies to address neglected diseases. Such initiatives are motivated by corporate social responsibility and ethical concerns, and a strategic eye on engaging emerging markets in developing countries. The Bill and Melinda Gates Foundation is another new and important player. It is trying to stimulate the emergence and application of innovative scientific techniques and approaches to neglected diseases and speed-up the development of new drugs, diagnostics and vaccines.

2.5 The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property

Another new force in the medicines development landscape is the *Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property*. The strategy and plan resulted from the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property[22].

The Strategy and Plan of Action were adopted in 2008 by the 193 WHO member countries after a six-year consultation and negotiation process. It is a mechanism to ensure long-term, needs-driven, research and development and a funding framework for medicines that affect developing countries. The strategy and plan propose clear objectives and priorities for promoting innovation, building capacity, improving access and mobilising resources. The funding levels called for are US$ 149 billion between 2009 and 2015 – an average of US$ 21 billion per year.

Implementation of the Global Strategy and Plan of Action at regional and country level is entrusted to the Secretariat for Public Health, Innovation and Intellectual Property (PHI) of the WHO.

Global Strategy and Plan of Action – 8 core elements

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of intellectual property
6. Improving delivery and access
7. Ensuring sustainable financing mechanisms
8. Establishing monitoring and reporting systems

An expert working group has been set up to examine current financing of product R&D and study proposals for innovative sources of funding. Its report is due in 2010. The implementation of the Strategy and Plan of Action at regional and country level has been entrusted to the Secretariat for Public Health, Innovation and Intellectual Property (PHI) of the WHO.

2.6 Noordwijk Medicines Agenda and Yaoundé Process

In parallel with the IGWG and Global Strategy process, the Organisation for Economic Cooperation and Development (OECD) and the Netherlands together brought a group of countries to discuss stimulating innovation and accelerating development and delivery of medicines for neglected and emerging infectious diseases. The approach included medicines, vaccines and diagnostics needed by developing countries[23].

The resulting call for action was called the Noordwijk Medicines Agenda[24, 25], a positive step by OECD countries to become more active in providing incentives for drugs research and production to deal with neglected diseases. The action plan recommended, among other things, increased networking and partnerships between research actors.

The Yaoundé Process grew out of a need identified by the Cameroon's Minister of Public Health, supported by some African participants at the Noordwijk meeting, to develop a 'complementary African agenda' to look at medicines access and long-term socioeconomic development *from the perspective of the African countries*. This 'complementary agenda' aimed to develop and strengthen an African vision on health innovation and medicines R&D and production, and build north-south partnerships. The Council on Health Research for Development (COHRED) was engaged to facilitate this work, named the 'Yaoundé Process'.

The primary goal of the Yaoundé Process was to strengthen health innovation in Africa and complement:

- the GSPOA on Public Health, Innovation and Intellectual Property by putting its principles into action at regional and country level.
- the work of NEPAD for harnessing political support of African leaders, harmonising regulations and processes in public health and health care systems, and for "shaping and driving a new research and innovation agenda".[26]

A platform for African countries to assess needs and design innovation strategies

The Noordwijk Medicines Agenda and the Yaoundé process, support African countries, global health players and the Global Strategy and Plan of Action, to:

- Assess the situation of innovation activities, projects and programmes in Africa today.
- Identify African countries' specific needs for technologies and skills to strengthen pharmaceutical R&D, production and delivery to improve populations' access to medical products.
- Implement the Global Strategy and Plan of Action at region and country level.
- Inform NEPAD's efforts to harness political support of African leaders, harmonise regulations and processes in public health and health care systems, and shaping a new research and innovation agenda.

This will lead to the creation of new evidence and tools to put African countries in a stronger position to negotiate with partners and assist countries to design national health innovation strategies and action plans.

Chapter 3

A picture of pharmaceutical innovation in Africa

Despite the dozens of initiatives in Africa for pharmaceutical innovation and access to medicines, a closer look points to the lack of a grand plan for the continent - defined by the needs of countries.

3.1 The African landscape is complex

This chapter presents a map of innovation initiatives and activities in Africa. This information aims to improve understanding of the current landscape and major challenges for the continent. It offers a starting point for further discussion and reflection on the current state of play for pharmaceutical innovation in Africa and encourages others to contribute useful information and participate in a dialogue.

This is the first attempt to provide a comprehensive view of all initiatives working to increase access to essential drugs in Africa. It is not complete. The study presents examples of initiatives and activities contributing to the improvement of pharmaceutical innovation and access to medical products in Africa. It attempts to give a clear view of what is currently in progress, who are the players. It points to issues that countries face in developing national strategies for pharmaceutical innovation approaches.

The first step was to identify the many programmes and initiatives designed to improve pharmaceutical innovation and access to essential drugs in Africa and group them into broad categories. This information is presented in annex 5. Step-two displayed them in a logical way. The resulting map (Figure 4) shows the different initiatives according to their main level of interaction – national, regional, global – and grouped by the elements of the pharmaceutical innovation process their mostly contribute to. The map helps to identify gaps and potential synergies (see Annex 6).

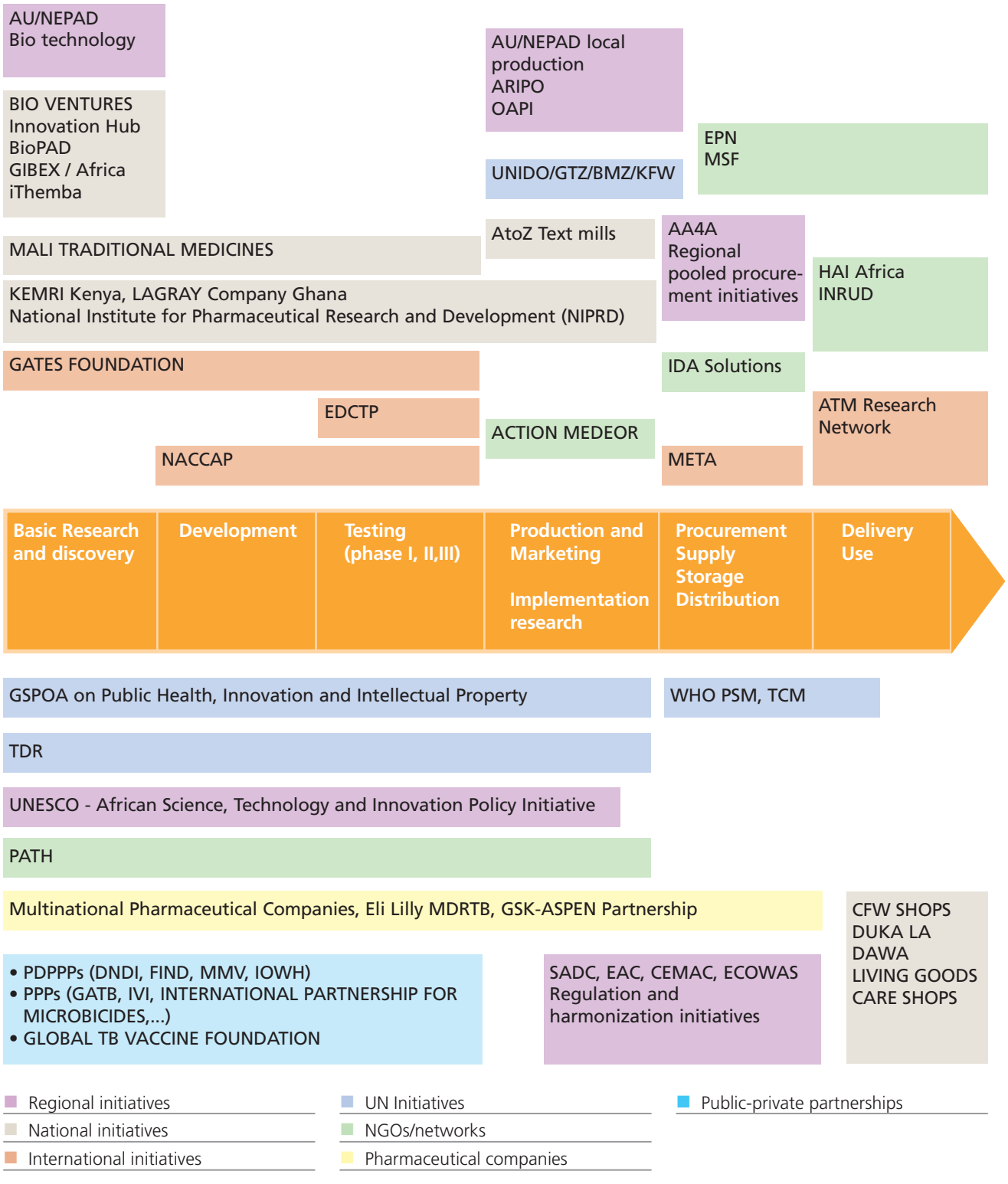
3.2 African traditional medicine has an important role to play

The World Health Organization (WHO) estimated that some 80% of people living in developing countries use traditional medicine to address their health care needs. In some rural areas (constituting about 70% of the continent's population), traditional medicine may be the only health care system that is available, accessible and affordable for them. Even in urban areas, many people consult Traditional Medicine Practitioners (TMPs), before going to Conventional Medicine Practitioners (CMPs) if traditional approaches fail to respond. It has also been observed that some patients routinely combine herbal medicines obtained from TMPs or open markets with conventional medicines. Evidently, the public has confidence in TMPs and the products they dispense. Cost may be a factor in the widespread use of traditional medicines. And certainly, the long history of traditional medicine use has made it an important and inseparable part of African culture.

The natural environment provides man with resources for his survival. Plants, animals and minerals constitute the major natural resources used by man for promotive, preventive, curative and rehabilitative health. In Africa, these resources have been used by traditional medicine practitioners who acquired their knowledge and skills through observation, spiritual revelation, experience, training and direct information from their predecessors over many centuries. In recognition of the crucial role that African traditional medicine plays in health care delivery in Africa, in 2001, the African Regional Committee of the World Health Organization adopted the Regional Strategy on Traditional Medicine which aims to promote the development and integration of traditional medicine into the public health care delivery system. In 2001, the Summit of African Heads of States declared 2001-2010 the Decade for African Traditional Medicine. In 2004, the African Union developed a Plan of Action and an Implementation Strategy for traditional medicines which were adopted by the Ministers

Figure 4

Examples of pharmaceutical innovation initiatives in Africa mapped along the drug development and access pipeline. (COHRED 2009)



The map of pharmaceutical innovation in Africa reveals a complex landscape with multiple actors – including governments, pharmaceutical companies, UN agencies and other international organisations, NGOs, Public Private Partnerships and civil society organisations. These players are engaging with countries at various levels and sectors, addressing different steps of the pharmaceutical innovation process.

A large number of initiatives have been identified. The information emerging points to the lack of a 'grand plan' – or coordinated approach to pharmaceutical innovation on the continent. There are gaps in different parts of the innovation process and much potential for duplication. Perhaps most striking is the picture of international agencies, and other health programmes and initiatives active across Africa, effectively shaping the innovation and medicines access policies for the continent, without the transparent or explicit involvement of national governments.

of Health in Africa and endorsed by the Summit of African Heads of State. In addition, the WHO developed tools which Member States can use to integrate African Traditional Medicine into the public health care delivery system.

3.3 Available evidence is not effectively disseminated

There is a reasonable amount of evidence on pharmaceutical innovation in Africa, but no centralized repository. Knowledge on the topic is shared within the circles of specialists involved in particular steps of pharmaceutical innovation but rarely outside each specific group. To complicate matters, much of this information is presented in a format that is not accessible to non-specialists, creating a barrier for its translation into actionable policies, strategies and action plans.

One striking example is the current debate on intellectual property rights as incentives or barriers to innovation and improved access to drugs. Many government officials in Africa find it difficult to make meaningful contributions to the discussions and to take appropriate decisions at national level as they lack expertise in intellectual property management.

Activities exist in Africa that cover almost every step of the pharmaceutical innovation process.

In the first meeting of the African Network for Drugs and Diagnostics Innovation[27], African researchers clearly identified the lack of bridges and information sharing between them and industry, investors and intellectual property managers as a key obstacle to developing their discoveries into usable, safe and affordable medical products.

There are gaps in the conceptual thinking on pharmaceutical innovation as it applies to the African context. Most current thinking 'for Africa' is based on research from the developed world, on experiences in the rapidly developing new economies – Brazil, Russia, India, China – and on studies done in selected African countries.

Furman and colleagues[28] propose a framework for assessment of national innovative capacity, but their research included only two African countries - South Africa and Mauritius. Morel and colleagues[29] highlight the 'need for innovation system theorists and global health practitioners to develop a more sophisticated literature on health innovation in developing countries'.

In addition, existing evidence is poorly disseminated. Some of those interviewed for this study highlighted communication barriers related to:

- A lack of inter-sectoral mechanisms to enable communication at international, regional and country levels, and between policy and technical levels.
- High turnover of policy makers, which makes it difficult to ensure a shared vision and a continuum of knowledge.
- Low absorptive capacity of countries.

Activities can be found in Africa that address almost every step of the pharmaceutical innovation process, but little seems to be done in terms of monitoring and evaluating the various initiatives to improve pharmaceutical R&D, production and access in the region. Also, the local activities identified seem to focus mostly on discovery, especially for traditional medicines, and on facilitating supply and use of medical products. Global efforts, in turn, tend to concentrate on the first steps of the process, with only a few initiatives focussing on delivery and access. The study found little evidence of explicit attempts to build pharmaceutical innovation capacity in countries as a part of these many initiatives.

3.4 Better coherence and coordination are necessary

Analysis of the current landscape suggests the need to improve coherence and to leverage the African strengths in pharmaceutical innovation – at continental, regional

and national levels. One such effort is the African Ministerial Council on Science and Technology (AMCOST) which adopted Africa's science and technology plan of action[30] in 2005. It focuses on improving the quality of science, technology and innovation policies in six areas:

- Supporting the African Science, Technology and Innovation Indicators Initiative (ASTIII)
- Improving regional cooperation in science and technology
- Building public understanding of science and technology
- Building a common African strategy for biotechnology
- Building science and technology policy capacity
- Promoting the creation of technology parks

The African Union's' *Pharmaceutical Manufacturing Plan for Africa* is another example. It charts the way for local production of medicines to treat HIV/AIDS, tuberculosis and malaria. Various public-private drug development partnerships (PPDPs) can also take a more coherent approach to local production, but some have questioned the extent to which these partnerships improve the capacity and promote the growth of the nascent African industry[31]. The current effort by AU/NEPAD to harmonise drug regulation around Regional Economic Communities (RECs) is another example.

But much still needs to be done for harmonising expectations and efforts across levels, especially between globally and nationally (or regionally) driven programmes.

3.5 Countries need to be placed at the centre of decisions for pharmaceutical innovation

While African governments show a growing interest in improving their populations' access to affordable essential drugs, there are currently no tools, no methods that countries can use to take action to strengthen pharmaceutical innovation in a way that addresses national priorities. African interests and demands exist at all levels of pharmaceutical innovation but very few deliberate strategies are in place to operationalise it.

The Global Strategy and Plan of Action process has demonstrated the eagerness of African countries' involvement in the global debate on needs-driven R&D for access to essential drugs. As a result, there is an increasing demand for pharmaceutical innovation from African countries. However, this demand tends to focus on local production and demonstrates insufficient understanding of the implications of embarking on this complex process, its consequences and other possible options to ensure medicines access – following a national or regional strategy.

Pharmaceutical innovation initiatives typically approach national partners in an uncoordinated manner, and are driven by their own objectives. International programmes will sometimes do national needs assessments and set objectives that should result from self-evaluation and priority-setting done by the country from a broader perspective of national health and development needs.

To embark on improving access to medicines, research and development and local production – and more generally to participate in putting the Global Strategy and Plan of Action into practice at country and regional level – African countries need to be at the centre of the decision making processes for pharmaceutical innovation.

It is their responsibility and prerogative to understand the system and critically assess where they want to go and how they want to get there. The role of the international community, then, is to inform and support national decision-making processes and make available the knowledge, technical tools, human and financial resources that countries require – not assuming control of country-level processes.

Chapter 4

Essential building blocks for national pharmaceutical innovation

This chapter discusses requirements and conditions for countries to consider when developing a pharmaceutical innovation strategy. After reflection on these points, decision makers and research managers can use the tools and guides in Chapter 5 to design their national strategies and put an innovation plan into action. A map of some of the main elements described below – elements that need to be put in place for a national innovation strategy to be effectively implemented – is located in Annex 7.

4.1 Prerequisites

4.1.1 Creating an investment-friendly environment

A solid and stable political system is the number one requirement for attracting investment to a country. A recent survey of[32] chief executive officers from East Africa noted political risk as the single most significant challenge for business in East Africa. These CEOs proposed that the private sector engage governments to deliver on good governance and management as a priority.

Linked to this are a number of infrastructure and framework components that underpin a knowledge-based economy. Governments' illustrate commitment to this through:

- The presence of a national science and technology/innovation policy.
- Effective government policies and laws on intellectual property and drug regulation, including effective structures for law enforcement.
- Incentives to attract foreign direct investment, such as tax breaks, local indirect tax exemptions and lower custom tariffs.
- Mechanisms to finance innovation through government funding or links with the private sector or external funders.
- Research institutions with specific mandates in core relevant areas of science, technology and innovation where Africa has comparative advantage.

Credible national priorities contribute to create a favourable environment

Evidence-based priority setting enables the focused targeting of resources, a process which facilitates innovation. With specific reference to the Southern African context, Du Toit[33] proposes the following principles for prioritising, innovation and research that are:

1) absolutely necessary for national competitiveness (e.g. information technology andbiotechnology);
2) present some "geographic" advantage (e.g. astronomy and "human origins");
3) present a "problem" advantage (e.g. HIV/AIDS vaccine for Africa);
4) present a "knowledge" advantage (e.g. traditional knowledge or deep-level mining).

4.1.2. Enabling policies and supportive initiatives

A comprehensive policy framework is also required – for health and health research, science and technology, industry, trade, law and education.

In emerging economies where proactive policies have been established to stimulate health innovation, a key early step has been to establish close collaboration between health and science and technology. Brazil offers a good example of close coordination

between the ministries of health and science and technology to spearhead national research and innovation for health.

During the past decade, many African countries have shown interest in developing their national health research systems. Recent evidence suggest, however, that only a few African countries have a health research policy in place.

A number of multilateral and bilateral initiatives exist in Africa to strengthen country capacity for policy formulation in the science, technology and innovation sector– many coordinated by the AU and NEPAD.

Improvement of Africa's policy environment is needed both nationally and at the regional level – as demonstrated by the present efforts of NEPAD and Africa's Regional Economic Communities to harmonise drug regulations in Africa.

Further efforts are also needed to better articulate national, regional and global policies.

Table 1: Examples of policy-level initiatives for science, technology and innovation in Africa

Focus	Initiative
Policy Development at national and regional level	• AU/NEPAD Consolidated Science and Technology Plan of Action • African Science, Technology and Innovation Policy Initiative – UNESCO collaboration • Africa Technology Policy Studies Network (ATPS) • UN Science and Technology Cluster support to the AU Consolidated Plan of Action
Influencing Policy at global level	• Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property GSPOA • IQSensato • Knowledge Ecology International • MSF Access Campaign • OXFAM • Third World Network

Advocacy for coherent global policy approaches

A number of initiatives seek to influence global policy on issues related to public health, trade and intellectual property management in LMICs, including Africa. Sustained advocacy efforts from the Médecins Sans Frontières (MSF) access campaign achieved drastic price reductions in developing countries for antiretroviral medicines (ARVs) for the treatment of AIDS-related conditions.

The generic antiretroviral fixed-dose combination Lamivudine/Stavudine/Nevirapine (3TC/d4T/NVP) now costs US $87 per patient per year. This is a price reduction of 99% compared to the cost of the 2001 originator product (US $10,000 per patient per year). The price difference before and after generic producers started making ARVs constitutes a more than a 99% price reduction[34].

4.1.3 Strengthening functional health research systems as essential foundations

Priority setting and research management

That research is to be essentially needs-driven is a central message of the GSPOA. However, there is still a long way to go to make this a reality for many low and middle income countries. While there are well trained researchers in many African countries, the extent to which they work on national priorities is often not in their power to decide. In many cases, the key question is indeed "who sets the priorities?" Many low and middle income countries contribute more to their overall budget for research institutions and workforce than they receive from external sources. Yet, it is the external contributions that often decide what research questions are being addressed.

Recent studies[35] show that research projects in Africa tends to be mostly financed by external sources. Most countries rely on foreign partners for research funds and these partners usually commission research as disease or condition specific – or vertical – programmes. For example, between 1991 and 2000, 100% of research project funds in Tanzania came from foreign sources[36]. Uganda does not provide any project funding for health research[37], while external research project income totals some $24 million[38].

This leads to a situation where national research production in many LMICs addresses only a few high profile health conditions – those for which funding is available – neglecting other major national priorities that can benefit from research. The recently published G-FINDER 2008 survey reveals that over $2.5 billion was spent on neglected disease R&D in 2007. Of this amount, almost 80% went to three diseases: HIV/AIDS, malaria and tuberculosis[39]. Other diseases responsible for high disease burden in Africa, for example helminth infections, childhood disability, hypertension or pneumonia, receive limited attention and financial support.

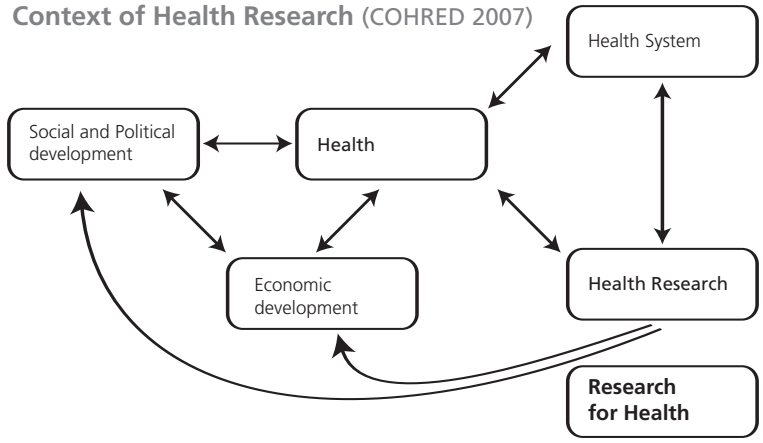
Not all countries in Africa have a health research policy and well installed processes to prioritise, plan and implement research with all concerned stakeholders – including negotiating with external research funders for ensuring that the research they support addresses national needs. Country-level mechanisms are needed at to help set national research priorities and manage research in a way that addresses them.

From health research to 'research for health'

Research can be a key driver of technical, social and economic development in low- and middle-income countries, but its full potential is rarely fully realised. Health research is essential for pharmaceutical and technical innovations, for improving health systems performance, to control epidemics of acute and chronic conditions, to measure impact of interventions and to give timely warning of potential environmental threats and risk factors.

The new concept of 'Research for Health'[40] - emphasizes a multi-sectoral approach in the use of research to improve health, health equity and development of countries.

Figure 5, 'Research for Health'



Individual and institutional capacity building

Development of the pharmaceutical innovation sector requires presence of a critical mass of knowledgeable, skilled and motivated professionals, and an enabling institutional environment.

There are a number of initiatives focused on building research capacity at institutional and individual level. At the most basic level are initiatives focusing on institutes of higher learning such as the Nelson Mandela Institute. At the more technical level, efforts are directed at training scientists in particular techniques or for researching on specific diseases of high prevalence in Africa– for example through the African Programme for Onchocerciasis Control, APOC, and the African Malaria Network, AMANET. While these and several others are reputed for building and strengthening disease specific research capacity – efforts for building up technical or managerial capacities that are applicable across national research systems have been much less deliberate and sustained.

For many years, capacity strengthening efforts tended to concentrate on developing individual capacities in specific domains and scientific specialities that were felt to face the greatest needs. Many stakeholders increasingly recognise the value of a systems approach to research for health and the need to build enabling institutional and national environments.

Research capacity gaps

In addition to the gaps mentioned above, Africa faces a lack of resources specific to the complex pharmaceutical research, production and delivery process. A 2008 health product survey identified the most significant human resource capacity gaps for pharmaceutical innovation as being in preclinical / safety pharmacology and raw material processing to GMP standards[41]. Experts consulted during our survey also highlighted gaps in capacity to conduct clinical trials quality assurance systems and drug regulation.

The European and Developing Countries Clinical Trials Partnership (EDCTP) is an initiative that aims to strengthen capacity for clinical trials, especially the regulatory and ethical review components through partnerships with African institutions. To achieve this, EDCTP collaborates with other organizations such as WHO, UNESCO, AMANET, COHRED, among others. These and other examples of initiatives to build up research capacity in Africa are highlighted in the table below. A more detailed mapping can be found in Annex 5.

"It is critical for low and medium income countries (LMICs) to achieve and sustain the minimum knowledge-based mass needed for creativity, credibility and innovation in health and development. The vigorous call to action for building and retaining the health workforce in LMICs must also include strategic action for research capacity strengthening."
(Lansang, GFHR Updates Vol. 4)

Table 2: Examples of initiatives to address research capacity gaps

Focus	Examples of Initiatives
Higher education	• Nelson Mandela Institute
Drug discovery and development	• African Network for Drugs and Diagnostics Innovation (WHO/TDR/ANDI) • AU/NEPAD panel on biotechnology • Global Institute for Bio-Exploration – Africa (GIBEX-Africa) • International Centre for Genetic Engineering and Biotechnology (ICGEB) • Natural Products Research Network of Eastern and Central Africa (NAPRECA) • Special program for research and training in tropical diseases (TDR)
Clinical trial capacity, including ethics review committees	• African Poverty Related Infection Oriented Research Initiative (APRIORI) • Council on Health Research for Development (COHRED) • European Developing Countries Clinical Trial Platform (EDCTP) • Initiative to Strengthen Health Research Capacity in Africa (ISHRECA) • Malaria Clinical Trial Alliance (MCTA) • Special program for research and training in tropical diseases (TDR)
Knowledge management	• WHO Health Research Systems Analysis (HRSA) • WHO International Clinical Trials Registry Platform (ICTRP)
Disease focused	• African AIDS Vaccine Program (AAVP) • African Program for Onchocerciasis Control (APOC) • African Malaria Network Trust (AMANET) • South African Malaria Initiative (SAMI) • Special program for research and training in tropical diseases (TDR) • Mali malaria research centre

4.2 Essential components

4.2.1 Intellectual property: The Achilles' heel?

Intellectual property is another essential issue that African countries must address. The challenge for countries is to work within intellectual property rules to provide incentives for pharmaceutical R&D based on pro-public health and pro-access principles.

Challenges abound. Not all African countries have adopted national intellectual property measures that protect their populations' health interests. They often lack the skills in intellectual property management and face difficulties negotiating patent conditions and existing agreements to ensure procurement of the most cost-effective and high-quality drugs to meet their specific disease needs. A 2009 NEPAD paper[42] highlights gaps for intellectual property management in science, technology and innovation in public health. These include knowledge gaps for:

- implications of intellectual property rights on technology transfer
- access to medicines and foreign direct investment
- implications of the range of TRIPs flexibilities.

Intellectual property and access

There is an ongoing debate on intellectual property and its influence on access to medicines in developing countries. One side argues that the high price of innovator medicines poses a major barrier to poor countries' access to essential and life-saving medicines. The other side feels that protection and reinforcement of intellectual property is a necessary incentive for innovation and for returns on the investments made to bring new products to market.

High medicine prices are linked to the patent life of the medicine. The 1994 TRIPs Agreement reinforced patenting requirements by allowing exclusive rights for a company to determine the price of a new product for up to 20 years from the time it comes to market. This agreement broadened the scope of protection to include both product and process patents, as well as patent protection on medicines and food products.

As a result, countries like India and China that were previously able to produce cheap generic medicines through reverse engineering can no longer do so. India and China have been the source of most of the generic medicines used in Africa, and the concern is that access to medicines could be severely hampered by this new regulation. In the PMPA, African ministers of health recognise that "*the fact that India and China had to comply with both process and product patent laws by 2005 was seen as a potential threat to affordability and access to essential drugs in Africa*[43]".

Intellectual property protection: impact on public health

The World Trade Organization (WTO) is an international organization of 148 Member Countries dealing with the rules of trade. In joining the WTO, Members adhere to specific agreements. Of these agreements, Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimumstandards for a set of intellectual property rights that WTO Members institute through national legislation.

TRIPS also contains provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. Patents on medicines have been one of the most hotly-debated topics since the adoption of the TRIPS Agreement because patents grant exclusivity for the duration of the patent term and result in patent holders having control over the production, supply, distribution and, by virtue of exclusivity, price.

It is argued that patents are crucial for pharmaceutical innovation and that, without them, there will be no financial incentive to fund the costs of discovery and development of new medicines. However,medicines prices in developing countries are often well above production costs. Developing countries account for a very small fraction of the global pharmaceutical market and the generation of income to fund more research and development is not dependent on profit from these markets. Indeed, until now, the patent protection system has provided very little incentive for research and development of new medicines needed for diseases afflicting developing countries, which highlights the ineffectiveness of relying solely on the private sector to develop essential medicines. In many countries where payment for pharmaceuticals is "out-of-pocket" and health insurance is rare, escalating and unrealistic prices play a central role in denying access to patients of life-saving medicines.

WHO Drug Information Vol 19, No. 3, 2005

While generic production is possible for many essential medicines because they are off-patent in most of the developing countries, this does not apply to new medicines, which are subject to 20-year protection. The TRIPS Agreement introduced global minimum standards for protecting intellectual property rights (IPR), including patents. The agreement now also requires all WTO Members, with few exceptions of the least-developed countries, to comply with the agreement by 2016, by adapting their laws to the minimum standards of IPR protection.

In 2001, the Doha Declaration on public health ('Doha Declaration') authorised the use of flexibilities such as compulsory licensing and parallel importation as means to address problems of access to essential drugs. However, in most developing country contexts, the effective implementation of these flexibilities is hampered by a number of constraints, that Musungu[44] and colleagues group into two levels: constraints associated with the incorporation and general implementation of the flexibilities, and constraints in the framing and implementation of supporting legal and policy measures.

"The patent system (as currently implemented) is a very expensive way to stimulate R&D. Consumers pay eight or nine dollars in higher prices to stimulate one dollar in R&D spending"
Love & Hubbard.[46]

In assisting Member States in their implementation of the TRIPS Agreement and the Doha Declaration, the WHO also has found that developing countries have difficulties obtaining access to accurate and up-to-date information on the patent status of essential medicines. Such difficulties often stem from the lack of capacity in national patent offices to administer the patent system (including managing effective search mechanisms) and to respond to the public health needs. This has the potential to compromise the procurement of the most cost-effective, quality medicines, and thus hinders the improvement of access to essential medicines. It further highlights the difficulties that developing countries face in capturing the promised benefits of an intellectual property system.

Since the DOHA Declaration, new mechanisms and policy measures have been put in force to maximize IP protection. The TRIPS-plus and related bilateral free trade agreements (FTAs) protect pharmaceutical markets by limiting / posing barriers to the exploitation of TRIPS flexibilities.[45] This further increases the difficulties facing countries with limited expertise and resources in intellectual property management

Regional initiatives by organizations such as ARIPO, OAPI, SARIMA and WARIMA in collaboration with WIPO offer potential avenues to address the intellectual property management gaps in Africa.

Improving intellectual property management skills in African countries will be a key factor of success for enhancing the African people's access to essential medical products.

Intellectual property and innovation

Concerned about the adverse consequences of intellectual property on access, public health advocates are increasingly calling for mechanisms to de-link the cost of R&D from the cost of the product and for prioritisation of public health over profit goals. New incentives are needed to foster innovation, which do not rely on the promise of benefits derived from intellectual property rights and exclusivity.

A number of mechanisms have been proposed as alternatives, including prize funds, R&D treaty, the health innovation facility, the UNITAID medicines patent pool, among others. Not all of them win unanimous support and more work needs to be done for analysing the advantages and disadvantage of the different proposals as objectively as possible.

The Expert Working Group (EWG) was established in 2008 by the World Health Assembly to review current financing and coordination of R&D and discuss innovative frameworks for financing R& D and stimulating innovation, as well as to examine the coordination of R&D. There are currently about 90 proposals circulating for new mechanisms that the EWG may have to consider. The working group proposes to analyse the mechanisms in terms of their ability to achieve the desired R&D goals rather than focussing on their type and nature (push or pull)[47]. As noted by the Taskforce on International Innovative Financing for Health Systems, "Largely, funds have been raised and delivered in much the same fashion…regardless of the development problem being tackled."[48]

With this in mind, the EWG has chosen a practical rather than a theoretical approach to help policy makers to decide which proposal to support or implement. "*Mechanisms will be examined in relation to their stated R&D goal rather than their 'type', with key questions being: What disease area, product type, innovation type, R&D area and R&D actors does this mechanism seek to fund and/or incentivize? How well does it achieve this objective? The evaluations will have a strong technical element, assessing the likely performance of proposals in the R&D world, as well as the policy world.*"

Examples of practical implementation of some intellectual property mechanisms in Africa are summarized in the table below.

Table 3: Examples of practical implementation of intellectual property mechanisms in Africa

Year	Policy regulations	Summary of mechanism	Examples of implementation in Africa
1994	WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)[49]	Mandates global minimum standards for the protection of intellectual property	
2001	Doha Declaration on TRIPs and Public Health[50]	Affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".	1. Compulsory licenses or government use authorizations for local production or importation of generic medicines: Gabon, Ghana, Ivory Coast, Swaziland, Zimbabwe[51], and Mozambique[52]
	'TRIPs Flexibilities'	Measures include compulsory licensing and parallel importation. Allows members to determine grounds upon which such licences are granted. Extends time by which LDCs are required to implement TRIPS obligations from 2006 to 2016.	2. Import of generic products[53]: Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of Congo, Djibouti, Gambia, Guinea, Guinea-Bissau, Lesotho, Malawi, Mali, Mauritania, Mozambique, Niger, Senegal, Rwanda, Tanzania, Togo, Uganda, Zambia. 3. Voluntary licensing agreements with pharmaceutical companies: Ethiopia, Kenya, South Africa, Tanzania, Zimbabwe.
2003	'August 30 Decision[54]'	Provides interim waiver on requirement that compulsory licensing be predominantly for the supply of the domestic market	Rwanda (Importer) and Canada (producer and exporter).[55]

4.2.2 Technology transfer: What needs to be shared and how?

Technology transfer concerns many aspects of the pharmaceutical innovation system such as transfer of knowledge, experience and technical tools. It also covers processes that improve research, production, delivery and use of medical products. Any one of these factors may be appropriate for Africa, depending on countries' context, priorities and resources.

It is often said that technology transfer could play a crucial role in solving the problem of pharmaceutical production in Africa. But in reality, little is known about the extent, nature and impact of current technology transfer initiatives.

Technology transfer is increasingly regarded as a more realistic and attractive option for partners on both sides. In this context, there is a need to better document existing technology transfer initiatives, their determinants (incentives and disincentives), successes and failures, and the lessons learned. This will allow testing of conventional wisdom on the difficulty of transferring technology to Africa, and finding new paths for putting in place the essential prerequisites on both industrial countries and African countries' sides to make technology transfer possible, sustainable and successful.

Current experiences suggest that important prerequisites are infrastructure and skills. Many believe that the willingness of the pharmaceutical industry to transfer its know-how and techniques is not sufficient for successful transfer of technology. Recipients of transferred technology must also have minimum absorptive capacity to receive and effectively appropriate the technology transferred – and work in a policy and political environment that is conducive to pharmaceutical innovation. Absorptive capacity is determined by the existence of a sustainable and efficient cadre of highly skilled scientists. Business intelligence is also crucial for dealing with trade, investment and industry challenges. A facilitative policy environment is essential to attract substantive investment.

Scarce information on technology transfer in Africa

Efforts to collect and analyse information on relevant experiences and their impact have been very scarce. In 2004, the UK Department for International Development (DfID) commissioned a study to document technology transfer experiences between developed and developing country firms in the pharmaceutical sector, and examine the motivations behind these agreements. To date, the DFID study[56] remains the only serious attempt to analyse technology transfer initiatives. Since 2004, the environment has changed, as have perspectives and opinions of major actors. More information on current technology transfers would be useful.

Information and perspectives gathered from those interviewed during this study – including representatives of the pharmaceutical industry – suggests that a better understanding of the expectations of the different partners and of the incentives will attract transfer of technology into low and middle income countries. It can facilitate more and better collaboration between industry in wealthy countries and emerging African players – to mutual benefit.

Table 4: Examples of transfer of technology in African countries

Company / Organization	Activity	Comments
Tanzania A to Z company	Production of Olyset, long-lasting insecticide-treated bed nets	Technology source: Sumitomo Chemicals, Japan
Kenya Advanced Bio-extracts	Growth and extraction of pharmaceutical grade artemesinin and artemesinin-based derivatives	Artemisia is grown locally in Kenya and Tanzania. Extracts are supplied to Novartis for production of artemesinin-based drugs such as Coartem.
South Africa Aspen Pharmacare	Local production of pharmaceutical products	Technology transfer with GlaxoSmithKline, Bristol-Myers Squibb, Gilead, Merck, for production of ARVs. Has received WHO pre-qualification status
Italy, South Africa, India International Centre for Genetic Engineering and Biotechnology (ICGEB)	Molecular biology and biotechnology	Offers training, funding and advisory services
Ethiopia, DRC Congo, Niger, Malawi, Mozambique Nutriset – plumpy'nut	Production of Plumpy'nut, a high-protein, high-energy peanut-based paste classified by WHO as a ready-to-use therapeutic food	Technology source – Nutriset – France

"'The role of the South as a 'technology user' is becoming increasingly problematic and raises the spectre of a cumulative and path-dependent growth in equalities between North and South in the future, particularly in science-based industries such as biopharmaceuticals."
Mytelka 2006: (From Mytelka L K; Pathways and policies to (Bio) Pharmaceutical Innovation Systems in Developing Countries, Innovation and Industry; Dec 2006)

4.2.3 Local pharmaceutical production: is it the solution?

In recent years, African governments have taken significant steps toward addressing their health challenges. These steps include improving access to medicines and developing local production. The 2005 AU Conference of Health Ministers: Gaborone Declaration and Roadmap Towards Universal Access To Prevention, Treatment and Care adopted a clear policy position: '*to pursue, with the support of our partners, the local production of generic medicines on the continent and to making full use of flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration on TRIPS and Public Health*'. The AU adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 and established a Technical Committee to undertake technical development of these efforts.

Benefits expected from local pharmaceutical production include:

- foreign exchange savings
- job creation (thus alleviating poverty and promoting social development)
- facilitation of technology transfer
- stimulation of export markets
- availing of cheaper raw materials
- improving/enhancing self-sufficiency in drug supply
- National pride/self-esteem

African Union policy on universal access to medicines

Based on the African Union (AU) assembly Decision by 55 African ministers of health during the Abuja Summit in January 2005 and on the 2005 Gaborone Declaration on a roadmap towards universal access to prevention, treatment and care, the AU policy position is '*to pursue, with the support of our partners, the local production of generic medicines on the continent and to making full use of flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health*'.

Current status

In 2007 the AU published a report on barriers for local production of essential medicines, particularly those needed to treat HIV/AIDS, tuberculosis (TB) and malaria. A situation analysis was done by the technical committee of the pharmaceutical manufacturing plan for Africa. As of 2005, 37 of the 46 WHO/AFRO countries had drug production activity, though only one (South Africa) had limited primary production of active pharmaceutical ingredient (API) and intermediates[57].

Technical barriers identified in this analysis included: weak national drug regulatory authorities, uneven distribution to the consumer market, human resource gaps (in training and retention), and legal barriers, especially with regard to the impact of the TRIPS agreement on the acquisition of API.

Table 5: Local production capacity, based on WHO/AFRO 2005 data[58]

Capacity for local production	Number of Countries
None; import all pharmaceutical products	9
Import API, product packaging and labelling; repackage bulk forms	34
Import API; produce finished dose forms; reformulate products (e.g. FDC)	25
Manufacture API and intermediates	1
All pharmaceutical industry activity	37

Snapshot of Pharma manufacturing in Africa

The 2008 International Finance Corporation report[59] confirms these findings and the fragmentation of pharmaceutical manufacturing capacities of African countries.

- Outside South Africa, more than 70 percent of Sub-Saharan Africa's estimated $1 billion in annual pharmaceutical production is concentrated in South Africa, where Aspen Pharmacare, the only vertically integrated manufacturer in the region, is the clear leader.
- Nigeria, Ghana and Kenya together represent about 20 percent of Sub-Saharan Africa's pharmaceutical production (see Figure A3.2). Of these three countries, only Kenya produces significant volumes for regional export—between 35 and 45 percent of Kenyan manufacturers' revenues come from exports to other Eastern African Community (EAC) and Common Market for- Eastern and Southern Africa (COMESA) countries.
- Overall, 37 Sub-Saharan African countries have some pharmaceutical production, with 34 having capacity for formulation and 25 limited to packaging or labelling.
- Only South Africa has a limited degree of API production. Most production outside South Africa is of non-complex, high volume, essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs, and vitamins.

In May 2008, African Ministers of Health met to update the progress of the PMPA[60]. Six priority areas were identified and countries were tasked with coordinating activity in these in areas. (see Table 6).

Table 6: Country coordination of priority areas of the pharmaceutical manufacturing plan for Africa

Priority area	Countries to coordinate
Mapping of local production capacity	Gabon
Situation analysis and compilation of findings	Cameroon
Manufacturing agenda	Kenya, Libya, Egypt
Intellectual property issues	South Africa, Angola
Political, geographical and economic considerations	South Africa
Financing	Nigeria

Local medicines production – UN programme

A United Nations Industrial Development Organization (UNIDO) programme[61] strengthens local production of essential generic drugs in developing countries. It works with small and medium-sized companies, business partnerships, investment promotion and through south-south cooperation. The project was initiated in 2005 and focuses on medicines for treatment of HIV/AIDS, malaria, tuberculosis and some neglected tropical diseases. The first phase of the project (2006 – 2008) centered on Africa and Asia with activity in eight African countries: Botswana, Lesotho, Mali, Nigeria, Senegal, Uganda, Zambia and Zimbabwe.

Appropriate decisions on local production need an in-depth analysis

Despite these intense regional efforts, some experts argue that local pharmaceutical production in many developing countries may not be a feasible or cost-effective option, and could bring to market more expensive products with limited ability to penetrate developing world markets[62]. Given the low consumer and institutional purchasing power in most African countries, the market for finished product is almost entirely dependent on the ability to access international funds. Access to these funds requires WHO prequalification status, an expensive and lengthy qualification process, which local producers find challenging to attain and maintain.

It has been argued that local pharmaceutical industries are subject to inefficiencies due to high start-up costs, the cost of subsidizing production, and higher prices of finished products. Because pharmaceutical production is capital-intensive and employs relatively few people, it cannot, as an isolated sector, lead to economic development. Some experts also feel that local production can promote development, but only when the market prescribes it, and that the survival or failure of these companies should be left to market forces[63].

Ultimately, the decision to manufacture pharmaceutical products locally lies with countries. Informed decisions on whether or not to embark on local production can be based on:

- The cost for a local producer to meet international quality standards. This includes WHO prequalification and continuous quality standards from manufacture to point-of-sale and use - including capacity for bioequivalence testing.
- Business performance: profitability and sustainability of local pharmaceutical production ventures, including ability to penetrate regional and international markets when local markets are not sufficient.

- Evidence on health impact: e.g. local production make pharmaceutical products more accessible? Are local products cheaper than imported equivalents? Is their quality comparable to that of originator products?

4.2.4 Pharmaceutical industry and health partnerships: what is their role?

There are currently over 200 ongoing health partnerships with the pharmaceutical industry aimed at promoting health in the developing countries through a wide range of access, capacity building and R&D programs[64] (details in Annex 5-G: Pharmaceutical partnerships in Africa). They are set in the context of the overall goal of achieving the health-related Millennium Development Goals and focus on a wide range of priority health issues, including HIV/AIDS, malaria, tuberculosis, tropical diseases, preventable diseases, child and maternal health, and chronic diseases.

The nature of the health partnerships varies and may comprise of single or multiple pharmaceutical companies and a wide range of partners, such as: governments, generic pharmaceutical manufacturers, the UN and other international organizations, NGOs and academia. A number of these partnerships are components of larger global initiatives, such as the Accelerating Access Initiative, PEPFAR Partnership for Paediatric HIV care, Stop TB Partnership, Roll Back Malaria, International Trachoma Initiative and the Global Alliance to Eliminate Lymphatic Filariasis.

The approaches used by partnerships to improve access are mostly commodity donation, preferential pricing, and technology transfer and licensing agreements with local pharmaceutical industries (see Annex 5-G). For example, technology transfer agreements with a number of multinational companies have facilitated the local production of generic antiretroviral medication for treatment of HIV/AIDS in Kenya, India and South Africa. Some examples of these are detailed in Table 7.

4.2.5 Delivery and access: are they neglected?

One of the central messages of the first African Health Report, published in 2007[68], is that the essential problem to be resolved for improving the health of African populations is to strengthen the fragile health systems of many African countries. Strong and efficient systems are essential to ensure regular access to medical products.

The challenges are many: Drugs, diagnostics and vaccines need to be properly transported, stored, prescribed and used, which requires adequate numbers of trained health personnel in strategic locations, as well as roads, stores and a reliable cold chain, to name a few. The Technical Committee of the PMPA notes, among other considerations, that "the transportation system should be functional so as to facilitate the distribution of medicines without much increase to the price of manufacturing[69]".

In addition, the problem of limited access to essential medicines should not be reduced to the issues of availability and affordability discussed in this report. Accessibility also involves physical access to health care facilities, gender issues and social acceptability. Much more needs to be done to improve procurement, delivery, prescription practice and rational use of medicines in many African countries. Also, while serious efforts need to be made to strengthen R&D activities that truly address the needs of low- and middle-income countries, increasing the availability of affordable drugs of good quality does not, on its own, guarantee universal access to life-saving drugs in Africa.

Table 7:

Technology transfer and ARV licensing in Africa[65]

Technology donor	Technology recipient	Comments
Boehringer-Ingelheim www.boehringer-ingelheim.com	Aspen Pharmacare South Africa	A non-assert declaration for production of nevirapine.
	Various	Boehringer Ingelheim is willing to grant and has offered a royalty-free licence to the Canadian company Apotex for production of nevirapine in Canada (and export to Rwanda as part of the triple combination "Apo Triavir")[66]
Bristol-Myers Squibb www.bms.com	Aspen Pharmacare South Africa	Transfer of intellectual property and technical know-how related to manufacturing, testing, packing, storage and handling of API and finished dosage form of Atazanavir.
	Various	Since 2001, BMS has a policy of not enforcing its patents for HIV products in sub-Saharan Africa and has immunity from suit agreements for stavudine and didanosine with 5 African generic companies.
Gilead Sciences www.gilead.com	Aspen Pharmacare South Africa	Manufacture and distribution of generic versions of Viread® and Truvada®
	Various	Non-exclusive licensing agreements with 10 Indian generic companies allowing distribution of generic versions of tenofovir in 95 developing countries, including in Africa
GlaxoSmithKline www.gsk.com	South African generic companies: Aspen Pharmacare, Thembalami Pharmaceuticals (Pty) Limited, Feza Pharmaceuticals, Biotech Pharmaceuticals, Cipla Medpro Kenyan generic companies: Cosmos Pharmaceuticals , Universal Corporation	Manufacture and distribution of generic versions of lamivudine and zidovudine[67].
Merck & Co. www.merck.com	5 South African generic manufacturers	Manufacture and distribution of generic versions of efavirenz.
Roche AIDS Technology Transfer Initiative www.roche.com	Aspen Pharmacare (South Africa), Cosmos Pharmaceuticals (Kenya), Universal Corporation (Kenya), Addis Pharmaceutical Factory (Ethiopia) Varichem Pharmaceuticals (Zimbabwe), Regal Pharmaceuticals (Kenya), CAPS Pharmaceuticals Ltd (Zimbabwe), Shelys Pharmaceuticals (Tanzania), Zenufa Laboratories (Tanzania)	Voluntary license for manufacture of generic versions of saquinavir. Since 2008, pan-African training seminars are held for local manufacturers

The WHO Essential Medicines Department spearheads most of the initiatives to ensure global access to safe, effective and quality pharmaceutical products, including in Africa. In addition there are many other regional, sub-regional and country-level efforts to promote delivery and access. These efforts vary in scope, focus and approach. While conducting a detailed analysis of all delivery and access initiatives was beyond the scope of this study, several illustrative cases are outlined in Annex 5: Detailed Mapping of Initiatives.

The Medicines Transparency Alliance (MeTA) is a joint initiative of the WHO, Health Action International (HAI) and the UK Department for International Development (DfID) that supports national efforts to enhance transparency and build capacity in medicines policy, procurement and supply-chain management. The ARV access for Africa (AA4A) aims to build capacity for supply chain management for ARV commodities. Other examples include the innovative Child and Family Wellness shops

(CFWshops) in Kenya, which adapt the traditional franchising model to distribute essential medicines in remote communities.

Although there is presently a growing interest for local production in many African countries, many stakeholders admit that, even if high-quality, low-price drugs were locally produced, the problem of most disadvantaged people accessing the drugs they need and using them effectively would not necessarily be solved. Some strongly argue that the overall process of improving access to drugs is heavily skewed towards the production side, while much more could be achieved in terms of equitable access by reducing the inefficiencies of the procurement and delivery side[70].

In some cases, pooled procurement alone could have significant positive impact on access. For instance, Kenya, Tanzania and Uganda try to jointly develop pooled procurement and hope to be able to decrease drug prices by 25% compared to the normal price. While it is often argued that one problem faced in some African regions is the small size of the potential market for certain drugs, one study showed almost minimal influence of a medicine's market size and retail price[71]; the price mostly depends on the reliability of payment and on the regularity of supply.

The Expert Committee of the PMPA has undertaken an analysis of the respective size of potential markets for locally produced drugs and has come up with estimations of countries grouping to create potentially viable markets[72]. This should facilitate the development of pharmaceutical production at regional level, based on geographic, economic, linguistic, and other criteria. The Committee considers that the dimension of the consumer market is essential in the definition of the regions for ensuring that regional production increases African populations' access to essential drugs through a real reduction of prices with the economy of scale.

Other strategies used to bridge medicines' access gaps include differential and tiered pricing, drug donation schemes and pooled procurement.

To strike the right balance, it is important to take into account the diversity of needs and resources that guide Africa's choice of approach for securing access to essential drugs. Some countries, such as Egypt and Tunisia, are in a position to produce essential medicines locally to meet most of their national needs. Others rely exclusively on imported medicines and will continue to do so for the short and medium-term. Improving access through appropriate tax measures or other incentives may be a crucial step for importing countries. However, measures facilitating access to imported drugs should not jeopardise efforts to produce drugs locally. Likewise, the goal of strengthening local manufacturing in Africa should not conflict with the need of many African countries to ensure to affordable medicines today.

4.3 Several cross-cutting issues are critical factors of success

4.3.1 Governance

For African countries to effectively strengthen national research and innovation for health, a range of interventions are needed – at the national, regional and global levels. These activities can be done by different stakeholders, public or private, operating in sectors such as health, science or economy. Mechanisms are needed to coordinate these efforts to ensure they contribute to providing national public goods, ensuring health equity, and strengthening pharmaceutical innovation.

The governance function is generally the government's mandate. The governance and management of the national 'innovation system for health' provides leadership and strategic direction to ensure that it produces research and medical products of good quality that are relevant to the country's needs. Governance functions include: strategic vision, system structure, policy formulation, priority setting, monitoring and evaluation, promotion and advocacy, and the setting of norms, standards and ethical frameworks[73].

Many African countries do not have a well-defined national health research

system, let alone a 'health innovation system'. Governance structures are one of the first elements these countries need to put in place to guide the development of appropriate policies and mechanisms and to minimise the risk of the various players acting in an uncoordinated manner.

4.3.2 Financing

Current investment in African pharmaceutical innovation is low.

Given the lack of economic incentives for development of products to fight diseases that affect Africa, alternative financing mechanisms are needed to catalyze pharmaceutical innovation on the continent. Governments' commitment to financing science and technology research and development are low worldwide, and in African countries, mostly absent (but this seems to be changing).

South Africa is an exception. Data from UNESCO reveal that while investment for R&D in Sub-Saharan Africa is generally less than 0.3% of GDP, South Africa invests 0.9% of its GDP.[74] Through its department of science and technology, the South African government funds the Council for Scientific and Industrial Research (CSIR) whose focus is on research, development and innovation in bioscience, nanotechnology and synthetic biology. As a part of its national biotechnology strategy, the South African Department of Science and Technology (DST) has set up three regional innovation centres that fund biotechnology: BioPAD, Cape Biotech and LIFElab.

Venture philanthropy, such as funds from the Bill and Melinda Gates Foundation, has in the last decade encouraged the creation of public-private partnerships that seek to develop much-needed innovator products, such as new antimalarial drugs or diagnostic tools easy to use in resource poor settings. Funding from the Gates Foundation has facilitated a number of regional and national initiatives including efforts to strengthen pharmaceutical innovation systems, such as the NEPAD research on innovation systems and the strengthening of regional drug registration.

Other than philanthropic sources, the Global Fund to Fight Tuberculosis, AIDS TB and Malaria (GFATM) also provides funding to enable access to interventions needed for these diseases. The Global Fund has launched the affordable medicines facility for Malaria (AMFm) and a mechanism to expand access to artemesinin-based combination therapies (ACTs) for malaria. Cost reduction is achieved by negotiating a lower price for ACTs, then paying a large proportion of this directly to manufacturers on behalf of buyers (the practice of buyer 'co-payment').

Other special funding mechanisms include UNITAID, which raises funds from a solidarity tax on airline tickets. UNITAID funds facilitate access to essential medicines and diagnostic tools for HIV/AIDS, malaria and tuberculosis.

Some venture capital funding is also available for pharmaceutical innovation in Africa. Examples include Bio-ventures, a South African- based biotechnology and life sciences venture capital fund founded in 2001.

While these efforts represent positive steps in the right direction, when considered in light of recent GSPOA estimates[75], they are unlikely to cover the huge costs required to strengthen innovation for health in low- and middle-income countries. More innovative approaches for financing research and innovation for health are urgently needed – and countries will need tools to decide which of the more than 90 proposals currently circulating best fit their own context and requirements. The evaluation framework presently developed by the WHO Expert Working Group will be essential to guide countries in their assessment and decisions on the most appropriate mechanism to finance their national pharmaceutical innovation.

Based on a practical rather than a theoretical approach, the EWG framework will help policy makers to decide which mechanism to support or implement – in relation to its stated R&D goal rather than its 'type'. The key questions to consider will be:

More innovative approaches for financing research and innovation for health are urgently needed. Countries need tools to decide which of the 90 + existing proposals best fit their context.

what disease area, product type, innovation type, R&D area and R&D actors does this mechanism seek to fund and/or incentivize? How well does it achieve this objective? The evaluations will have a strong technical element, assessing the likely performance of proposals in the R&D world, as well as the policy world.

Whatever the mechanism chosen for financing a particular R&D project, who makes the decisions/designs/sets up the characteristics and objectives of each mechanism is extremely important for ensuring that they are relevant to the needs of LMICs, realistic and sustainable to the extent needed. The evaluation and accountability of the different mechanisms are essential.

African experts at the Pretoria meeting identified three sources of financing for pharmaceutical innovation: private funding, public funding and joint ventures. The experts noted that commercial organisations determine their entry points in the innovation chain and raise their own resources. They felt that public funding should be used primarily to create an enabling environment for local manufacturing and to invest in areas that do not attract immediate private sector interest – such as drug, vaccine or diagnostics discovery for neglected diseases. The group proposed the creation of an Innovation Fund supported by a business plan to put the it into action regionally or continent-wide. Possible financing options mentioned were: direct taxation (import levies); indirect taxation (consumption tax on luxury goods like tobacco); joint ventures, product development 'public private partnerships' (such as Drugs for Neglected Diseases Initiative – DNDi or Medicines for Malaria Venture - MMV); loans and loan guarantees; trading concessions at the World Trade Organization; and donor funding.

The future solution will most probably rely on a combination of mechanisms. Whatever the incentives for strengthening the R&D, production and delivery of the affordable medicines, diagnostics and vaccines needed in low and middle income countries, they should end up ensuring a predictable and sustainable funding of innovation for health, an innovation which will be essentially targeted at country self-defined needs and will contribute to the creation of global public goods.

4.3.3 Legal and regulatory framework

Whatever choices African governments make with regard to interventions designed to boost pharmaceutical innovation, their political commitment must translate into fostering and implementing the essential legal changes or improvements needed to attract the various stakeholders to engage into the national effort. The legal and regulatory framework needs to be developed or improved with regard to many sectors of the national activity, including health, education, trade and industry, science and technology, tax and finances, among others. Establishing a strong drug regulatory system is perhaps the most essential.

Drug regulation

While putting in place the general legal and regulatory framework required for minimising risk factors and promoting social and economic development through strengthened health R&D, African countries must pay particular attention to developing the regulatory system which will ensure that medical products – be they imported or locally produced – will be safe and of good, sustained quality, and will be rationally used. To achieve this, all pharmaceutical products need to be subjected to pre-marketing evaluation, market authorization, and post-marketing review. These are complex procedures that need highly specialized legal, administrative and technical skills, and few African countries have the capacity to perform all functions.

Drug regulation functions revolve around the concept of Quality Assurance, which defines the set of activities undertaken to ensure that the medicines are in compliance with the required quality for the intended purpose. This process includes Good Manufacturing Practices (GMP) that guarantee that the medical products are manufactured in a consistent manner – and are controlled in accordance with the specifications established at the time of the products registration, for their intended use. GMPs are essential to ensure the quality and traceability of the medicines. The role of National Regulatory Authorities (NRA) is fundamental to monitoring the compliance to GMP standards and to building trust in the process and, ultimately, in the quality and safety of the products.

As African experts[76] underline, the essential role of the NRA is indeed to protect the citizen's health by ensuring the safety and efficiency of health products, establishing the necessary legal and regulatory frameworks to this end, and monitoring their application.

Assessments conducted by WHO have highlighted significant challenges to effective functioning of national drug regulatory authorities, the key ones being human resource gaps and weak or absent legal and regulatory frameworks. The current trend is towards harmonisation of regional drug regulation, based on the obvious benefits that would accrue from pooling individual country capacities.

In February 2009, NEPAD, in collaboration with partners, held a workshop on harmonisation of drug registration in Africa. Their proposal is to situate regional drug-registration efforts at the regional economic communities (RECs) which are the: Community of Sahel-Saharan States (CEN-SAD), Common Market for Eastern and Southern Africa (COMESA), Economic Community of West African States (ECOWAS), East African Community (EAC), Economic Community of Central African States (CEEAC/ECCAS), Southern African Development Community (SADC), Intergovernmental Authority of Development (IGAD) and Arab Maghreb Union (AMU/UMA).

Proposed guiding principles[77] are: Collaboration among Member States and with other RECs by establishing intra- and inter-REC collaborative forums; sharing expertise and using risk-based approaches to minimise duplication of effort and allocate resources efficiently; implementation of the "Regulatory Documentation Package" developed by WHO; and sustaining project activities after initial (financial) support has been withdrawn. Political will and commitment was highlighted as the key to success of regional cooperation.

In addition to training, mechanisms need to be put in place to ensure the retention of trained professionals to pass on their experience to others. These mechanisms include salaries commensurate with their responsibilities, career prospects, and minimum permanent contractual engagement at the enterprise after training. The 'brain drain' while undesired, is natural if the working conditions are not adequate for workers.
Source: Technical analysis of the local capacity of African countries to produce essential medicines including HIV/AIDS, malaria and TB drugs. Technical Committee on the Pharmaceutical Manufacturing Plan for Africa, October 2007, Addis Ababa.

4.3.4 Human resources and knowledge management

Human resources

Strengthening pharmaceutical R&D, production and delivery in any country requires wide-ranging expertise and skills in multiple sectors and at different levels of the system. For the health sector alone, pharmacists and health care providers are needed as much researchers, laboratory technicians and drug regulators and inspectors. But lawyers, intellectual property specialists, economists, investors, as well as teachers and skilled industry labour will be also needed to contribute to a functional health innovation system. If indigenous national capacities are not available, countries may compensate by calling upon their neighbours and pulling scarce resources together for collectively covering the range of interventions needed. This however requires a critical mass of appropriate human resources across the region and sufficient capacities in every networking country for managing national or sub-regional health innovation systems.

The lack of human resources in the health sector is widely recognised as one of the most important problems to be solved in Africa today. The main message of the African Regional Health Report[78], published for the first time in 2006, states that,

"firstly, Africa can build on its recent progress only by strengthening its fragile health systems; and secondly, that these systems remain weak today due to a lack of adequate human and financial resources."

Data is scarce on human resources for health research, but general data on human resources for health are quite telling. While Africa bears 25% of the world disease health burden, it has only 1.3% of the health workforce[79]. This is partly the result of migration of health workers out of their home countries, in search of better salaries and working conditions. For example, more than 23% of America's 771,491 physicians received their medical training outside the USA, the majority (64%) in low-income or lower middle-income countries. A total of 5,334 physicians from sub-Saharan Africa are in that group, a number that represents more than 6% of the physicians practicing in sub-Saharan Africa now. Nearly 86% of these Africans practicing in the USA originate from only three countries: Nigeria, South Africa and Ghana[80].

As a proxy for human resources available for pharmaceutical research, drug regulation and distribution, it is interesting to consider the data available on pharmacists in a few countries[81]. While countries like Cameroon or Côte d'Ivoire have some 700 and 1300 pharmacists respectively, others like Benin or Niger have only 11 and 20. To put those numbers in perspective, it is interesting to compare to countries like Iraq (with more than 7500 pharmacists) and Pakistan (more than 8000).

Looking at these figures, it would seem straightforward to argue that careful planning is needed – at least between the health and education sectors – to ensure that appropriate human resources with the necessary skill sets will be available at country and/or regional level for the mid- to long-term. Such efforts for better matching education content and scope with public health needs along the pharmaceutical production and access pipeline will need to be supported by proactive policies and strategies to retain human resources for health research and innovation.

"In the longer term, the development of innovative capacity for health research in developing countries will be the most important determinant of their ability to address their own need for appropriate health-care technologies."
"Public health, innovation and intellectual property rights" Report of the Commission on, Intellectual Property Rights, Innovation and Public Health (CIPIH) WHO, 2006.

Open sources of information

Access to knowledge is central to the process of innovation. Pharmaceutical companies have large amounts of data on early discoveries that have never been developed. This is a valuable source of new knowledge that developing countries' research institutions and pharmaceutical companies can tap. In the past, agreements have been negotiated for creating open registries, but such negotiations need to be repeated for every company and are far from being common practice. Many pharmaceutical companies see sharing their databases as a threat to their competitivity.

In recent years, new mechanisms have been created to facilitate access to and dissemination of information on different aspects of the pharmaceutical R&D process. The Special Programme on Research and Training for Tropical Diseases (TDR) supported the creation of networks to improve the access of researchers to scientific information on drug R&D and production. Examples include the Compound Screening Network, and the Drug Target Network – that have databases with potential drug targets.

WHO has created the International Clinical Trials Registry Platform that offers this information to all those involved in health care decision-making. These and other publicly-accessible databases and compound libraries are vital tools to improve access to scientific information and support further research in low and middle income countries. These examples are a start, but much more remains to be done. Other initiatives to create open registries should be encouraged.

The problem of limited access to information is compounded in Africa, where relevant information, especially related to traditional medicine, is kept in small circles of local experts, and seldom finds its way to a broader research community. Access to information is further hampered by poor Internet access in some African countries.

4.3.5 Partnerships

In her 2006 study, Mytelka[82] describes how, despite capacity gaps and through effective linkages with regional and international networks, some countries have accelerated progress in pharmaceutical innovation. She highlights the importance of interaction between four types of policies – those that strengthen the knowledge base, stimulate capacity building, open spaces for local firms and create incentives for innovation.

One example is the successful research, development and local production of Niprisan, a drug for management of sickle cell disease. This success was possible through collaboration between local traditional healers and researchers at the Nigeria Institute for Pharmaceutical Research and Development, guided by a policy that encouraged a focus on local health needs and provided space for the emergence of indigenous Nigerian firms.

This approach is also supported by earlier work by Furman and colleagues[83], who proposed that national innovative capacity depends upon the strength of a nation's common innovation infrastructure (cross-cutting factors which contribute broadly to innovation throughout the economy), the environment for innovation in a nation's industrial clusters, and the strength of linkages between these two. More recently,[84] Singer, Daar, and colleagues have proposed a 'convergence innovation model' to catalyse life sciences innovation and commercialisation in Africa. This model would help address linkage gaps between science, business and capital.

At the global level, partnership approaches facilitate research, development, production and delivery of medicines in Africa. Many of these focus on research and development for neglected diseases and diseases that contribute to Africa's high burden of disease – mainly HIV, tuberculosis and malaria. These public-private-product-development partnerships are responsible for some 75% of all neglected disease drug development[85]. They include the TB Alliance (drugs for tuberculosis), Medicines for Malaria Venture (anti-malarials), Institute for One World Health (technologies and drugs for a range of diseases including diarrhea and malaria), and Drugs for Neglected Diseases Initiative (kinetoplastid parasitic diseases). The extent to which these partnerships practically promote the growth of the nascent African industry has been questioned, as most of these partnerships are based in developed countries, with sometimes insufficient representation of African researchers at senior staff or board level[86].

'A key factor in developing policies is to recognize the importance of innovation systems, the interconnectedness of the innovation process, and the need to link together the activities of different players in the public and private sectors.'
"Public health, innovation and intellectual property rights" Report of the Commission on, Intellectual Property Rights, Innovation and Public Health (CIPIH) WHO, 2006.

Chapter 5

Tools and approaches

The Pharmaceutical Innovation tools presented in this chapter were jointly developed by The George Institute for International Health and COHRED.

5.1 General approaches to developing a pharmaceutical innovation system

This chapter offers reflection, tools and guidelines that countries can use to design a national strategy for pharmaceutical innovation.

The critical starting point for a strategy that supports pharmaceutical innovation is to clearly define the country's ultimate goals. Does the strategy strike a balance between creating a commercial national pharmaceutical sector and improving the population's access to medicines? For example, if the objective is mainly access – not production and sales – this public health goal may be better served by importing cheaper medicines, or by employing other strategies such as tiered pricing.

The tools presented in this chapter have been developed to assist decision makers and planners interested in strengthening their national pharmaceutical innovation capacity to address this question.

The tools are:

- a system development framework
- an innovation grid to guide policy makers on the steps needed to achieve access, manufacturing and R&D capacity
- a list of pharmaceutical innovation initiatives
- a database of pharmaceutical innovation literature

Why pharmaceutical innovation: access or commerce?

Pharmaceutical innovation policies need to balance access and industrial goals

Country planners need to reflect on a number of questions:

- **Do we need to produce medicines locally or provide maximum access to our population**
- **Do we want to create a pharmaceutical technology sector to drive economic development.**

Both paths are useful and not mutually exclusive but different skills and investment are needed for each. Decision makers must be clear on the balance they want to achieve, and craft a strategy that meets their goals — economic development, improved access, or both.

Experiences to help developing countries move up the innovation ladder

Successful pharmaceutical innovation is the result of a complex web of interactions between many stakeholders, including multiple government ministries, regulatory authorities, and private and public research, development, teaching and healthcare delivery institutions.

African countries, such as South Africa or Kenya, with high pharmaceutical innovation capacity have followed different development pathways to get there and their experiences offer alternative models for developing countries to move up the innovation ladder.

The implementation phase of a national strategy brings a new set of tasks and questions. Decisions need to be made on what structures, policies and activities need to be in place to ensure they can reach their chosen goal. These include health research systems, regulatory and intellectual property systems; industry; tax and tariff policies; ethics boards; governance structures and policies; financing systems; human resources strategies; or ways to engage community involvement.

Designing an effective and realistic national innovation strategy

Few African countries like South Africa, Kenya and Nigeria, have in place most of the essential steps of the pharmaceutical innovation process – or will be able to have them in the near future. Some countries have assessed their needs and potential to produce and deliver medicines and have made strategic choices on where they can excel in part of the pharmaceutical production chain.

- Mauritius has opted to develop specific elements of the pharmaceutical R&D and production process. It is developing its capacity for clinical trials.
- Guinea Bissau is poorly resourced and lacks most prerequisites for developing pharmaceutical innovation system. It has started developing a national health research policy and building up a functional system for health research.

- **Tunisia** has defined excellence in specific aspects of the pharmaceutical innovation chain as a national science and technology priority. It recognises that, as a small country it cannot excel in all aspects of pharmaceutical innovation and has chosen to add value at specific areas of the chain

Developing country governments interested in building national pharmaceutical innovation capacity face the task of deciding how to move forward, how and where to get involved and which policies they need to have in place to move along the development pathway (e.g. regulatory and intellectual property systems; industry, tax and tariff policies; ethics review committees; governance structures and policies; financing; human resources strategies; and community involvement).

Access to pharmaceutical innovation can be achieved in many ways, ranging from importing drugs and vaccines to building and relying upon a domestic pharmaceutical industry that develops its own medicines (see Figure 7: Innovation milestones). Deciding on the best path, the country needs to assess their current capacity, available options, and which of these options are likely to deliver the best results with regard to health and/or economic goals.

Two new mechanisms have emerged that aim to put countries in the driver's seat for access and local medicines production – the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the African Union Pharmaceutical Manufacturing Plan. Together, they form the first comprehensive policy framework and promise of long-term funding to support countries' strategies for pharmaceutical innovation.

To put these mechanisms into action at national level, country decision makers need to gain skills and perspectives to asses their needs and make the right choices to support their pharmaceutical development. The Pharmaceutical Innovation Framework tool and case studies presented in this chapter were designed to support countries to move forward.

Findings from this study point to a growing pharmaceutical-innovation sector in Africa. Countries seem to have two contrasting motivations for pursuing pharmaceutical innovation – improving public health needs and developing a local pharmaceutical sector that can generate profits. The balance between the public health and the economic agendas is a delicate one and may account for some of the tensions at global level and the increased calls for prioritization of health over profits.

5.2 Framework for developing a national pharmaceutical innovation system

National pharmaceutical innovation system development

The starting point for strengthening a country's pharmaceutical innovation system is to present a clear picture of the current state of affairs – and the areas where development should be targeted. Taking this view, countries can apply a number of approaches, tools and methods to implement a strategy of system development or strengthening.

Figure 6 provides a framework that decision makers can use to develop a national innovation system for health. It provides a roadmap for engaging all stakeholders – including all relevant governmental sectors, civil society and private sector – in a collaborative process of assessment, priority setting and design of a health and pharmaceutical innovation strategy. Such processes are generally led and managed by the government. But all other partners need to be involved to ensure the relevance and success of the effort.

What can we realistically do?

The starting point for developing a pharmaceutical innovation or access strategy is a well-structured reflection. It should involve different ministries and other players active in medicines access – and will help decide what can be realistically achieved.

Key questions:

Should we manufacture locally?

Do we have the skills, and can we build and maintain infrastructure over a 15 year horizon?

What innovative capacities need to be developed?

If our objective is better delivery of medicines to these populations a procurement and distribution programme may be more effective than organizing local production.

Stage 0: Basic requirements

Three components must be in place for a country to start building or strengthening pharmaceutical innovation:

- Political stability and security
- A minimum of infrastructure, such as roads, reliable power supply and water supply
- A functioning banking and economic sector, with external partners that put reasonable business risk in perspective.

A show of commitment from political leaders and decision makers is fundamental to creating a conducive environment for pharmaceutical innovation. The multi-sectorial nature of pharmaceutical R&D, production, access and use (including health, science and technology, trade, industry, education) calls for early commitment and coordination across these actors. Advocacy and awareness activities may be needed to get partners' involvement across these sectors – both from government and non-governmental groups.

Stage 1: Prerequisites

If the basic requirements for a stable environment have been satisfied, a number of crucial elements need to be in place to launch the effort with a reasonable chance for success. Two key prerequisites are:

- Governance and management mechanism:
  The government must be willing to take action, catalyse changes and make solid initial decisions. Doing so should translate into first-level actions for securing a basic management system; bringing together representatives of the main sectors of activity for minimal oversight and decision-making on the innovation effort; setting up priorities; and developing strategies

How can countries use the Global Strategy and Plan of Action to meet their innovation needs

The Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (GSPOA) is a landmark document – the result of a seven-year consultation and agreement between 193 member countries of the World Health Assembly. This is the first global policy of its kind that links the world of global health research with countries' needs.

For low-income countries, the GSPOA is an important tool to guide negotiations with potential partners for pharmaceutical innovation. To move into action, countries need tools and resources to help analyse their specific national context and decide how to apply pharmaceutical innovation, and with which partners they can achieve this.

The first step for countries is to assess their situation and develop a clear vision of how the GSPOA, the African Union Pharmaceutical Manufacturing Plan and other international initiatives can help address specific national needs. Approaches to health research and pharmaceutical production in Africa take many forms. In this light, there is no single solution for implementing the Global Strategy and other mechanisms.

Countries need to set priorities and develop implementation plans and timelines for strengthening their pharmaceutical innovation. The choice of strategic approach centers on two questions:

1) What is the preferred path to improving access to medicines in the country;
2) If the choice is local production of medicines and other health products – how will a country balance this with its objectives for local production as a path toward public health or economic-development?

- Public health priorities:
  To make well-informed decisions for improving access to affordable, high-quality and safe drugs, decision makers need to be aware of the national health status and disease burden, as well as of the medical products that have been identified as essential. This can be accomplished by developing a national list of health priorities and corresponding essential medicines. Public health priorities will be better defined by involving all stakeholders, including civil society and the private sector from the start.

Stage 2: Assessment and decision-making

In the context of health and pharmaceutical innovation, countries should first prioritise major objectives in terms of public health and economic development. To this end, the George Institute for International Health, in partnership with the Council on Health Research for Development (COHRED) have developed a grid to guide countries to make decisions on pharmaceutical innovation.

Using the grid, national decision makers and managers of pharmaceutical innovation will be guided to consider existing information on their public health needs and resources. Using the Framework, policy makers will:

- Assess where the country is in terms of R&D, production, delivery and use of medical products
- Identify gaps and overlaps in their pharmaceutical innovation systems
- Make decisions on where to focus in order to achieve innovation milestones, improve access, and support R&D or manufacturing.

Excerpts of the proposed grid are presented in Figures 7 and 8.

Stage 3: Essential building blocks

Once the priority area and innovation milestones are selected, some additional research may be needed for a more detailed assessment of the current national resources and needs in that particular field for deciding on priorities and taking the first concrete steps toward putting in place supportive policies, a basic skill set in health and science and technology, as well as necessary mechanisms for management and evaluation.

- Policy framework: Several policies, laws and regulations may be required to ensure the success and sustainability of a national pharmaceutical innovation system. These include, for example: health research policy, trade and investment policy, intellectual property policy, drug regulations, industrial policy and good manufacturing practices.
- Human resources: Even if no particular system exists to stimulate R&D, production and delivery of medical products, at least a few knowledgeable and committed individuals must be available for planning, implementing and supervising the interventions in the different sectors concerned, such as scientists, regulators, managers, among others.
- Financial resources: Basic financial support needs to be available for enabling the first assessment and decision-making process and for designing strategies for first implementation. This seed funding usually comes mostly from public sources, national or external (bilateral or multilateral) donors.

The choice of essential components to put in place first and the sequence of steps to achieve objectives will vary, depending on the country's priority focus. For instance, a focus on access will require countries to establish or strengthen the relevant legislation

Figure 6:

Framework for developing a national pharmaceutical innovation system (COHRED 2009)

Using health innovation to improve population health, health equity and development

Stage of development	Actions needed
Basic requirements - supportive environment	
Political commitment to pharmaceutical innovation and improved access to medical products	Advocacy, awareness, data and discussion. Identify key individuals/groups that can initiate and catalyse the process.
Political support across government sectors: health, science and technology, trade, industry, education, legal	Develop a common understanding of pharmaceutical innovation. Mobilisation across sectors for a multisectorial approach to innovation
Business environment and basic infrastructure	Increase reliability of essential infrastructure, e.g. banking system, power supply, transport,
Level 1 needs – pre-requisites	
Management mechanism for pharmaceutical innovation and access to medical products	Establish mechanisms and structures appropriate to the country's existing structures and aspirations. These need to be multisectorial. Particular attention should be given to collaboration between health and S&T sectors.
Public health priorities	Credible and regularly updated public health priorities Complementary priorities for health research and pharmaceutical innovation - essential drugs, diagnostics and vaccines
Level 2 needs – assessment and decision-making	
Assessment of current national situation of pharmaceutical innovation	Identifying where the country sits in terms of innovation milestones; where are the major gaps; who are the major stakeholders. The COHRED/GI Pharmaceutical Innovation Assessment framework provides a guide to these activities
Decision on pharmaceutical innovation goals	Informed by the assessment and public health and development strategies, focus on one of the 3 milestones, access, manufacturing or R&D and /or set national goals for the component chosen or for each component
Level 3 needs –essential building blocks	
Policy framework for pharmaceutical access, manufacturing and R&D	A number of policies need to be in place for each component, for example: Access: drug regulations, trade policy, tax policy Manufacturing: industrial policy, good manufacturing practices
Human Resources	R&D: research policy, intellectual property management Develop a human resources strategy and plan aligned with priorities Address all relevant sectors: public health, science and technology, industry, judiciary, economy, trade, education
Stable, predictable financing	Develop a pharmaceutical innovation financing strategy, Ensure it addresses national and foreign funding from the public and private sectors
Level 4 needs – Collaboration	
Partnerships	Regional, inter-country collaborations for product development, clinical trials, cross-registration, quality control. National PDPPPs; North-South and South-South transfers of knowledge, processes and technologies
Level 5 needs – optimising the pharmaceutical innovation system	
Improving pharmaceutical innovation system components	For example: *Access* - Pooled procurement - Community based delivery *Manufacturing* - Technology transfer arrangements; - Good manufacturing practices - Post market quality control *R&D* - Good research contracting; - Intellectual property management; - Clinical trials ethics; - Merit-based promotion system of scientists *All levels* - Community demands for medical products - Monitoring & evaluation - Institution building.

and regulation on drug regulatory authorities, intellectual property and trade agreements. A focus on R&D may require building up or reinforcing the national health research system. And a focus on manufacturing will require the country to address major issues related to transfer of knowledge, processes and technologies, trade agreements and intellectual property, good manufacturing practices and quality control.

Stage 4: Complementing resources and capacities

Depending on priorities established and the decisions made, additional policies and regulations will need to be developed and implemented, specialised capacities may need to be built up, reinforced and maintained, and predictable and reliable financing secured, in order to ensure sustainability. At this stage, strengthening collaborations with key national and external partners will be crucial for mid- and long-term success.

One issue to consider is that many African countries will – in the short term – not soon be in a position to undertake some of the interventions needed for good performance of the pharmaceutical innovation and access system. In such cases, it may be more feasible for several countries within an African region to develop complementary capacities and to "outsource" some steps to be more cost-effectively performed in a neighbouring country. For example, a country with well-developed and reliable laboratory facilities could perform quality control for neighbours' medical products. Similarly, education and training of groups of professionals with very specific skills (for example, drug regulators and controllers or intellectual property managers) could take place in one country within each region.

Stage 5: Optimising the pharmaceutical innovation system

Once the country has the essential building blocks in place to achieve the top-priority innovation milestones, it can develop or strengthen other elements of its pharmaceutical system and move to the next milestone. As the country moves forward, many additional elements will likely need to be developed in different sectors.

National pharmaceutical innovation system development

The starting point for strengthening a country's pharmaceutical innovation system is to present a clear picture of the current state of affairs – and the areas where development should be targeted. Taking this view, countries can apply a number of approaches, tools and methods to implement a strategy of system development or strengthening.

For countries, the first step in designing a pharmaceutical innovation strategy is to assess the current situation and decide at which level to enter the innovation process, focusing on:
- Improved access to imported medicines
- Manufacturing
- Research & development

These choices are not necessarily mutually exclusive and countries may determine realistic objectives for each milestone, depending on current level of development and available resources.

5.3 Pharmaceutical Innovation Grid for assessment, priority setting and strategy design

Innovation Grid

Because the innovation grid has been developed from the perspective of a government decision maker, practical steps and technical capabilities are the focus, rather than theoretical considerations. In particular, the grid is designed to help countries:

- Assess where they are in terms of the innovation milestones outlined in Figure 7.
- Identify gaps in progress against each innovation milestone
- Identify practical steps needed to achieve the next innovation milestone

More generally, this grid can help to identify bottlenecks and opportunities for strengthening pharmaceutical innovation, and determine how to transition from one level of innovation to the next.

This grid can also guide formulation of other frameworks and guidelines, for example those that explore how to phase growth initiatives, step by step, in a sustainable manner.

The grid allows policy makers to assess their current capacity with respect to innovation milestones at national level:

- Ability to access low-cost, safe efficacious and quality imported medicines
- Ability to manufacture medicines (generics)
- Ability to research and develop innovative medicines

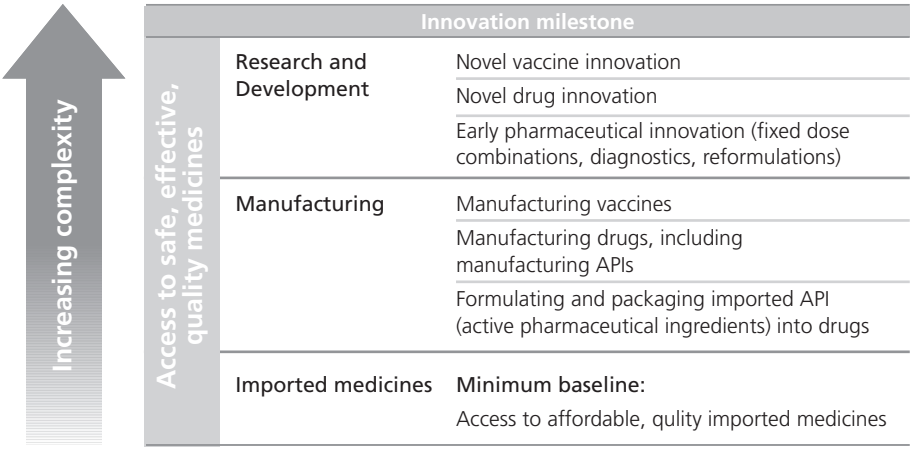
The grid also identifies the capabilities and policies required to achieve each milestone, as well as which actors will be responsible for taking action. Activities are allocated as follows:

- Department of Health (including hospitals and public research centres)
- Department of Education (including universities)
- Department of Science and Technology
- Department of Trade
- Department of Taxation and Finance
- Regulatory authorities (including medicines and IP regulators)
- Industry
- Other (civil society groups, regional organisations).

The grid and its three innovation milestones are a practical tool to help countries address a complex area with inter-linked interventions by multiple partners. The grid provides a simple tool to help understand and navigate this complex landscape. In particular, the classification into three over-arching areas and seven milestones should help countries to phase in their approach to strengthening innovation based on a detailed and fair assessment of resources. However, access is applicable to the entire spectrum of innovation and should be considered as a cross-cutting issue.

To better understand how the grid can be applied, see Figure 8, an excerpt that focuses on the "access" milestone. (More detailed demonstrations of the grid are provided in case studies outlined in Section 3.1.)

Figure 7, Innovation milestones: 7 critical complexity levels



Checklist for designing a pharmaceutical innovation strategy

In this example, a policy maker assessing where their country is situated in terms of access to affordable, quality, imported medicines can read from left to right across the table.

Figure 8, Summary of Grid

Innovation milestones	Legislative framework	Dept. of Health / public hospitals / public research centres	Dept. of Education / public universities	Dept of Science and Technology	Dept. of Trade	Dept. of Tax	Regulatory authorities	Industry	Examples: initiatives to engage with
Access Imported medicines									
Manufacturing - Formulating, packaging imported Active Pharmaceutical Ingredients (APIs) to finished products - Producing drugs, including APIs - Producing vaccines									
Research and Development - Early pharmaceutical innovation (Fixed dose, diagnostics, reformulations) - Novel drug innovation (small molecules) - Novel vaccine + other biologics innovation (large molecules)									

Questions that may arise:

- Is there relevant and necessary legislation and regulation in place (e.g. an intellectual property policy that includes the TRIPS flexibilities, a national medicines policy; a legislative mandate for regulatory authority activities, such as clinical trial review, product recall, pharmaceutical factory inspections)?
- Has the country signed up for all procurement mechanisms that give access to low-cost, quality imported products (e.g. the Global Fund, UNICEF, GDF, GAVI, AMFm)?[xx]
- Are the necessary customs controls in place to monitor the quality of products coming into the country?
- Has a review been done of taxes, tariffs and duties on pharmaceuticals along the supply chain, and where possible, have these been minimised?
- Has the national patent office (or regional patent group) optimised implementation of the TRIPS flexibilities?
- Is there a Medicines Regulatory Authority (MRA) able to conduct the regulatory tasks outlined in the grid, either alone or in conjunction with regional regulatory groupings?

A country that can answer 'yes' to all or most of these questions is very well placed to start building towards the next chosen innovation milestone, be this in manufacturing or product development.

Pharmaceutical Innovation Grid

Innovation milestones		Policy and Legislative framework	Dept. of Health / Public hospitals / Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Imported medicines											
Access to safe, effective, quality medicines	Imported medicines	- Intellectual Property policy to maximise access (e.g. parallel importing, compulsory licencing) - National Medicines policy (guidance to safety, efficacy, quality, best use of medicines) - Laws mandating all National Regulatory Authority (NRA) functions - Drug pricing policy - National formulary and National Essential medicines list possibly based on WHO Essential Medicines List (EML) - National pharmacopoeia possibly based on WHO International pharmacopoeia Institutionalise use of the WHO QSM scheme for dossier review Participation in relevant regional initiatives e.g. • NEPAD/AU harmonization of medicines regulation • Regional IP organizations (e.g. ARIPO/ OAPI) • Regional economic communities (e.g. SADC, ECOWAS)	- Transparent and efficient drug procurement system including: - Tendering - Access to centralised vaccine procurement funds (UNICEF and GAVI vaccines etc) - Access to centralised drug procurement funds (Global Drug Facility for TB drugs, AMFm etc) - Access to other subsidised products (PEPFAR, Clinton Foundation etc) - Familiarity with WHO prequalification and EML decisions - May need an Ethics Review Board (if local bridging trials are needed)	Production of human resources (e.g pharmacists) Problem solving oriented tracking	- Funding for implementation and operational research	- Minimisation of import tariffs and duties on pharmaceutical products including diagnostics - Customs controls in place for genuine and counterfeit pharmaceutical imports - Enhancing inter regional trade and harmonisation	- Minimisation of internal taxes along the supply chain of pharmaceutical products	National Patent Office able to: - Optimise implementation of TRIPS flexibilities National Regulatory Authority able to conduct: - Licensing of premises and practices - Licensing of manufacturers and distributors - Marketing functions (e.g assess regulatory dossiers [alone or with regional partners]; leverage registration of novel drugs from stringent regulatory agencies) - Postmarketing functions (e.g collection of medicine samples, quality and counterfeit testing laboratories, pharmacovigilance system, enforce product recalls and mandate punitive measures for counterfeited or substandard products) - Control of drug advertising and promotion	N/A	Public awareness campaigns on TRIPS flexibilities Campaigns against counterfeiting	SADC importation guidelines WHO prequal / WHO expert committee to review dossiers WHO prequalification of quality control laboratories WHO GMP certifications PIC/S scheme West African Drug Regulatory Authorities Network (WADRAN) African Organisation for Intellectual Property, African Regional Intellectual Property Organisation Centralised procurement agencies: GDF, GAVI, Global Fund, UNICEF, Clinton Foundation, IMFM, PREPFAR, UNIDAD Harmonisation activities lead by Regional Economic Communities (RECs) WHO assessment tool for medicines regulatory Agencies

Innovation milestones		Policy and Legislative framework	Dept. of Health/ Public hospitals/ Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept. of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Manufacturing											
Access to safe, effective, quality medicines	Formulating and packaging products from imported API (Active Pharmaceutical Ingredients) and excipients into finished drugs	Investment policy Industrial policy Incentives to local manufacturers and possible restrictions or importations		Promoting industrial pharmacy programs in university Promoting technology transfer and skills transfer North-South and South-South Foster business management skills & entrepreneurships courses and degrees Foster project management skills and accounting courses and degrees	N/A	- Minimisation of import tariffs and duties on imported APIs - Customs controls in place for genuine and counterfeit API imports and exports - Punitive tariffs (Anti dumping policies)		National Regulatory Authority able to: - Recognise evaluation of APIs by foreign or international competent authorities (e.g. FDA, EMEA) or Certificates of Quality from WHO prequalification system (for HIV/AIDS, TB and malaria) - Quality audit and license domestic tabletting/ packaging manufacturers Reference laboratories to control identity, safety and quality of imported APIs	Pharmaceutical firms able to: - Comply with Good Manufacturing Practice for formulation/tabletting - Identify API certified suppliers and test identity quality and safety of procured APIs - Prepare Drug Master File for registration of APIs to national regulatory authority - Conduct small to large-scale manufacture and distribution (local/ regional) - Specify API requirement e.g formulation design, which can affect properties of finished drug - Commercialize products appropriately for the local market		WHO API pre-qual ICH St Lukes Foundation training in industrial pharmacy African Vaccine Regulatory Forum Developing country vaccine regulatory network African diaspora
	Producing drugs, including producing phytomedicines, APIs and excipients				N/A			National Regulatory Authority able to: - Assess API and generic registration submissions (i.e. review scientific and manufacturing data + GMP certification scheme and inspections of domestic producers) Post-marketing: random sampling and testing of API batches and generic medicines, site visits, enforcement of product recalls, punitive measures for non-compliers Quality audit and license domestic API/drug manufacturers Full audit trail of API/excipient supply chain	Pharmaceutical firms able to: - Produce APIs to GMP standards and pharmacopoeia requirements - Undertake formulation, process and scale-up of generic drugs - Conduct studies of generic formulations (e.g. stability, bioequivalence) - Prepare regulatory dossiers for generic drug registration, using both data from their own studies and referencing quality, safety and efficacy data from original drug regulatory file		
	Producing vaccines				N/A			National Regulatory Authority / National Control Laboratory: Capacity to carry out lot-by-lot inspection of vaccine Quality audit and license domestic vaccine manufacturers	Access to manufacturing facilities specifically tailored to large scale vaccine GMP-standard production e.g. - Sealed fermentation facilities - to ensure safety while culturing organisms that are potent pathogens - Asceptic production/purification facilities - to ensure sterility of vaccine - Large-scale harvesting facilities - to ensure maximum yields Ability to maintain and demonstrate a completely controlled production process (i.e. given variable nature of biological processes): - Ability to carry out stability and potency studies - Maintain potency and yield during sterile filtration of particle containing solutions - Full tracking of manufacturing batches - Capacity for lot-by-lot release of the vaccine - required for vaccines to ensure product consistency Dedicated in-house quality control laboratory responsible for assay development and processing		

Innovation milestones	Policy and Legislative framework	Dept. of Health / Public hospitals / Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Research and Development										
Access to safe, effective, quality medicines — Early pharmaceutical innovation (Fixed dose combinations, diagnostics, reformulations)	- Science and Technology policy - AU parliamentary policy setting on use of African manufacturers Investment incentive for local African manufacturing (e.g. preferential pricing)	- Some clinical trial sites able to carry out GCP standard licensure trials - Ethics Review Board to review trial design	- Tertiary science education and research covering applied pharmaceutical sciences (e.g. medicinal chemistry, pharmacology, biostatistics) - Laboratories able to work to international licensure standards (Good Laboratory Practice) to conduct any preclinical studies - Ability to act as sponsor for clinical trials - Harmonisation between universities (R&D registry)	- Funding for clinical trials	N/A	R&D tax breaks	National Regulatory Authority able to: - License and inspect laboratories, manufacturing facilities and clinical trial sites to ensure compliance with international quality standards (GLP, GCP, GMP) - Define data requirements (e.g. data needed to register fixed dose combination) - Maintain national register of clinical trials - Review regulatory dossiers for authorisations for clinical trials and for (non-novel) new drug applications (since original components already approved and used in humans)	Public or private sector firms able to: - Access rights to original drugs and their registration data for further development (e.g. combination with other drug or new formulation) - Conduct limited preclinical studies, bioequivalence studies and clinical trials to international licensure standard - Undertake formulation, process and scale-up of manufacture - Prepare regulatory dossiers for clinical trial authorisation and drug registration, using both data from their own clinical studies and referencing quality, safety and efficacy data from original drug regulatory file - Design and implement clinical development plans for drugs - Sponsor drug trials		EMEA Article 58 Health research Web African diaspora WHO/TDR/ANDI
Novel drug innovation (small molecules)		- National funding of research and existing research infrastructure (e.g. medical research council) - A robust network of clinical trial sites able to carry out licensure trials to international standards	- Tertiary science education and research covering basic and applied sciences (e.g. target identification, pharmacology etc) - Technology Transfer Office facilitating translation of university innovations to third parties for product development - Laboratories, including animal facilities, able to work to international licensure standards for discovery work and preclinical studies - Ability to systematically evaluate and screen traditional medicines for successful compounds to be identified, developed and marketed	- Funding for basic and translational research - Coordination and integration of institutions and departments working on science and technology	N/A	N/A	National patent office able to: - Process patent applications and enforce patenting laws - Reasonable cost of obtaining and maintaining patent National Regulatory Authority able to: - Define data requirements for registration of novel drugs - Review complex regulatory dossiers for novel drug applications	Pharmaceutical firms able to: - Access compound libraries and screening facilities - Conduct discovery activities, preclinical studies, and design and implement complex drug clinical development plan to international licensure standards - Prepare complex regulatory dossiers for clinical trials authorisation and novel drug registrations		Malaria Clinical Trials Alliance (MCTA) In Depth network African Malaria Network Trust (AMANET)
Novel vaccine and other biologics innovation (large molecules)	- IP law extending to biologics	- Extensive clinical trial site network able to carry out large scale vaccine licensure trials - Reference laboratories able to carry out immunogenicity tests	- Tertiary science education and research covering basic and applied vaccine research (e.g. antigen development; vaccine formulation) - Tertiary industrial/ engineering education covering biologics manufacturing processes and requirements - Access to certified animal facilities and GLP laboratories for preclinical vaccine studies (e.g. toxicity) including biosafety requirement - Access to vaccine delivery systems and adjuvants - Ability to carry out preclinical vaccine studies, (e.g. toxicity)	- Funding for clinical research - Support for platform technologies	N/A	N/A	Patent office able to process patents for biologicals National Control Laboratory able to: - Define data requirements for registration of novel vaccines - Test biologics National Regulatory Authority able to: - License and inspect vaccine laboratories, manufacturing facilities and clinical trial sites - Review complex regulatory dossiers for use of novel biological products in clinical trials and for their registration - Carry out post-marketing approval controls of vaccine lots - Audit and certify vaccine manufacturing plant	Public or private sector firms able to: - Access adjuvants and vaccine delivery technlogies - Prepare regulatory dossiers for clinical trial authorisation and registration of biological products - Carry out vaccine discovery and preclinical work, including feasibility studies for large scale vaccine manufacturing - Design and implement clinical development plans for vaccines - Sponsor vaccine trials (high liability) Small and large-scale vaccine GMP standard manufacturing facilities		Developing Countries Vaccine Regulators Framework (DCVRN) African Vaccine Regulatory Forum (AVAREF) International AIDS Vaccine Initiative (IAVI) Vaccine PDPs, e.g. Meningitis Vaccine Project, Rotavirus meningitis project European Malaria Vaccine Initiative (EMVI), Malaria Vaccine Initiative (MVI), Global TB Vaccine Foundation (AERAS) Vaccine PDPs, e.g. Meningitis Vaccine Project, Rotavirus meningitis project European Malaria Vaccine Initiative (EMVI), Malaria Vaccine Initiative (MVI), Global TB Vaccine Foundation (AERAS)

A country that cannot answer "yes" on most points might instead choose to maximise their ability to access existing medicines before the move toward local manufacturing or R&D. While such a decision would be driven partly by a desire to secure the health of their population, it also would reflect the reality that before more advanced innovation milestones can be reached, earlier and more fundamental elements must be in place.

A domestic pharmaceutical industry will require that many of the capacities outlined at the 'access' level be in place, including a functioning Patent Office, a National Medicines Policy, an MRA with the ability to review clinical trials and inspect factories, and tax policies that do not impact on the affordability of medicines in circulation.

5.4 Database of Pharmaceutical innovation initiatives

Three additional resources have been developed to assist policy makers interested in strengthening domestic pharmaceutical innovation capacity:

- A list of pharmaceutical innovation initiatives
- A database of pharmaceutical innovation literature
- Case studies using the capacity-building tools

List of pharmaceutical innovation initiatives

The last column of the grid gives examples of current initiatives that can help governments achieve an innovation milestone, for instance, information on where they can seek help or partnerships and opportunities for shared or subsidised resources. For instance, a developing country might find, after assessing their situation against the grid, that they have gaps in their ability to fully access low-cost, quality imported medicines. By referring to the 'initiatives' column, they can identify groups or programmes to assist in filling these gaps.

For example:

- WHO drug and vaccine pre-qualification, which verifies the safety, quality and efficacy of medicines to support national Medicines Regulatory Authorities, whose resources are stretched
- Regional networks of regulatory authorities (e.g. West African Drugs Regulatory Authority Network (WADRAN) and harmonisation activities led by Regional Economic Communities such as the Southern African Development Community (SADC), the East African Community (EAC) and the Common Market of Eastern and Southern Africa (COMESA) that can provide shared product testing and factory inspections or work on harmonising medicines regulation
- Regional intellectual property organisations (e.g. ARIPO, OAPI)
- Centralised procurement agencies that can secure quality medicines for developing countries at very favourable prices (e.g. UNICEF for EPI vaccines; GDF for TB drugs; GAVI for a range of newer vaccines; Clinton Foundation for ARVs; Global Fund)

Many countries will already be aware of or signed up to many of these initiatives, however the checklist allows any gaps to be quickly identified. Please note that because the framework is a work in progress – and because new initiatives are continually developed – not all initiatives are yet logged. This also applies for the list of initiatives presented in Annex 5.

Database of pharmaceutical innovation literature

One other resource to assist pharmaceutical innovation decision makers is presented in this report: a database of literature (Annex 1: Tools - Article Database) relevant to each

innovation milestone outlined in Figure 7 and 8. Here's how this will work: Policy makers assessing a country's situation in terms of access to imported medicines can search the database for articles relevant to 'access'. Using key words, policy makers can narrow the search to articles on 'intellectual property' or 'pricing'. Although key articles have been included in the database, it does not include all materials on each topic. The database will expand, however, as new key articles are published.

Using the grid: three important points

1. The innovation milestones and the grid are a simplification of a very complex arena. These tools are designed to give policy makers an overview and to provide an entry point for more detailed work. Capturing the level of detail involved in every activity is beyond the scope of these tools.
2. Although the skills needed to achieve each milestone are substantially more complex than those associated with the preceding milestone, this does not mean that milestones must be followed in a linear fashion. For example, although "R&D" are often mentioned together, the research and the development of pharmaceuticals are, in fact, two very different tasks. 'Development' is an industrial activity and is within reach of countries with existing industrial capacity. 'Research' is the invention and development of new medicines. This is a scientific activity requiring skills in sophisticated science, pharmacology and medicine, and a comprehensive clinical trial network.
3. Innovation milestones included in the grid are designed to guide national policy makers. However, some activities might be approached at the regional level should objectives be shared by neighbouring countries and if harmonization initiatives are pursued.

For example, a country with limited manufacturing capacity but a robust science and biotechnology research sector – that can conduct licensure-standard clinical trials – can potentially enter the innovation pathway at the early drug innovation stage, and from there explore 'upward' and 'downward' strategies. The country may decide to build its drug discovery capacity, relying on joint ventures for clinical development or out-licensing to Indian or South African groups for manufacture of finished products. Alternatively, it may decide to develop its capacity for domestic pharmaceutical manufacturing, with a primary focus on simple re-formulations and combinations as a prelude to moving to full pharmaceutical innovation.

The move to develop manufacturing or research capacity requires that most of the prerequisites outlined in the first 'access' level of the grid be in place (access, manufacturing and research and development). This must be done before addressing legislative, regulatory, tax, customs and patent policies covering pharmaceutical use. Countries embarking on this growth curve will need to establish or strengthen governance and management mechanisms around research and innovation for health. Inter-sectoral cooperation is needed between stakeholders from the relevant government players (such as health, science and technology, legal, trade, finance and education), civil society, intergovernmental other international organisations, and the private sector. This includes training efforts to address identified capacity gaps.

5.5 Country case studies

The following case studies illustrate how capacity-building efforts might play out in "the real world." Please refer to the grid detailed in Figure 8, as you consider how a country can assess its position in terms of pharmaceutical innovation milestones, determine gaps and assess opportunities for expanding its innovation capacity.

Case study 1 - Approach for African country A

Country A is a mid-size African country with a population of under 50 million and an average life expectancy of around 50 years.

Legislative, policy and institutional framework in Country A

- For pharmaceutical management:
  - Pharmaceuticals Act from the 1950s
  - National Pharmaceutical Policy (which ensures the safety, efficacy, quality and best use of medicines). The policy is comprehensive and was updated and strengthened in the past 5 years
  - Up-to-date legislation dealing with importation of counterfeit pharmaceuticals
  - Pharmacy Board to regulate implementation of the Pharmaceutical Act and Policy
  - National formulary of pharmaceutical products
- For science and technology:
  - Science and Technology Act from the 1970s
  - Science and Technology Policy
  - National Council for Science and Technology, which heads the public research system
- For management of intellectual property issues:
  - An up-to-date Intellectual Property Act that complies with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement
  - A National Patent Office, however this reviews only around 5 patents per year, most pertaining to agricultural products, not pharmaceuticals
  - The government is currently building IP capacity at the main national university and through foundation of a specific IP research institute.

Level of access to safe, effective, quality medicines in Country A

- Country A has a healthy domestic pharmaceutical market consisting mostly of imported Indian generic medicines
- The Ministry of Health procures medicines on behalf of public hospitals through an international bidding process, and increases access to quality affordable medicines by using international initiatives such as the Global Fund, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), UNICEF, the Clinton Foundation and GAVI.
- Country A's regulatory authority has capacity to review less complex regulatory dossiers (e.g. generic drugs), taking an average 6-12 months to review and register a generic product. However, it has limited experience in assessing more complex dossiers, e.g. for novel drugs or vaccines
- Country A has a WHO-accredited National Quality Control Laboratory that can accurately and reliably test and verify the quality of generic drugs, and of simple toxoid vaccines
- Medicine prices are not regulated in Country A and there are significant price variations across regions and sectors. Public and Mission procurement attain competitive prices below international reference prices, but patient prices are relatively high compared with neighbouring countries.
- Country A's intellectual property laws include TRIPS flexibilities, such as compulsory licensing and parallel importation. Compulsory licensing has yet to be used, however parallel importation of ARVs has been used.

Manufacturing capacity in Country A

- Country A's pharmaceutical manufacturing base has grown dramatically over the last decade, with over 30 registered pharmaceutical manufacturers collectively supplying 50% of the regional market. However, the scope of manufacturing is limited, with companies predominantly repackaging formulated drugs and processing bulk components (imported APIs and excipients) into drugs. The bulk of locally manufactured preparations are non-sterile, over-the-counter (OTC) products.
- Country A hosts branches of several multinational pharmaceutical companies, including GlaxoSmithKline, Astra Zeneca, Pfizer, Sanofi Pasteur, Eli Lilly and Novartis. These have regional sales, marketing and sometimes manufacturing functions in Country A, but no local R&D programmes.
- Most local pharmaceutical manufacturers have made an effort to adopt good manufacturing practices (GMP) but compliance is far from ideal, and inadequate GMP enforcement has been identified as the main reason for poor quality products.
- Country A encourages domestic manufacturers by providing low import duties on active pharmaceutical ingredients (APIs) and other tax benefits. Country A is also a signatory to various African regional treaties that exempt many regional goods from import duty (including possibly pharmaceuticals?).

Pharmaceutical research capacity in Country A

- Country A has a strong research and tertiary education base in both the private and public sectors, with a number of universities conducting biotechnology and information technology (IT) programmes.
- The National Medical Research Institute has a long history of sophisticated health and clinical research
- Country A has an impressive clinical trials network and extensive experience in clinical research. Several centres have the capacity to conduct large-scale drug and vaccine trials to international licensure standards, and have trialled drugs, diagnostics or vaccines for hepatitis, HIV/AIDS and its opportunistic infections, malaria, tuberculosis, schistosomiasis and filariasis, among others.
- Ethics review committees are in place to approve clinical trials, and all trials are approved by the pharmaceutical regulatory authority. However, there is no national clinical trial register.
- An IP audit showed that IP management by researchers was improving with two R&D institutions and three universities having technology transfer offices, although not all were fully functional.
- However, early stage pharmaceutical innovation is very limited (i.e. discovery of potential new medicines).
- Human resource shortages are a brake on Country A's pharmaceutical innovation capacity.
- National funding for research is limited, and this is a significant constraint on research. Recognizing the problem, the government recently set up a US$3m innovation fund to facilitate research in science, technology and innovation.

Opportunities

This assessment shows that Country A has established a solid legislative, regulatory, research and education base to support pharmaceutical innovation, and identifies two key areas of opportunity for Country A to expand its pharmaceutical innovation capacity:

1. Given its large domestic and regional market, strong science base, and existing pharmaceutical tabletting and packaging industry, this analysis suggests Country A is in a good position to expand its pharmaceutical manufacturing capacity, including future production of active pharmaceutical ingredients. Areas to target to move to this next level are domestic GMP qualification, and upgrading of manufacturing facilities and skills for API manufacturing.
2. Country A's strong clinical trial network and sophisticated research capacity lend themselves to a move into early pharmaceutical innovation, for instance product reformulations or development of novel fixed-dose combinations of existing products. Key challenges will be to address human resource shortages (including pharmacology and pharmaceutical skills), increase funding streams to domestic applied research, and increasing regulatory capacity to overview dossiers and clinical trials of new product formulations and combinations.

Case study 2 - Approach for African country B

Country B is a small African country with a population of under 5 million. Courtesy of economic growth, it has a relatively high GDP in African terms and, as a result, is now seeing the 'double burden of disease' typical of countries in epidemiological transition. That is, infectious diseases commonly seen in developing countries, but also an increasing burden of non-communicable diseases more common to high-income countries. As a result, Country B is increasingly being targeted by pharmaceutical companies as a potential site for clinical trials of products for non-communicable diseases such as diabetes, cancer and cardiovascular disease.

Legislative, policy and institutional framework in Country B

- For pharmaceutical management:
  - Pharmacy Act (early 1980s) mandating registration of pharmaceutical products and regulation of pharmacies, but now considered out of date
  - A Pharmacy Board whose main function is to regulate pharmacies and pharmacists. The Board also registers medicines for domestic use, but has limited capacity to review and assess new medicines
  - National formulary of pharmaceutical products
  - No dedicated Medicines Regulatory Authority, and no nationwide pharmacovigilance or counterfeit control systems, although plans are underway (see Clinical Trial Bill)
  - A new Clinical Trial Bill, due to be passed in 2009, will include provisions for a new medicines regulatory authority and pharmacovigilance committee
  - Country B is a member of several regional economic communities working to harmonise medicines regulatory standards and quality Assurance
- For science and technology
  - A Science and Technology Policy is in place
- For management of intellectual property issues:
  - A Copyrights Act and Patents and an Industrial Designs and Trademarks Act are in place, both of which comply with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement

- Country B recently ratified the TRIPS protocol allowing it to produce drugs under compulsory licensing for export to regional economic communities. However, its small manufacturing base (see below) will restrict its ability to do so
- Country B has built a good health care system

Level of access to safe, effective, quality medicines in Country B

- Almost all of Country B's pharmaceuticals are imported, mainly from Indian manufacturers.
- Country B has some of the highest pharmaceutical tariffs in Africa, with 2001 data ranking it in the top 15 African countries for tariffs on active pharmaceutical ingredients and finished products, including a 10% mark-up on the CIF (cost, insurance and freight) price
- Country B is involved in initiatives by several Regional Economic Communities to secure pooled procurement of medicines in order to lower costs

Manufacturing capacity in Country B

- Manufacturing capacity is very modest. There are two domestic generic manufacturers and no multinational pharmaceutical companies (MNCs).

Pharmaceutical research capacity in Country B

- Country B has limited technical expertise in research, and the health research agenda focuses on non-communicable diseases such as cardiovascular disease, asthma and cancer
- Country B has a Central Health Laboratory with biochemistry, microbiology, virology and pathology divisions. It conducts research in the areas of diabetes, hepatitis B and HIV/AIDS
- A national university conducts research and has a medical studies centre
- Research volume is modest. The Research Council, the country's main research centre, has funded only 33 biomedical research projects in the last 15 years
- Five state hospitals have the capacity to conduct trials, but there is no trial network
- Country B has a Research Ethics Committee, but no regulatory review of clinical trials
- Country B is currently undertaking a major reform of its legislation to ensure it can maximise the opportunity to host clinical trials of industry products

Opportunities for Country B

This assessment shows that Country B is at the earliest Innovation Milestone. Some fundamentals are in place, or will be in place shortly, including a good health care system, and legislation and regulation for medicines and intellectual property. The manufacturing base is limited, however, and there is limited technical expertise in pharmaceutical research. This suggests Country B is not well-positioned to embark on pharmaceutical manufacturing or innovation research at this point in its development.

This assessment suggests priorities for Country B would be to:

- Put in place the fundamental elements of innovation, including:
  - Developing a National Pharmaceutical Policy covering safety, efficacy, quality, best use of medicines, prescribing practices, generic use.
  - Institute a National Council for Science and Technology to head and coordinate the public research system

- Focus on improving access to affordable, quality, imported medicines for the population
  - Review membership of global procurement mechanisms for affordable quality products (e.g. GDF, UNICEF, AMFm.)
  - Review pharmaceutical tax and tariff policies
  - Implement legislation dealing with importation of counterfeit pharmaceuticals
  - Support the new MRA to review dossiers of imported generic products (either nationally or in conjunction with regional regulators)

If Country B wishes to attract clinical trials from industry, the following areas would be priorities:

- Support the new Medicines Regulatory Authority to register, evaluate and approve clinical trial protocols and plans to inspect clinical trial sites
- These MRA activities could be developed domestically but a quicker, more cost-efficient approach could be to liaise with regional or other external regulators to conduct joint trial approvals and inspections while the MRA is in the early stages
- Develop a mechanism to coordinate clinical trial reviews and inspections by the current Research Ethics Committee and the proposed new MRA
- Create clinical trial hubs in the existing hospitals, and use these to build trial networks in the surrounding areas
- Upgrade the proposed trial hubs, field sites and laboratories to international standards (GCP and GLP)
- Conduct training in data management and in meeting international standards including ICH, GCP, GLP
- Consider membership of the African Vaccine Regulatory Forum (AVAREF), set up in 2006 to support MRAs and Ethics Committees in African countries that were targeted for clinical trials of new vaccines
- Encourage the proposed National Council for Science and Technology to work with the National University to develop a curriculum relevant to pharmaceutical trials and research (e.g. applied pharmacology, immunology, epidemiology).

Chapter 6

The way forward – Conclusions and recommendations

6.1 Where are we now?

This report provides the evidence base and direction for the initiative *Strengthening Pharmaceutical Innovation in Africa*. Its purpose is to contribute to the improvement of health, equity and development in Africa, through better access to essential drugs by supporting health knowledge and technology transfer and a public goods approach to pharmaceutical R&D and production.

The initiative provides a road map for African countries and their supporters to engage productively in pharmaceutical innovation – primarily, but not exclusively, driven by improving access to essential drugs. Economic development on its own remains a second important driver for pharmaceutical innovation, as highlighted in the Pharmaceutical Manufacturing Plan for Africa.

The work leading to this report resulted in **two major outputs**:

- **A map of the many pharmaceutical innovation efforts in progress in Africa** linked to improving access to drugs. This map is a first effort to show the complexity of the field. It is an essential tool to help countries understand the nature of the international efforts that apply regionally and possibly in their own countries. This understanding is the basis for rational decision making and for developing the capacity to exercise appropriate governance of pharmaceutical innovation within their borders – or across borders with neighbouring countries.
- **a "pharmaceutical innovation framework and grid"** which guides decision makers through the options for countries interested in starting pharmaceutical innovation to improve drug access or develop their economy. This tool encourages countries to ask themselves serious questions about their level of engagement and provides options for immediate and longer term action. It serves as a road map for countries to make a difference through pharmaceutical innovation – not just in terms of drug production but also by creating an environment that favours efficiency in procurement, regulation and logistics management, for example.

As this work unfolded, two important developments occurred that have or may have a direct impact on pharmaceutical innovation in low and middle income countries in general, and in Africa in particular. These include;

- the adoption of *the Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property (GSPOA)* by the World Health Assembly in 2008
- the *Bamako 2008 Ministerial Forum on Research for Health* in Mali, which brought together, for the first time, ministers of health and ministers of science and technology to discuss "research for health" – including pharmaceutical innovation.

The emphasis given to pharmaceutical innovation by these two global activities and the availability of practical tools that countries can use to start operationalising pharmaceutical innovation create momentum for full implementation of the Declaration of the Algiers Ministerial Conference on Health Research, the Bamako Call for Action, the WHO GSPOA on Public Health, Innovation and Intellectual Property and the African Union Pharmaceutical Manufacturing Plan, among others.

The partners believe that the approach we have developed and the tools we propose can help the various stakeholders in Africa to take such concrete steps and put in place coherent strategies to implement the measures recommended by these important events and documents.

Under NEPAD's guidance, this African initiative for improved access to medicines and local production will contribute to the expansion of a well functioning innovation system for health in Africa that makes the best use of African human capacity and natural resources to improve health on the continent – and contribute to its economic development.

Soon after the Pretoria meeting where African experts reviewed the report – improved and approved the approach and tools – the initiative Strengthening Pharmaceutical Innovation in Africa was endorsed by the African Ministerial Conference on Science and Technology as a starting point for African countries to put into action the Global Strategy and African Pharmaceutical Manufacturing Plan.

This provides impetus for the first steps of implementing the initiative and will help identify countries where the approach can be applied and tested.

6.2 Major findings and conclusions of the analytical process

6.2.1 A growing demand for pharmaceutical innovation in Africa – and globally

> "The leadership of the African Union is committed to ensuring access to essential medicines for countries in need, irrespective of their level of technological development and manufacturing capacity."
>
> Pharmaceutical Manufacturing Plan for Africa, Ministers' meeting, 10-13 April 2007

Pharmaceutical Manufacturing Plan for Africa – 6 priority areas

In 2007 the African Union adopted the Pharmaceutical Manufacturing Plan for Africa to focus on:

- **Mapping**
- **Situation Analysis and Compilation of Findings**
- **Manufacturing Agenda**
- **Intellectual Property Issues**
- **Political, Geographical and Economic Considerations**
- **Financing**

There is a tremendous interest in pharmaceutical innovation as a way to improve health and access to drugs for the poorest people and countries. As a result, there is also a growing demand from low and middle income countries and regions to become more active partners in finding lasting solutions in that area. This is demonstrated, among others, by the time and resources devoted by the Member States of WHO – for almost two and a half years – to the complex negotiations of the Intergovernmental Working Group (IGWG) that developed the GSPOA.

National interest:

While most African countries got increasingly involved in reflections shaping the international debate on access to essential medical products, Kenya – together with Brazil – was instrumental in the World Assembly's discussions of 2008 and 2009 as well as in the IGWG, thus taking an active role in the development of the GSPOA. Nigeria played an essential facilitating role in the creation of the African Network for Drug Discovery and Innovation (ANDI) supported by WHO/TDR. South Africa is home to some of the most successful ventures of the continent in the pharmaceutical production, like ASPEN Pharmacare, and is the only African country producing Active Pharmaceutical Ingredients; small biotech companies emerge regularly; and the country has one of the most efficient drug regulation systems of Africa. Smaller countries like Ghana – with the creation of the La Gray pharmaceutical company – also develop their private pharmaceutical industry, and others, like Rwanda, make deliberate and sustained efforts to build – almost from scratch – a comprehensive system to ensure their people's regular access to safe and good quality medicines. These are only a few examples of an increasingly dynamic pharmaceutical sector in Africa.

Regional interest:

In October 2008, African researchers, pharmacists, academics, representatives of the African Manufacturing Association and African expatriates gathered in Abuja, Nigeria

to create ANDI (WHO/TDR), which aims to facilitate the development of African discoveries and research results – including traditional medicine – into usable medical products of good quality, by pooling regional resources and promoting better interaction between researchers and drug developers and producers.

In February 2009, NEPAD, with funding from the Gates Foundation and the technical support of WHO, brought together all Regional Economic Communities and most of the National Regulatory Authorities of Africa to spearhead regional and national efforts for strengthening and harmonising drug regulation across the continent. In February 2010, the African Union Commission, together with NEPAD and COHRED organised a special meeting of an Extended Technical Committee of the Pharmaceutical Manufacturing Plan for Africa, with support from the Netherlands' Ministry of Foreign Affairs and the Swiss Agency for Development and Cooperation to review the initial version of the report, its study and tools – Strengthening Pharmaceutical Innovation in Africa – prepared by NEPAD, COHRED and contributions from the George Institute for International Health. The meeting brought together a unique cross-sectoral gathering of experts and stakeholders active in all aspects of pharmaceutical innovation on the continent.

Global interest:

The debates in WHO for developing the Global Strategy and Plan of Action mobilised a lot of interest, including experts in the pharmaceutical industry and non-governmental organisations who informed the debates of the Intergovernmental Working Group. The discussions around the financing of the Strategy and Plan of Action are mobilising all stakeholders in innovation and research for health in active debates – through open electronic consultations – on how to provide incentives for innovation without undermining access to medicines.

Many NGOs like MSF, Save the Children, HAI, or more recently IQSensato, participate actively to the debates on access to medicines and play an essential role in questioning the decisions of the international health research community and holding the public stakeholders accountable for their decisions on pharmaceutical innovation and access.

The private sector too is developing new approaches to keep up to speed and respond to the growing demand for more equity in drug production and access. More than 200 public private partnerships have emerged during the past decade to build up capacity, to transfer technology and knowledge, and to support research and facilitate access to medical products in developing countries. New research centres have been created or supported by the pharmaceutical industry in the South to better cater for the needs of low and middle income countries, like the Novartis Centre in Singapore or the International Vaccines Research Centre in Korea

Global and national interests are not necessarily convergent.

There is a difference in the nature of the interest demonstrated towards pharmaceutical innovation at the different levels. African countries seem in general more interested in the trio of discovery, traditional medicine and biotechnology, in addition to better understanding and improving procurement and delivery, while at global level the interest is more on discovery, development and testing. Delivery and procurement generate less interest at global level in general.

For this reason alone, countries need to be partners in the global drive towards more equitable access to drugs. It is only when adequately addressing all facets of the R&D, production and delivery of medical products that effective solutions will be possible. Coherence and complementarity of the efforts at all levels is certainly one of the keys to long term success in that domain.

6.2.2 Complexity of the landscape of pharmaceutical innovation

This study identified more than 120 different initiatives or programmes active in access to medical products in Africa. A number of these are global initiatives with an exclusive or partial focus on Africa. These partnerships bring together small groups of players (2-3) and extend to groupings of 20-30 different entities. They are from the public and private sectors – some groupings are all public, others all private, and some public-private. There are gaps at all levels, as most initiatives work in specific parts of the innovation spectrum. Donor countries and international organisations are also members of several partnerships, and these activities are not necessarily coordinated – despite membership overlap, creating a lack of coherence, even within institutions.

Almost no country in Africa, and very few in other low and middle income countries – with the notable exception of Brazil – have a 'grand plan' for pharmaceutical innovation. There are lots of actors and initiatives but paucity on long term vision, comprehensive approaches, coherence and coordination. There is lots of information, although not widely disseminated and seldom analysed within a more general context, but much less evidence on what works. There is even less evidence of whether national policies on pharmaceutical innovation are evidence-informed or, simply, work.

To make sense of this and to determine where appropriate action can be taken by countries and in countries, we need tools and approaches that simplify, that encourage understanding and synergy, and that can lead to the identification of practical steps forward. The 'Pharmaceutical Innovation Grid' is intended to provide this guidance.

6.2.3 Lack of approaches to help countries make decisions on engagement

The intersection between public health, pharmaceutical production and intellectual property rights remains a complex and disputed domain. Countries need tools and support to make rational decision about their engagement into pharmaceutical innovation in ways that fit their heterogeneous needs and resources. They must undertake an in-depth analysis of public health and innovation issues at regional and national level, develop strategies to address the gaps identified and put in place the essential building blocks of a pharmaceutical innovation system – all of which are core to ensuring that their people have access to essential medical products .

Low and middle income countries – already faced with overwhelming disease burden, fragile health and science and technology systems, and limited human resources in the pharmaceutical innovation domain – are now also faced with a veritable tsunami of efforts to improve access to drugs.

Early reactions to the pharmaceutical innovation map show that many - even well-resourced initiatives and actors – are unaware of the complexity of the landscape, let alone the governments in low and middle income countries that are to benefit from these efforts. Before they can have an overview, based on evidence and reliable analysis, they cannot even hope to exercise minimal governance in this area.

The 'grid' is a world first – there have been no previous attempts to create such an enabling tool. It encourages system thinking and will promote coordination, coherence, overview and oversight, and a focus on national priorities in health and science and technology.

Our hope and assumption is that the map and the 'pharmaceutical innovation grid' developed as part of the Yaoundé process will enable African countries to refine their analysis of pharmaceutical innovation, and that African decision makers can use these two tools for catalyzing progress in areas identified by the PMPA Technical Committee or others, as may be relevant in individual counties and regions. However, the Grid also has generic appeal and may well be applicable in countries beyond Africa.

6.3 Proposed next steps

6.3.1 Operationalising strategies and plans of action.

The GSPOA and the African Union's PMPA are aspirational statements that need to be translated into work plans and approaches to implementation. The development of the 'Pharmaceutical Innovation Grid' aims to support countries to translate these global plans into action at national, regional and continental level.

This report, its pharmaceutical innovation tool – the Framework and Grid – were considered to be extremely useful by he African Union's Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa.

The review confirmed convergence of the findings of this study with an analysis done by the Expert Committee in 2007. They recommended using the report and the tools it proposes to inform and support the African Union in developing a business plan for the PMPA. They also recommended using them to contribute to achieving the goals of the PMPA.

The experts of the Extended Technical Committee said that the tool provides a mechanism for coordinating and harmonising among different stakeholders involved in implementing the PMPA. This, they said, creates the basis for monitoring and evaluation of some aspects of the GSPOA and the PMPA, and provides evidence to support the implementation of specific aspects of these two strategies. The study findings and tool also support priority setting for implementing these mechanisms – nationally, regionally and for the African continent. It assists countries and regions to identify gaps and use these as evidence to gain donor and partner support.

Participants in the Pretoria meeting recommended:

- Establishing short and long-term objectives and milestones for pharmaceutical innovation and manufacturing in Africa.
- Prioritising the creation of mechanisms to stimulate research and development, technology transfer and other conditions needed to facilitate and strengthen manufacturing in Africa.
- Creating a coordination mechanism to ensure better synergy and improved intra and inter-regional support.
- Establishing a mechanism to capture and keep up-to-date information about country developments.
- Making the tool and related documents available in all official African Union languages and adapting its formulation to a language that is understandable across sectors, professional cultures and backgrounds.

Participants recognised that establishing strong communication mechanisms is essential to the effective use of the tool, and that to achieve their goals; the different stakeholders will need to meet, share information and resources and generally improve their collaboration.

> AMCOST commends the NEPAD Agency for its programmes on pharmaceutical innovation and harmonization of medicines registration in the AU member states in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA), AU Health Strategy, AU Pharmaceutical Manufacturing Plan for Africa and CPA
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> AMCOST Resolution, March 2010

6.3.2 Obtaining high-level political support for implementation

In additional to having appropriate technical tools and approaches, political support is essential to the long term success of pharmaceutical innovation playing a proper role in improving health, equity and development.

The Pretoria meeting was a first important step toward getting broad African review and support for the pharmaceutical innovation strengthening process initiated by NEPAD, COHRED and their partners. The participants to the meeting recognised that successful national pharmaceutical innovation requires a combined effort of political support, technical expertise and financial commitment between several sectors (such as education, finance, law and trade), particularly between health and science and technology.

As a first step toward securing political support for the initiative on '*Strengthening Pharmaceutical innovation in Africa*' the report, tool and Pretoria Meeting Statement of partners were presented in Mach 2010 to the meeting of the African Ministerial Conference on Science and Technology (AMCOST), which commended the work accomplished by NEPAD and its partners. Several of its member countries expressed an interest in implementing the Framework and Grid.

6.3.3 Starting implementation

Capacity building is recognised as vital to strengthening pharmaceutical innovation in Africa.

To define the focus and content of the workshop series, essential capacities and skills will need to be prioritised according to countries' and regions' specific gaps and needs. Key areas to be strengthened have already been identified for each milestone.

Access:

- Health care policy making must be strengthened and regulations enforced to address the challenges of substandard drugs, dumping of drugs close to expiry, and donated drugs that may result in mono-therapy and increase the risk of resistance
- The capacity of governments to handle well-meaning donations must be improved to make sure that they do not undermine access or the capacity of local manufacturers.
- The capacities of medicines regulatory authorities must be strengthened to ensure access to safe, efficacious, high quality medicines
- Capacity should be developed in inspection, quality control, laboratories' work and management. Quality assurance systems are critical; this responsibility should be located at different levels of pharmaceutical innovation.
- There is a need to build capacity in international intellectual property laws and regulations
- Regional collaborations should be explored to address capacity constraints in laboratory technologies, and in other areas, such as policy making or enforcement mechanisms. Countries would benefit from the lessons of other countries.
- Participants recognised that enforcement depends largely on national mechanisms like training and strengthening judiciary institutions.
- Strengthening capacity in health insurance will contribute to sustainable financing and improve access.

Manufacturing:

- Achieving WHO prequalification for African products is a very significant hurdle, but is important as it is considered the hallmark of certification. It calls for specific capacities, facilities, and for personnel skilled in prequalification standards. The high capital investment needed to meet the minimum standards and the prohibitive costs of borrowing capital are a major hindrance.
- Universities should realign their training curricula to produce the right calibre of personnel
- African governments should establish a fund that lends at low interest since commercial rates are prohibitive
- Partnerships should be harnessed and fostered with agencies like UNIDO to assist African companies working towards WHO prequalification
- Governments must assist local manufacturers to overcome the challenges of WHO prequalification, especially given the cost of bio-equivalence studies. Local companies could benefit from 'preliminary prequalification' if they reach certain milestones. Companies could be prequalified rather than qualifying particular products
- Strengthening regional capacity offers good alternatives. Some countries are looking to establish common facilities like bio-equivalence centres, common review and inspection of facilities, harmonised review process of dossiers – that account for certification by another agency within the region6
- Capacity building is needed for handling of traditional medicines and phyto-medicines and cultivation of medicinal plants. This also implies the capacity development of national regulatory authorities, including expertise in taxonomy, quality control of medicinal plants, microbiology.
- Local manufacturers' competitiveness must be increased, of example through an increased marginal preference for locally manufactured medicines.
- Feasibility studies are needed to strengthen the case for financing of local manufacturing capacity.
- Improvements in Africa's manufacturing capacity will create an enabling environment and address critical criteria for improved competitiveness, such as the cost of power.

Research and development

- R&D is expensive and calls for collaboration.
- An enabling research environment should be created, for example through supporting research ethics
- Institutions in Africa need to build up the necessary capacity – human resources and institutional strengthening – to draw and attract funding for R&D. This could be done among others through funding Masters, PhDs and other degrees for creating scientific leaders in Africa
- Infrastructure development and networking opportunities should be supported to create a critical mass across research institutions in Africa
- Regional centres of excellence should be encouraged through collaborations that foster regional partnerships, promote local ownership and are able to attract independent funding that allows the development of research
- Recognising that specific institutions have competence in certain areas of research, support should be provided to them to move into other areas beyond their current areas of research, for example moving from malaria to tuberculosis research
- There is a need to develop capacity for testing of products from the very outset rather than at later stages

- Partnerships between private sector and research institutions should be promoted to build capacity in real novel drug discovery. Governments and institutions like AU/NEPAD should lobby and encourage the creation of a mechanism that supports funding of competitive proposals that lead to the commercialisation of products
- Capacity building needs of traditional medicine require particular attention as the AU decade for traditional medicine will end this year. Capacity is needed in the area of developing remedies, training people in pharmacology, in mixture of active components from many plants (as distinct from pure substances)
- States should be encouraged to allocate 2% of their national budget for research 7

The African experts at the Pretoria meeting of the Extended Technical Committee of the Pharmaceutical Manufacturing Plan for Africa (February 2010) concluded that human resources development is crucial in all areas of R&D, and monitoring and evaluation are critical to the success of pharmaceutical access, manufacturing and research and development.

Workshop series - Increasing technical understanding of pharmaceutical innovation

Governments and regulatory authorities in low and middle income countries need to have the best available information to make informed decisions on where to engage with the pharmaceutical innovation process. Given the complexity of the domain, it is essential to provide a multi-year, on-going workshop series open to all interested countries in Africa. All players in the pharmaceutical innovation field will be able to contribute, both financially and technically. It is foreseen as a 4-6 workshop series per years over 3-5 years, covering different regions and languages.

Workshop follow-up may include mentorship, partnerships and other mechanisms of increasing national capacities.

The challenges and possible solutions highlighted in the Pretoria meeting confirm that capacity building and training needs are diverse, specific to the African countries and regions concerned and cover a broad range of issues. Countries need to carefully evaluate their most pressing needs and design their capacity building strategies accordingly. However, some of the gaps to be addressed are quite similar from one country to the next and it has been repeatedly stressed that regional strategies and collaborations could efficiently help developing the skills and capacities needed across Africa.

A good example of regional efforts now in progress is the harmonisation of drug regulation, supported by NEPAD and the Regional Economic Communities (RECs), for which regional capacity building strategies are being developed.

In a similar way, it is envisaged that the initiative Strengthening Pharmaceutical Innovation in Africa will collaborate with African RECs and other partners to establish a series of workshops to increase African countries' capacities in areas identified as critical for implementing pharmaceutical innovation, for example – drug regulation, intellectual property management, laboratory techniques, research management and leadership.

Implementation – pilot countries

One of the major inputs of the Pretoria meeting, enhanced by the technical workshops series, will be a concerted effort by NEPAD, COHRED and the other partners of the project – donors, technical experts and other stakeholders – to work with interested countries for the first phase of implementation. As resources will be limited, strong emphasis will be put on a "pilot country" approach – in which countries are included on the basis of interest expressed, feasibility and level of commitment.

One critical step in the implementation will be the dissemination of the report Strengthening Pharmaceutical Innovation in Africa, its approach and tools. Implementation should start with further assessment of the situation by the technical partners, including NEPAD and COHRED, in countries and regions – to encourage ownership of the approach. The tool will be adapted and translated into the African Union official languages and people will be supported to use it. Existing knowledge on the status of each country should be included in the assessment.

Another essential step is to establish or reinforce local production facilities that address priority needs defined by African countries and comply with quality and safety standards. Key elements for developing local manufacture will be:

- **Developing a framework for facilitating technology transfers and joint ventures** with access to venture capital facilities. This can be facilitated by the AU, following the examples from malaria nets and tuberculosis.
- **Mobilising resources:** this is a role for the African Union, that can get support in their negotiations from many partners, like UNECA.
- **Mobilising private sector partners to start manufacturing**, for example through Chambers of Commerce and local associations.

It will also be essential to have in place fully functional regulatory authorities for quality assurance, with the help of WHO and relevant authorities, and make sure that local manufacturers comply with Good Manufacturing Practices, obtain pre-qualification and can register their products through a reliable and appropriate process.

At the same time, the African Union could facilitate the creation of incentives for African manufacturers, for example through public tenders.

Good distribution practices should also be established; WHO and other experts can assist African countries to develop relevant policies.

Implementation in pilot countries should be driven by national governments. Specific national approaches will depend on each country's specific situation, its objectives, most crucial gaps and key resources. Facilitation provided by technical experts should allow for a flexible use of the Framework and Grid. This will ensure a thorough assessment of the country's current innovation status, the adaptation of the tool and approach to the country's situation, and encourage development of a partnership between the main national players in pharmaceutical innovation.

6.3.4 Developing of additional tools, frameworks and guidelines if and when needed

It is very clear that the map and grid developed as part of this project are just the beginning of what is needed to support countries in operationalising pharmaceutical innovation. During the implementing phase, other frameworks may be developed as complements to the first pharmaceutical innovation grid proposed and to facilitate the implementation of some of its components. More information is needed to better understand some of the essential elements for building up innovation systems, how to prioritise them within a particular African national context, and in which sequence to put them in place. Another adaptation needed of this Version 1.0 of the Grid is one that offers a phased approach.

6.3.5 Monitoring and evaluating

COHRED and NEPAD have already decided on an extensive collaboration on an innovative web-based framework for the management of research systems. For the health field it is the Health Research Web (www.healthresearchweb.org) and for the African Science and Technology Innovation Indicators project it is the African Science & Technology Web (www.africanscienceweb.org).

The advantages of this system are that it offers the first Pan-African research management information system, suitable for national, regional and institutional use, and the fact that it is controlled by the countries.

NEPAD and COHRED will collaborate in adapting this web-based platform to measure and communicate progress in implementing the GSPOA in Africa and the African Union's PMPA.

6.4 Conclusion

This paper highlights the tremendous momentum currently focused on pharmaceutical innovation in Africa. Collective and concerted efforts to help countries harness these energies for the advancement of public health and socio-economic development are both timely and useful.

While political awareness has increased with the recent endorsement of essential policy directions and plans –especially of the GSPOA at global level, and of the African Union at regional level –African countries will need support to translate these into national policies and strategies and, above all, concrete actions. The present report is the first result of a process aiming to bring along the practical changes needed to move towards more innovation for health in Africa by Africa.

Annex 1
Tools - Innovation System Framework

Stage of development	Actions needed
Basic requirements - supportive environment	
Political commitment to pharmaceutical innovation and improved access to medical products	Advocacy, awareness, data and discussion. Identify key individuals/groups that can initiate and catalyse the process.
Political support across government sectors: health, science and technology, trade, industry, education, legal	Develop a common understanding of pharmaceutical innovation. Mobilisation across sectors for a multisectorial approach to innovation
Business environment and basic infrastructure	Increase reliability of essential infrastructure, e.g. banking system, power supply, transport,
Level 1 needs – pre-requisites	
Management mechanism for pharmaceutical innovation and access to medical products	Establish mechanisms and structures appropriate to the country's existing structures and aspirations. These need to be multisectorial. Particular attention should be given to collaboration between health and S&T sectors.
Public health priorities	Credible and regularly updated public health priorities Complementary priorities for health research and pharmaceutical innovation - essential drugs, diagnostics and vaccines
Level 2 needs – assessment and decision-making	
Assessment of current national situation of pharmaceutical innovation	Identifying where the country sits in terms of innovation milestones; where are the major gaps; who are the major stakeholders. The COHRED/GI Pharmaceutical Innovation Assessment framework provides a guide to these activities
Decision on pharmaceutical innovation goals	Informed by the assessment and public health and development strategies, focus on one of the 3 milestones, access, manufacturing or R&D and /or set national goals for the component chosen or for each component
Level 3 needs –essential building blocks	
Policy framework for pharmaceutical access, manufacturing and R&D	A number of policies need to be in place for each component, for example: Access: drug regulations, trade policy, tax policy Manufacturing: industrial policy, good manufacturing practices
Human Resources	R&D: research policy, intellectual property management Develop a human resources strategy and plan aligned with priorities Address all relevant sectors: public health, science and technology, industry, judiciary, economy, trade, education
Stable, predictable financing	Develop a pharmaceutical innovation financing strategy, Ensure it addresses national and foreign funding from the public and private sectors
Level 4 needs – Collaboration	
Partnerships	Regional, inter-country collaborations for product development, clinical trials, cross-registration, quality control. National PDPPPs; North-South and South-South transfers of knowledge, processes and technologies
Level 5 needs – optimising the pharmaceutical innovation system	
Improving pharmaceutical innovation system components	For example: *Access* - Pooled procurement - Community based delivery *Manufacturing* - Technology transfer arrangements; - Good manufacturing practices - Post market quality control *R&D* - Good research contracting; - Intellectual property management; - Clinical trials ethics; - Merit-based promotion system of scientists *All levels* - Community demands for medical products - Monitoring & evaluation - Institution building.

Innovation milestones		Policy and Legislative framework	Dept. of Health / Public hospitals / Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Imported medicines											
Access to safe, effective, quality medicines	Imported medicines	- Intellectual Property policy to maximise access (e.g. parallel importing, compulsory licencing) - National Medicines policy (guidance to safety, efficacy, quality, best use of medicines) - Laws mandating all National Regulatory Authority (NRA) functions - Drug pricing policy - National formulary and National Essential medicines list possibly based on WHO Essential Medicines List (EML) - National pharmacopoeia possibly based on WHO International pharmacopoeia Institutionalise use of the WHO QSM scheme for dossier review Participation in relevant regional initiatives e.g. • NEPAD/AU harmonization of medicines regulation • Regional IP organizations (e.g. ARIPO/ OAPI) • Regional economic communities (e.g. SADC, ECOWAS)	- Transparent and efficient drug procurement system including: - Tendering - Access to centralised vaccine procurement funds (UNICEF and GAVI vaccines etc) - Access to centralised drug procurement funds (Global Drug Facility for TB drugs, AMFm etc) - Access to other subsidised products (PEPFAR, Clinton Foundation etc) - Familiarity with WHO prequalification and EML decisions - May need an Ethics Review Board (if local bridging trials are needed)	Production of human resources (e.g pharmacists) Problem solving oriented tracking	- Funding for implementation and operational research	- Minimisation of import tariffs and duties on pharmaceutical products including diagnostics - Customs controls in place for genuine and counterfeit pharmaceutical imports - Enhancing inter regional trade and harmonisation	- Minimisation of internal taxes along the supply chain of pharmaceutical products	National Patent Office able to: - Optimise implementation of TRIPS flexibilities National Regulatory Authority able to conduct: - Licensing of premises and practices - Licensing of manufacturers and distributors - Marketing functions (e.g assess regulatory dossiers [alone or with regional partners]; leverage registration of novel drugs from stringent regulatory agencies) - Postmarketing functions (e.g collection of medicine samples, quality and counterfeit testing laboratories, pharmacovigilance system, enforce product recalls and mandate punitive measures for counterfeited or substandard products) - Control of drug advertising and promotion	N/A	Public awareness campaigns on TRIPS flexibilities Campaigns against counterfeiting	SADC importation guidelines WHO prequal / WHO expert committee to review dossiers WHO prequalification of quality control laboratories WHO GMP certifications PIC/S scheme West African Drug Regulatory Authorities Network (WADRAN) African Organisation for Intellectual Property, African Regional Intellectual Property Organisation Centralised procurement agencies: GDF, GAVI, Global Fund, UNICEF, Clinton Foundation, IMFM, PREPFAR, UNIDAD Harmonisation activities lead by Regional Economic Communities (RECs) WHO assessment tool for medicines regulatory Agencies

Innovation milestones		Policy and Legislative framework	Dept. of Health/ Public hospitals/ Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept. of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Manufacturing											
Access to safe, effective, quality medicines	Formulating and packaging products from imported API (Active Pharmaceutical Ingredients) and excipients into finished drugs	Investment policy Industrial policy Incentives to local manufacturers and possible restrictions or importations		Promoting industrial pharmacy programs in university Promoting technology transfer and skills transfer North-South and South-South Foster business management skills & entrepreneurships courses and degrees Foster project management skills and accounting courses and degrees	N/A	- Minimisation of import tariffs and duties on imported APIs - Customs controls in place for genuine and counterfeit API imports and exports - Punitive tariffs (Anti dumping policies)		National Regulatory Authority able to: - Recognise evaluation of APIs by foreign or international competent authorities (e.g. FDA, EMEA) or Certificates of Quality from WHO prequalification system (for HIV/AIDS, TB and malaria) - Quality audit and license domestic tabletting/ packaging manufacturers Reference laboratories to control identity, safety and quality of imported APIs	Pharmaceutical firms able to: - Comply with Good Manufacturing Practice for formulation/tabletting - Identify API certified suppliers and test identity quality and safety of procured APIs - Prepare Drug Master File for registration of APIs to national regulatory authority - Conduct small to large-scale manufacture and distribution (local/ regional) - Specify API requirement e.g formulation design, which can affect properties of finished drug - Commercialize products appropriately for the local market		WHO API pre-qual ICH St Lukes Foundation training in industrial pharmacy African Vaccine Regulatory Forum Developing country vaccine regulatory network African diaspora
	Producing drugs, including producing phytomedicines, APIs and excipients				N/A			National Regulatory Authority able to: - Assess API and generic registration submissions (i.e. review scientific and manufacturing data + GMP certification scheme and inspections of domestic producers) Post-marketing: random sampling and testing of API batches and generic medicines, site visits, enforcement of product recalls, punitive measures for non-compliers Quality audit and license domestic API/drug manufacturers Full audit trail of API/excipient supply chain	Pharmaceutical firms able to: - Produce APIs to GMP standards and pharmacopoeia requirements - Undertake formulation, process and scale-up of generic drugs - Conduct studies of generic formulations (e.g. stability, bioequivalence) - Prepare regulatory dossiers for generic drug registration, using both data from their own studies and referencing quality, safety and efficacy data from original drug regulatory file		
	Producing vaccines				N/A			National Regulatory Authority / National Control Laboratory: Capacity to carry out lot-by-lot inspection of vaccine Quality audit and license domestic vaccine manufacturers	Access to manufacturing facilities specifically tailored to large scale vaccine GMP-standard production e.g. - Sealed fermentation facilities - to ensure safety while culturing organisms that are potent pathogens - Asceptic production/purification facilities - to ensure sterility of vaccine - Large-scale harvesting facilities - to ensure maximum yields Ability to maintain and demonstrate a completely controlled production process (i.e. given variable nature of biological processes): - Ability to carry out stability and potency studies - Maintain potency and yield during sterile filtration of particle containing solutions - Full tracking of manufacturing batches - Capacity for lot-by-lot release of the vaccine - required for vaccines to ensure product consistency Dedicated in-house quality control laboratory responsible for assay development and processing		

Innovation milestones		Policy and Legislative framework	Dept. of Health / Public hospitals / Public research centres	Dept. of Education / Public universities	Dept of Science and Technology	Dept. of Trade	Dept of Taxation and Finance	Regulatory authorities	Industry	Civil society groups	Examples of relevant initiatives / Groups to engage with
Research and Development											
Access to safe, effective, quality medicines	Early pharmaceutical innovation (Fixed dose combinations, diagnostics, reformulations)	- Science and Technology policy - AU parliamentary policy setting on use of African manufacturers Investment incentive for local African manufacturing (e.g. preferential pricing)	- Some clinical trial sites able to carry out GCP standard licensure trials - Ethics Review Board to review trial design	- Tertiary science education and research covering applied pharmaceutical sciences (e.g. medicinal chemistry, pharmacology, biostatistics) - Laboratories able to work to international licensure standards (Good Laboratory Practice) to conduct any preclinical studies - Ability to act as sponsor for clinical trials - Harmonisation between universities (R&D registry)	- Funding for clinical trials	N/A	R&D tax breaks	National Regulatory Authority able to: - License and inspect laboratories, manufacturing facilities and clinical trial sites to ensure compliance with international quality standards (GLP, GCP, GMP) - Define data requirements (e.g. data needed to register fixed dose combination) - Maintain national register of clinical trials - Review regulatory dossiers for authorisations for clinical trials and for (non-novel) new drug applications (since original components already approved and used in humans)	Public or private sector firms able to: - Access rights to original drugs and their registration data for further development (e.g. combination with other drug or new formulation) - Conduct limited preclinical studies, bioequivalence studies and clinical trials to international licensure standard - Undertake formulation, process and scale-up of manufacture - Prepare regulatory dossiers for clinical trial authorisation and drug registration, using both data from their own clinical studies and referencing quality, safety and efficacy data from original drug regulatory file - Design and implement clinical development plans for drugs - Sponsor drug trials		EMEA Article 58 Health research Web African diaspora WHO/TDR/ANDI
	Novel drug innovation (small molecules)		- National funding of research and existing research infrastructure (e.g. medical research council) - A robust network of clinical trial sites able to carry out licensure trials to international standards	- Tertiary science education and research covering basic and applied sciences (e.g. target identification, pharmacology etc) - Technology Transfer Office facilitating translation of university innovations to third parties for product development - Laboratories, including animal facilities, able to work to international licensure standards for discovery work and preclinical studies - Ability to systematically evaluate and screen traditional medicines for successful compounds to be identified, developed and marketed	- Funding for basic and translational research - Coordination and integration of institutions and departments working on science and technology	N/A	N/A	National patent office able to: - Process patent applications and enforce patenting laws - Reasonable cost of obtaining and maintaining patent National Regulatory Authority able to: - Define data requirements for registration of novel drugs - Review complex regulatory dossiers for novel drug applications	Pharmaceutical firms able to: - Access compound libraries and screening facilities - Conduct discovery activities, preclinical studies, and design and implement complex drug clinical development plan to international licensure standards - Prepare complex regulatory dossiers for clinical trials authorisation and novel drug registrations		Malaria Clinical Trials Alliance (MCTA) In Depth network African Malaria Network Trust (AMANET)
	Novel vaccine and other biologics innovation (large molecules)	- IP law extending to biologics	- Extensive clinical trial site network able to carry out large scale vaccine licensure trials - Reference laboratories able to carry out immunogenicity tests	- Tertiary science education and research covering basic and applied vaccine research (e.g. antigen development; vaccine formulation) - Tertiary industrial/ engineering education covering biologics manufacturing processes and requirements - Access to certified animal facilities and GLP laboratories for preclinical vaccine studies (e.g. toxicity) including biosafety requirement - Access to vaccine delivery systems and adjuvants - Ability to carry out preclinical vaccine studies, (e.g. toxicity)	- Funding for clinical research - Support for platform technologies	N/A	N/A	Patent office able to process patents for biologicals National Control Laboratory able to: - Define data requirements for registration of novel vaccines - Test biologics National Regulatory Authority able to: - License and inspect vaccine laboratories, manufacturing facilities and clinical trial sites - Review complex regulatory dossiers for use of novel biological products in clinical trials and for their registration - Carry out post-marketing approval controls of vaccine lots - Audit and certify vaccine manufacturing plant	Public or private sector firms able to: - Access adjuvants and vaccine delivery technlogies - Prepare regulatory dossiers for clinical trial authorisation and registration of biological products - Carry out vaccine discovery and preclinical work, including feasibility studies for large scale vaccine manufacturing - Design and implement clinical development plans for vaccines - Sponsor vaccine trials (high liability) Small and large-scale vaccine GMP standard manufacturing facilities		Developing Countries Vaccine Regulators Framework (DCVRN) African Vaccine Regulatory Forum (AVAREF) International AIDS Vaccine Initiative (IAVI) Vaccine PDPs, e.g. Meningitis Vaccine Project, Rotavirus meningitis project European Malaria Vaccine Initiative (EMVI), Malaria Vaccine Initiative (MVI), Global TB Vaccine Foundation (AERAS) Vaccine PDPs, e.g. Meningitis Vaccine Project, Rotavirus meningitis project European Malaria Vaccine Initiative (EMVI), Malaria Vaccine Initiative (MVI), Global TB Vaccine Foundation (AERAS)

Article Database

Strengthening Health Innovations in Africa

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
The Business of Health in Africa Partnering with the Private Sector to Improve People's Lives	International Finance Corporation	2007	The Business of Health in Africa, International Finance Corporation / World Bank	Product development partnerships (PDPs), business, Science & Technology	x	x	x	x
Health Innovation Systems in Developing Countries: Strategies for Building Scientific and Technological Capacities	Mugabe J	2006	NEPAD	Technology transfer, public health challenges, scientific & technological capacity, programmatic & institutional measures, regional & international collaboration	x	x	x	x
The Changing Scene	Global Forum for Health	2004	Report on Health Research, 2003-2004, Chapter 1, Global Forum for Health	Incentives & finance mechanisms, product development partnerships (PDPs)	x	x	x	x
Out of Africa: the pharma challenge; Africa faces a barrage of challenges in its search for cheaper medicines, and so too do pharmaceutical companies	Smith D	2008	Pharmaceutical Technology Europe 20(4): 41(3)	Intellectual property systems, pharmaceutical Industry, regulation, Pharmaceutical Inspection Co-operation Scheme (PIC/S)	x	x	x	
Developing Health R&D Systems: Partnerships for Capacity Building in International Technology Transfer	Salicrup L et al.	2004	NIH Office of Technology Transfer, Submission for Global Forum for Health Research Panel Discussion	Technology Transfer, intellectual property, biotechnology	x	x	x	
Combating Diseases Associated with Poverty Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships	Widdus R & White K	2004	Workshop paper, Initiative on Public-Private Partnerships for Health	Product development partnerships (PDPs), Finance	x	x	x	
Is biotech the answer to Africa's health needs?	Siringi S	2001	The Lancet 358(9298): 2056-2056.	Biotechnology, interview with Julius Meme, Permanent Health Secretary Kenya	x	x	x	
Paging Dr Ricardo: A Dose of Economics for Healthier Pharmaceutical Production	Bate R	2008	Health Policy Outlook	Business, entrepreneurship	x	x		
Local Pharmaceutical Production in Developing Countries	Bate R	2008	Discussion Paper no. 1, Campaign for Fighting Diseases	Local production, economic policy, private sector	x	x		
Pharmaceutical Manufacturing Plan for Africa Phase II	Technical Committee of the Pharmaceutical Manufacturing plan for Africa, African Union	2008	Special session of the African Union conference of Ministers of Health	Local production	x	x		
Pharmaceutical Manufacturing Plan for Africa	Technical Committee of the Pharmaceutical Manufacturing plan for Africa, African Union	2007	Third session of the African Union conference of Ministers of Health	Pharmaceutical manufacturing	x	x		
Improving Access to Medicines in Developing Countries: Application of New Institutional Economics to the Analysis of Manufacturing and Distribution Issues	Attridge J & Preker A	2005	HNP (World Bank) Publication	New institutional economics, private sector	x	x		

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
Guidance for Industry: Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV	US FDA	2004	US FDA	Regulatory requirements, fixed dose combinations, co-packaged drug products	x	x		
Intellectual property organizations and pharmaceutical patents in Africa	Deiss R	2006	Social Science & Medicine 64 (2007) 287-291	Intellectual property Systems, HIV/AIDS - antiretrovirals	x		x	x
Health research and innovation: recent Spanish policies	de Pablo F & Noguer I	2008	Global Forum Update on Research for Health, volume 5: 54-57	Health & innovation policy, innovation, government policy, Spain	x		x	
Ethics, evidence and innovation	Goodman K	2008	Global Forum Update on Research for Health, volume 5: 88-90	Research ethics, innovation, Millennium Villages project	x		x	
Research and innovation in Brazil: the institutional role of the ministry of health	Serruya S et al.	2008	Global Forum Update on Research for Health, volume 5: 24-27	Health innovation systems; innovation, research, government policy, Brazil	x		x	
Commercializing African health research: building life science convergence platforms	Singer P & Daar A	2008	Global Forum Update on Research for Health, volume 5: 143-150	Innovation, convergence platforms, Ghana, Tanzania, Rwanda	x		x	
Public-Private Partnerships and Scientific Imperialism	Tucker T & Makgoba M	2008	SCIENCE 320: 1016-1017	Public private partnerships	x		x	
Building the Case for National Systems of Health Innovation	Chataway J	2007	NEPAD Background Policy Paper	Health innovation systems; Brazil, Cuba, China, India, South Africa, policy framework	x		x	
Lessons learnt at the World Bank Global Forum on Science, Technology and Innovation	Doorman F	2007	Conference Presentation, World Bank Global Forum on Science, Technology and Innovation	Health & innovation policy; science and technology initiative	x		x	
Investing in STI in Sub-Saharan Africa:Lessons from Collaborative Initiatives in Research and Higher Education	Fine J	2007	Conference Presentation, World Bank Global Forum on Capacity Building for Science	Education, building science, technology and innovation capacity, poverty reduction, NEPAD, AMCOST	x		x	
Technological And Social Innovation: A Unifying New Paradigm For Global Health	Gardner G et al.	2007	Health Affairs 26 (4): 1052–1061	Innovation, product development partnerships (PDPs)	x		x	
Mapping Africas advanced public health education capacity	Ijsselmuiden C et al.	2007	Bulletin of the WHO 85.12 p914	Public health education, mapping	x		x	
The structure and function of research ethics committees in Africa: A case study	Kass N et al.	2007	PLoS Medicine 4(1): e3	Research ethics; Research Ethics Committees (REC)	x		x	
The big idea: prizes to stimulate R&D for new medicines	Love J & Hubbard T	2007	Chicago-Kent Law Review volume 82, Number 3	Incentives, drug discovery	x		x	
Workshop on Developing Local Production and Supply Capacity in the Pharmaceutical Sector: the Role of Intellectual Property Rights	United Nations conference on trade and development (UNCTAD)	2007	Final report, United Nations conference on trade and development	Intellectual property systems, training	x		x	
The role of technology transfer offices in building the South African biotechnology sector: an assessment of policies, practices and impact	Wolson R	2007	Technology Transfer 32(4): 343	Technology transfer, biotechnology, government policy, South Africa	x		x	
Off the beaten path	Buckley J et al.	2006	Nature Biotechnology 24: 309-315	Biotechnology, Australia, Chile, Cuba, China, India, South Korea, South Africa	x		x	

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
Pathways and Policies to (Bio) Pharmaceutical Innovation Systems in Developing Countries	Mytelka L	2006	Industry and Innovation 13(4): 415-435	Product development partnerships (PDPs), biopharmaceuticals, India, Cuba, Taiwan, Iran, Egypt, Nigeria	x		x	
Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action	WHO	2006	WHO, Fifty-ninth World Health Assembly	Intellectual property Systems	x		x	x
Regulatory frameworks in developing countries	Longstaff et al.	2005	Nature Biotechnology 23(4)	Regulatory requirements	x		x	
Innovative Developing Countries and Health Innovation Networks	Morel C	2005	Presentation	Product development partnerships (PDPs), education, Brazil	x		x	
Health Innovation Networks to Help Developing Countries Address Neglected Diseases	Morel C et al.	2005	Science 309(5733): 401-4	Health Innovation Networks, innovative developing countries, product development partnerships (PDPs)	x		x	
Health Innovation in Developing Countries to Address Diseases of the Poor	Morel C et al.	2005	Innovation Strategy Today 1 (1): 1-15	Product development partnerships (PDPs), health innovation Systems, innovative developing countries, government policy	x		x	
Emerging Challenges and Opportunities in drug registration and regulation in developing countries	Hill S & Johnson K	2004	DFID Health Systems Resource Centre (HSRC)	Regulatory requirements, registration process, harmonization	x		x	
Introduction: promoting global health through biotechnology	Thorsteinsdóttir H et al.	2004	Nature Biotechnology 22	Biotechnology, intellectual property, linkages, health policy, Brazil, China, Cuba, Egypt, India, South Africa	x		x	
Do Patents for ARV Drugs constrain access to AIDS treatment in Africa?	Attaran A & Gillespie-White L	2001	JAMA 2001, 286(15):1886-1892	Intellectual property systems, antiretrovirals	x		x	
Scientific Capacity Building To Improve Population Health: Knowledge As A Global Public Good	Freeman P & Miller M	2001	Fogarty International Center/US National Institutes of Health - Prepared for the WHO Commission on Health and Macroeconomics, Working Group 2: Global Public Goods	Education, capacity building	x		x	
Public-private partnerships drive innovation to improve the health of poor populations	Elias et al.	2008	Global Forum Update on Research for Health, volume 5: 157-160	Meningitis Vaccine Project, PATH, Public-private partnerships (PPPs)	x			x
How can developing countries harness biotechnology to improve health	Daar A.S et al	2007	BMC Public Health 7:346	Harnessing biotechnology, finance, ethics, politics	x			x
Access to vaccine technologies in developing countries: Brazil and India	Milstien J et al.	2007	Vaccine 25 (2007) 7610–7619	Intellectual property systems; technology transfer	x			x
The introduction of new vaccines into developing countries IV: Global Access Strategies	Mahoney R et al.	2006	Vaccine 25: 4003-4010	Product development partnerships (PDPs)	x			
Medicine prices, availability and affordability in 36 developing and middle income countries: a secondary analysis	Cameron et al.	2009	The Lancet, volume 373, issue 9659: 240-249	Pricing, Essential medicines, Cost	x			
UNITAID: innovative financing to scale up access to medicines	Bermudez J	2008	Global Forum Update on Research for Health, volume 5: 182-185	Incentives & finance mechanisms; innovation, finance	x			

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
Health markets and future health systems: innovation for equity	Bloom et al.	2008	Global Forum Update on Research for Health, volume 5: 30-33	Health systems, innovation, conceptual framework, monitoring systems, Nigeria, Bangladesh	x			
Pharmaceutical Pricing Policies in a Global Market	Directorate for Employment, Labour and Social Affairs, Health Division, OECD	2008	Executive Summary	Pricing policy, cost of medicines	x			
Policies for innovation: evidence based policy innovation - transforming constraints into opportunities	González Block M	2008	Global Forum Update on Research for Health, volume 5: 72-74	Health & innovation policy, case studies, evidence, South-South collaborations	x			
The Role of Prizes in Developing Low-Cost, Point-of-Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis	Love J	2008	MSF expert meeting on IGWG and R&D for tuberculosis	Incentives, tuberculosis, diagnostics	x			
The Algiers Declaration	Ministers of Health and heads of delegation of African countries	2008	Ministerial Conference on Research for Health in the African Region	Health & innovation policy	x			
Exploring evidence-policy linkages in health research plans: A case study from six countries	Syed B et al.	2008	Health Research Policy and Systems, 6:4	Health & innovation policy; evidence policy interface, case studies, Bangladesh, India, China, Afghanistan, Uganda, Nigeria	x			
Innovation and access: medicines for the poor- the IGWG strategy and plan of action	Wijnberg B & Monster M	2008	Global Forum Update on Research for Health, volume 5: 114-118	Intellectual property systems; innovation, multi-lateral strategy	x			
Strategy for a Treaty on R&D	Love J	2007	Conference presentation, MSF TB symposium	Health & innovation policy, incentives, tuberculosis	x			
Government's role in developing solutions for diseases that disproportionately affect developing countries	Makinde D	2007	NEPAD: West Africa Biosciences Network Dakar, Senegal	Health & innovation policy; biotechnology, African Union & NEPAD Action Plan	x			
Governing Science, Technology and Innovation in Africa: Building National and Regional Capacities to Develop and Implement Strategies and Policies	NEPAD	2007	NEPAD	Health & innovation policy, capacity building	x			
Poverty and Disease Burden vs Medical Education in sub-Saharan Africa	Shehu B & Ameh E	2007	Editorial, Annals of African Medicine; 6(4) 139-141	Education, Health & Research, training capacity, sub-Saharan Africa	x			
Multi-country Regional Pooled Procurement of Medicines: Identifying Key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island Countries	WHO	2007	Meeting report, WHO	Procurement, strategy & constraint, pool procurement, government policy	x			
Counterfeit Pharmaceuticals and the International Pharmaceutical Federation (FIP) working group on Counterfeit Medicines	Anisfeld M	2006	Journal of Pharmacy Practice 19(3): 178-181	Drugs, counterfeits	x			
Status of national health research systems in ten countries of the WHO African Region	Kirigia J & Wambebe C	2006	BMC Health Services Research 6(1): 135	Research system mapping	x			

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
Systems of Innovation and Underdevelopment: An Institutional Perspective	Oyelaran-Oyeyinka B	2005	United Nations University, Institute for New Technologies, The Netherlands	Product development partnerships (PDPs), inter-organizational collaboration	x			
Harnessing genomics to improve health in Africa - an executive course to support genomics policy	Smith A & Mugabe J et al.	2005	Health Research Policy and Systems 3(1): 2	Health & innovation policy; genomics, Science & technology, regional networks, business model, NEPAD	x			
Patents and Access to drugs in developing countries: An ethical analysis	Sterckx S	2004	Developing World Bioethics Volume 4 Issue 1 (2004) 58-75	Intellectual property systems; WTO-TRIPS, DOHA declaration	x			
TRIPS: Consequences for developing countries Implications for Swedish development cooperation	Bystrom M & Einarsson P	2001	Consultancy Report SIDA	Intellectual property Systems; TRIPS	x			
Preventing ARV anarchy in sub-Saharan Africa	Harries D et al.	2001	Lancet: 358: 410–14	Health & innovation policy, antiretrovirals, supply policy	x			
Economics, health and development: some ethical dilemmas facing the World Bank and the international community	Wagstaff A	2001	Journal of Medical Ethics, 27:262–267	Health economics, World Bank, population health	x			
Why pharma must go Hollywood	Bernal L	2007	http://www.the-scientist.com/2007/2/1/42/1/	Industry		x	x	
El lado oscuro de la producción y comercialización de medicamentos	Cortés A	2007	Editorial, Colombia Médica 38 (4)			x	x	
Pharmaceuticals: Local Manufacturing	Seiter A	2005	HNP (World Bank) Publication	Pharmaceutical production, governance		x	x	
Local Production of essential medicines, including ARV: issues, challenges and perspectives in the African Region	WHO, Regional committee for Africa	2005	WHO, Regional Committee for Africa, fifty-fifth session	Local Production, antiretrovirals, policy framework		x	x	
Manufacture of antiretrovirals in developing countries and challenges for the future	WHO	2004	WHO, Executive Board, 114th Session	Pharmaceutical production, industrial policy, drug policy, antiretrovirals		x	x	
Proposed harmonized requirements for the licensing of vaccines in the Americas	Pan-American Network on Drug Regulatory Harmonization (PANDRH)	2008	Pan American Health Organisation (PAHO)	Vaccine regulation, Americas		x		x
The Indian and Chinese Health Biotechnology Industries: Potential Champions of Global Health?	Frew S et al.	2008	Health Affairs 27(4): 1029-1041	Biotechnology, innovation, government policy, India, China, business strategy, industrial platform		x		
Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines An overview of Key Concepts, Isssues and Opportunities for Future Research	Kaplan W & Laing R	2005	HNP (World Bank) Publication	Local production, health policy, industrial policy		x		
The new landscape of neglected disease drug development	Moran M et al.	2005	London School of Economics, Wellcome Trust	Pharmaceutical Manufacturing, Innovation		x		
Out of Thailand, into Africa	Moran M et al.	2004	Nature 430: 136-137	Generics		x		

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
Process and Issues for Improving Access to Medicines: The evidence base for domestic production and greater access to medicines	Guimier J et al.	2004	DFID Health Systems Resource Centre (HSRC)	Domestic production, industrial capacity, government strategy and policy		x		
Clinical development of marketed drugs for new uses	Katz R	2008	American Society for Experimental NeuroTherapeutics (ASENT), 10th Annual Meeting	Regulatory requirements, paediatric vaccines			x	x
Science, medicine and research in the developing world: a perspective	Gotch F & Gilmour J	2007	Nature Immunology 8(12) 1273- 1276	Research capacity, technology transfer, Uganda			x	x
Malaria drug and vaccine trials in Africa: obstacles and opportunities	Lang T & Kokwarob G	2007	Transactions of the Royal Society of Tropical Medicine and Hygiene 102(1): 7-10.	Product development partnerships (PDPs), Malaria, clinical trials, drug development, vaccine development, capacity building			x	x
Accelerating Health Product Innovation in sub-Saharan Africa	Masum H et al.	2007	Innovations: Technology, governance, globalisation, 2(1): 129-149	Innovative product development, product development partnerships (PDPs), health convergence centres, entrepreneurship			x	x
GSK Public Policy on Clinical Trials in the Developing World	GSK	2006	GSK Government Affairs, Europe and Corporate	Clinical trials, industry			x	x
Medicine Regulatory Authorities: current status and the way forward	WHO, Regional office for Africa	2006	WHO, Fifty-sixth session	Regulatory requirements, policy framework			x	x
Leveraging the Private Sector for Public Health Objectives	Grace C	2004	DFID Health Systems Resource Centre (HSRC)	Technology transfer, pharmaceutical sector			x	x
Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study	Bate R et al.	2008	PLoS ONE 3(5)	Malaria, Anti-malarial drugs, drug quality			x	
Ethical aspects of innovation in health	de Freitas Drumond J	2008	Global Forum Update on Research for Health, volume 5: 82-85	Research ethics, innovation			x	
Fresh thinking about the declaration of Helsinki: A comprehensive approach to ethical research	Goodyear M et al.	2008	BMJ, 337:1067-8	Research ethics			x	
Innovation and incentives: why pharmaceutical companies are becoming interested in neglected tropical diseases	Matlin A	2008	Global Forum Update on Research for Health, volume 5: 161-163	Incentives, innovation, pharmaceutical companies			x	
Technology transfer perspectives in globalising India (drugs and pharmaceuticals and biotechnology)	Agarwal S et al.	2007	Journal of Technology Transfer 32(4): 397	Technology transfer models, biotechnology, policy, incentives			x	
Research Ethics Committees in Africa: Building Capacity	Benatar S	2007	PLoS Medicine 4(3): e3	Research ethics, education			x	
EDCTP Annual Report	EDCTP	2007	EDCTP	Clinical trials			x	
Ethics committees in Western and Central Africa: Concrete Foundations	EFFA P et al.	2007	Developing World Bioethics 7 (3) 136-142	Research ethics, ethics committees, western Africa, central Africa, clinical trials, community network			x	

Title	Author	Date of Publication	Source	Key Words	Access	Manufacturing	Drug Innovation	Vaccine Innovation
The Declaration of Helsinki: Mosiac tablet, dynamic document, or dinosaur?	Goodyear M et al.	2007	BMJ ;335:624-5	Research ethics			x	
Clinical Trial Capacity in East Africa: A Pilot Survey	Kimanani E	2005	Drug Information Journal 39(2): 177-184	Clinical trials, East Africa, ICH GCP			x	
Pharmaceuticals: Drug Regulation in Low and Middle Income Countries	Seiter A	2005	HNP (World Bank) Publication	Regulatory requirements, drug regulation process			x	
Aspects of Quality Assurance: Pre-qualification of HIV drugs	WHO	2003	WHO Drug Information 17(3)	WHO pre-qualification, drug quality			x	
Current Status of Clinical Trials in Kenya	Kimanani E	2002	Drug Information Journal 36(1): 31-39.	Clinical trial capacity, Kenya			x	
Guidance for Industry: General Principles for the Development of Vaccines to Protect Against Global Infectious Diseases	US FDA	2008	US FDA	Regulatory requirements, paediatric vaccines				x
Financing of vaccine R&D - gaps and opportunities for innovation	Wilson P & Hecht R	2007	Global Forum Update on Research for Health, volume 4: 88-93	Incentives & finance mechanisms; R&D, vaccine, funding, product development partnerships (PDPs)				x
WHO guidelines on nonclinical evaluation of vaccines	WHO	2005	WHO Technical Report Series, No. 927	Toxicity assessments, adjuvants				x
Guidelines on clinical evaluation of vaccines: regulatory expectations	WHO	2004	WHO Technical Report, Series No. 924	Regulatory requirments, clinical trials, research ethics				x
Global Institute for BioExploration - Africa-working for a healthy and sustainable continent	Global Institute for Bioexploration (GIBEX)	2008	Brochure, Global Institute for Bioexploration (GIBEX)	Product development partnerships (PDPs)				

Annex 2
Abbreviations and acronyms

AA4A	ARV Access for Africa
ARV	Anti Retro Viral
AAVP	African AIDS Vaccine Program
AAHA	Aid Alignment and Harmonisation
ACTs	artemesinin-based combination therapies
AFRO	WHO Regional Office for Africa
AMANET	African Malaria Network
AMCs	advance market commitments
AMCOST	African Ministerial Council on Science and Technology
AMFM	Affordable Medicines Facility for Malaria
AMU/UMA	Arab Maghreb Union
ANDI	African Network for Drugs and Diagnostics Innovation (WHO/TDR)
API	active pharmaceutical ingredient
APOC	African Programme for Onchoceriasis Control
APRIORI	African Poverty Related Infection Oriented Research Initiative
ARIPO	Africa Regional Intellectual Property Organization
ARV	antiretroviral
ASTII	African Science, Technology and Innovation Indicators Initiative
AtM	AtM Index. Access to Medicines Index
AU	African Union
AVAREF	African Vaccine Regulatory Forum
BMGF	Bill and Melinda Gates Foundation
BMZ	Bundesministerium Für Wirtschaftliche Zusammenarbeit (German Federal Ministry for Economic Development Cooperation)
BRICs	Brazil, Russia, India, China
CEEAC/ECCAS	Economic Community of Central African States
CEN-SAD	Community of Sahel-Saharan States
CFWshops	Child and Family Wellness shops
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CMH	Commission on Macroeconomics and Health
COHRED	Council on Health Research for Development
COMESA	Common Market for Eastern and Southern Africa (COMESA)
CSF	cost, insurance and freight
CSDH	Commission on Social Determinants of Health
CSIR	Council for Scientific and Industrial Research
DfID	Department for International Development
DNDi	Drugs for Neglected Diseases Initiative
DST	Department of Science and Technology (South Africa)
EAC	Eastern African Community
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EDCTP	European Developing Countries Clinical Trial Platform
EDR	Extreme Drug Resistance
EPI	Expanded Programme on Immunisation
EWG	Expert Working Group
FDA	Federal Drug Administration
FIND	Foundation for Innovative New Diagnostics

FTA	Free Trade Agreement
GAVI	Global Alliance for Vaccines And Immunisation
GDP	gross domestic product
GDF	Global Drug Facility
GFATM	Global Fund for, HIV/AIDS, Tuberculosis and Malaria
GIBX	Global Institute for Bio-Exploration-Africa
GMP	Good Manufacturing Practices
GSK	GlaxoSmithKline
GSPOA	Global Plan and Strategy of Action on Public Health, Innovation and Intellectual Property
HAI	Health Action International
HRSA	Health Research Systems Analysis (WHO)
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
ICEGB	International Centre for Genetic Engineering and Biotechnology
IFC	International Finance Corporation
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
ICTRP	WHO International Clinical Trials Registry Platform
IDA	International Development Association
IGAD	Intergovernmental Authority of Development
INRUD	International Network for Rational Use of Drugs
ISHRECA	Initiative to Strengthen Health Research Capacity in Africa
IPR	intellectual property rights
KEI	Knowledge Ecology International
LDCs	least-developed countries
LMICs	low- and middle-income countries
MCTA	Malaria Clinical Trial Alliance
MDGs	Millennium Development Goals
MeTA	Medicines Transparency Alliance
MMV	Medicines for Malaria Venture
MNCs	Multinational pharmaceutical companies
MSF	Médecins Sans Frontières
NACCAP	the Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases
NAPRECA	Natural Products Research Network of Eastern and Central Africa
NEPAD	New Partnership for Africa's Development
NIPRID	Nigeria Institute for Pharmaceutical Research and Development
NGO	non-governmental organization
NMA	Noordwijk Medicines Agenda
NRA	National Regulatory Authorities
OECD	Organization for Economic Co-operation and Development
OAPI	Organisation Africaine de la Propriété intellectuelle
OTC	over-the-counter (medicines)
PDPPP	Product Development Public Private Partnerships
PEPFAR	President's Emergency Plan for AIDS Relief
PIC-S	Pharmaceutical Inspection Cooperation Scheme
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPP	public-private partnership
PPDDP1	public-private drug development partnerships
PSMIP	Public Service Management Insurance Plan
R&D	research and development
RECs	regional economic communities

SADC	Southern African Development Community
SAMI	South African Malaria Initiative
SARIMA	South African Research and Innovation Management Association
SME	subject-matter expert
STI	Science, Technology and Innovation (Rwanda)
TDR	Special Programme on Research and Training in Tropical Diseases
TRIPs	Trade-related aspects of intellectual property rights
TWN	Third World Network
UNITAID	international facility for scaling up access to treatment for HIV/AIDS, malaria and tuberculosis
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNIDO	United Nations Industrial Development Organisation
WADRAN	West African Drugs Regulatory Authority Network
WARIMA	West African Research and Innovation Management Association
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Annex 3
Glossary

Innovation:
As defined by the Commission on Intellectual Property Rights, Public Health and Innovation (CIPIH): '*3 D'- 'Discovery, Development, and Delivery'*

Neglected diseases:
As defined as type II and III diseases by the Commission on Macroeconomics and Health (CMH):

- Type II: incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries (e.g. HIV/AIDS, tuberculosis)
- Type III: overwhelmingly or exclusively incident in developing countries (e.g. African sleeping sickness (trypanosomiasis), African river blindness (onchocerciasis)

Health products tools:
Terms used to refer to medicines, vaccines and diagnostic devices.

Technology transfer /transfer of technology
As defined by the United Nations (accessed from DFID 2004), as the *'Process of sharing knowledge, skills, expertise and know-how*', divided into four categories:

- Technoware, including physical objects and equipment
- Humanware, including skills and human aspects of technology management and learning
- Infoware, including designs, blueprints, and document-embodied knowledge on information and technology
- Orgaware, including organisational knowledge needed to operate a given technology

Research for health
In the most traditional and narrow sense of health research, 'medical research' deals with the medical conditions of individuals and aims to solve the core health problems of individuals, families and countries.

Based on the recognition that the health of populations can be greatly improved by better understanding population characteristics and behaviour, 'population health' or 'public health' research focuses on epidemiology, social and development sciences, including economics. It is supplementary to 'medical research', which describes great benefit of health and health equity worldwide.

The ministerial summit on 'knowledge for better health', held in Mexico in 2004, defined commitments to 'health systems research' – that is, the type of operational research that helps improve performance and coverage of health systems. This followed evidence that in low-income countries, simple improvements in health care provision could result in major health improvements.

These types of research ('medical', 'population' and 'health systems' research) are aimed at conditions that affect health directly – for example, through better medicines, behaviour change or improved health care provision. Important as these are, this view of 'health research' does not address the multi-sectoral nature of health nor does it address the potential for social and economic benefits and development. The concept of 'research for health' attempts to address all these issues. Health research does not only solve direct health problems, it can also provide employment, lead to innovation, support institutional development, enhance a culture of evidence-informed policy throughout government, and even contribute to employment and economic growth.

WHO prequalification project

The WHO Prequalification project ensured unified standards of quality, safety and efficacy for medicines needed to treat HIV/AIDS, malaria and tuberculosis. Any manufacturer wishing their medicines be included in the pre-qualified products list must present extensive information on the product (or products) to allow qualified assessment teams to evaluate quality, safety and efficacy. The inspection teams also assesses the manufacturer's working procedures for compliance with WHO Good Manufacturing Practices (GMP). The standards against which the assessment teams evaluate both the quality specifications of medicines and the manufacturing sites are based on the principles and practices agreed upon by the world's leading regulatory agencies and adopted by the WHO Expert Committee on Specification for Pharmaceutical Preparations.

Drug regulation

Medicine (drug) regulation is the totality of all measures – legal, administrative and technical – needed to promote and protect public health by ensuring that: medicines meet required quality, safety and efficacy standards; health professionals and patients have the necessary information to enable rational use of medicines; medicines are appropriately manufactured, stored, distributed and dispensed; illegal manufacturing and trade are detected and adequately sanctioned; promotion and adverting is fair, balanced and aimed at rational drug use; and access to medicines is not hindered by unjustified regulatory work

Intellectual Property (IP)

Creative ideas and expressions of the human mind that have commercial value and are entitled to the legal protection of a property right. The major legal mechanisms for protecting intellectual property are copyrights, patents, and trademarks. IP rights enable owners to select who may access and use their intellectual property and to protect it from unauthorized use.

Business risk

Refers to the 'probability of loss inherent in a firm's operations and environment (such as competition and adverse economic conditions) that may impair its ability to provide returns on investment

Annex 4
Research Capacity Strengthening matrix

COHRED has developed a research capacity strengthening matrix (RCS Matrix) to illustrate that capacity strengthening needs to be considered from different levels to become comprehensive. The RCS Matrix guides managers to improve national capacities to focus their interventions on improving research capacity where they are most needed and most likely to contribute to the sustainability of the health research system.

Countries that are willing to further engage into pharmaceutical innovation and local production of medicines may find this matrix useful when guiding assessment of the status of their health research and innovation systems and when identifying priority needs for capacity strengthening. Ultimately, only countries with functional health research systems are best placed to take up the challenge of pharmaceutical R&D and production.

Level of development	Locus of intervention Nature of intervention	Individual	Institution	Research system	Socio-economic and political	International collaboration and linkage
1	'capacity building'	master level training	grants management	basis of NHRS	Increase demand for research	good parnership
2	'capacity strenghtening'	doctoral level training	merit-based promotion system	research ethics review capacity	civil society engagement	fair research contracting
3	'performance enhancement' equity-focus	networking researchers, peer reviews	research communication	monitoring and evaluation of output and impact	focus on health, equity and soc-economic development	focus on research competitiveness

Annex 5
Detailed mapping of initiatives

Annex 5-A: Global Initiatives

Global Initiatives

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) Created by WHA in 2004	Mandated by WHA resolution 56.27 to '…collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries…'	Intellectual Property Rights, Innovation, Public Health	A time-limited body to consider the relationship between intellectual property rights, innovation and public health. A report of commission's findings was published in 2006	WHO Commission members
Intergovernmental Working group (IGWG) on Public Health, Innovation and Intellectual Property Created by WHA in 2006	Mandated by WHA resolution 59.24 "to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission; such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area."	Public health, innovation, intellectual property	First session: December 2006 Second session 1st part: November 2007 2nd part: April – May 2008 www.who.int/gb/phi/	WHO secretariat WHO member states Experts
TDR Special program for research and training in tropical diseases An independent global programme of scientific collaboration. Established in 1975.	Aim: To help coordinate, support and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged. Focus on neglected infectious diseases that disproportionately affect poor and marginalized populations.	Research and training on neglected infectious diseases	Facilitates global research and training through partnerships with research institutions, ministries of health, disease control programmes, industry, academia and non-governmental organisations. Is developing a strategy to help implement the WHO Global Strategy and Plan of Action, particularly regarding elements 1, 2 and 3 http://www.who.int/tdr/	Co-sponsored by: UNICEF, UNDP, World Bank, WHO WHO is the executing agency
WHO Technical Cooperation on Essential Medicines (TCM) Based in WHO Geneva	TCM's priority is to assist countries in their efforts to increase the availability, affordability and rational use of high-quality medicines. It achieves this by supporting country and regional structures and by building medicines expertise.	Priority areas: Medicines Policy and Supply Management; Regulation and Registration; Intellectual Property Rights; Traditional Medicines	www.who.int/medicines/areas/technical_cooperation/en/	WHO secretariat WHO member states
UNESCO – African Union (AU) / NEPAD Science and Technology (S&T) initiative Based in Paris	Contribute to AU consolidated plan through - Assessment of the status of science and technology policy formulation - Facilitation of initiatives for Science, Technology and Innovation (STI) policy development in countries where these are absent - Development of common African STI indicators - Creation of an African STI observatory - Creation of a science park	Research and Development Statistics Policy development	Inaugural meeting of the S&T cluster took place in July 2004 www.unesco.org	African Union United Nations science and technology cluster in support of AU/NEPAD : UNESCO (convener) UNECA, UNIDO, WIPO, UNEP, UNDP, IAEA, ILO, UNCTAD, OSAA, UNU MERIT, FAO, WHO

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
UNIDO GTZ BMZ KFW	UNIDO supports the establishment, expansion and upgrading of pharmaceutical subject-matter experts (SMEs) in selected least-developed countries (LDCs) through promotion of business partnerships, investment promotion and South–South cooperation. Activities include: Workshops on utilization of TRIPS flexibilities: Ethiopia (2005), Tanzania (2006), Thailand (2007) Regional workshop on pharmaceutical production in West & Central Africa, Dakar 2007 (http://pharma-dakar.wikispaces.com/) Research on pharmaceutical sector profiles of Lesotho, Uganda, Zambia, Zimbabwe, Nigeria, Senegal, Laos, and Cambodia.	Local production of essential medicines for HIV/AIDS, tuberculosis, malaria.		Implemented by UNIDO
Health Research Systems Analysis (HRSA) Initiative	To produce, share and utilize research for better health and health equity, and integrate knowledge gained within all levels of health systems	National Health Research Systems	www.who.int/rpc/health_research/background/en/index.html	• WHO • WHO member states • Alliance for Health Policy and Systems Research (AHPSR) • Council on Health Research for Development (COHRED) • Global Development Network (GDN) • Global Forum for Health Research • Johns Hopkins Bloomberg School of Public Health (JHSPH) • Rockefeller Foundation (RF) • Swedish International Development Agency (SIDA/Sarec) • Wellcome Trust (WT)
IQSensato Established 2007 Based in Geneva	Mission: To shape international policy-making on development by harnessing the multidisciplinary research and analytical capacities in, and from developing countries. Current projects include implementation of the WHO Global Strategy on Public Health, Innovation and Intellectual Property	Research and Policy Think Tank	September 2008: Multi stakeholder consultation on implementation of the strategy www.iqsensato.org	
Grand Challenges in Global Health Initiative Founded in 2003	Goal: To fund research that promises to greatly advance work against diseases that disproportionately affect people in the developing world. Focus on 14 grand challenges	Funding	Grand challenges explorations is a new initiative launched in October 2007 to spur innovations in global health research. http://www.gcgh.org/	Gates foundation Canadian Institutes of Health Research Foundation for the National Institutes of Health Wellcome Trust
NACCAP Netherlands – African Partnership for Capacity Development and Clinical Interventions Against Poverty-related Diseases Launched in 2002	Aims at long-term investment in R&D activities in Africa thereby strengthening the capacity of African R&D centres.	R&D Sub - Saharan Africa	www.nwo.nl/naccap	Netherlands African governments
EDCTP – European and Developing Countries Clinical Trials Partnership Founded in 2003	Aims to accelerate development of new or improved tools (drugs, vaccines, and microbicides) against HIV/AIDS, malaria and tuberculosis Funds mainly phase II and III clinical trials for HIV/AIDS, TB, Malaria in Sub-Saharan Africa	Clinical Trials, Capacity Development Strengthening Regulatory and Ethics Review Mechanisms	Over 80 million Euros approved for research into prevention of HIV/AIDS, tuberculosis and malaria in Africa (in June 2008) www.edctp.org	16 participating European member states, sub-Saharan countries, relevant public private partnerships, philanthropic organisations and private sector

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
International Centre for Genetic Engineering and Biotechnology (ICGEB)	ICGEB provides a scientific and educational environment of the highest standard and conducts innovative research in life sciences for the benefit of developing countries The centre is dedicated to advanced research and training in molecular biology and biotechnology.	Biotechnology Transfer Training Funding Advisory services	Components in Trieste, New Delhi and Cape Town. www.icgeb.trieste.it	Interactive network with 38 affiliated centres in 59 ICGEB member states. ICGEB is part of the UN system.

Annex 5-B: Regional Initiatives

Regional Initiatives

AU/NEPAD High-level African panel on modern biotechnology	To facilitate open and informed regional multi-stakeholder dialogue on, inter alia, scientific, technical, economic, health, social, ethical, environmental, trade and intellectual property protection issues associated with or raised by rapid developments in modern biotechnology.	Biotechnology	'1Freedom to innovate' (2007) is a report by a panel of experts, suggesting specific and practical measures to advance development, quality of life and environmental sustainability through biotechnology. www.nepadst.org/biopanel/index.shtml	AU member states Regional Economic Communities
AU Pharmaceutical Manufacturing Plan (PMPA) for Africa Phase I Adopted in 2005 by AU conference of ministers	AU ministers of health at the AU assembly held in 2005 in Abuja undertook to pursue, with the support of partners, the local production of generic medicines on the continent, and to make full use of the flexibilities within the DOHA declaration on TRIPS and Public Health.	Local Production	1st meeting of technical committee held in 2007 (Addis Ababa). www.africa-union.org/../DOCS/Annex%204%20-%20Search%20tool%20local%20manufacturing%20Oct%202007.doc	AU member states
AU PMPA phase II Meeting held in May 2008	6 priority areas: 1. Mapping of local production capacity (coordinator – Gabon) 2. Situation analysis and compilation of findings (coordinator – Cameroon) 3. Manufacturing agenda (coordinator – Kenya, Libya, Egypt) 4. Intellectual property issues (coordinator Angola, South Africa) 5. Political, geographic, economic considerations (coordinator - South Africa, AU commission) 6. Develop sustainable financing systems (coordinator – Nigeria)	Local Production	www.africa-union.org/root/ua/conferences/2008/mai/sa/17mai/2%20PHASE%20II%20PLAN%20FOR%20IMPLEMENTATI.	AU member states
African Science, Technology and Innovation Policy Initiative Launched October 2007	To develop national science, technology and innovation (STI) policies for African countries without one. Project duration 2008 – 2010 Part of UNESCO's contribution to AU consolidated plan of action for science and technology	Policy Development	http://www.unesco.org/science/psd/thm_innov/africa_innov.shtml STI policy review and formulation began in 2008: Benin, Burundi, Central African Republic, Madagascar & Tanzania.	AU member states UNESCO
African Network for Drugs and Diagnostics Innovation (ANDI) Launched 2008 Secretariat in TDR	ANDI aims to promote and sustain African-led R&D innovation through the discovery, development and delivery of affordable new tools, including those based on natural products and traditional medicines. ANDI plans to also support capacity and infrastructure development in Africa.	Research and Development	www.who.int/tdr/svc/news-events/events/tdr/andi Not operational yet. Business plan presented in October 2009	WHO TDR African scientists based in Africa and in the diaspora

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Africa Technology Policy Studies Network (ATPS)	Its mission is to improve the quality of science, technology and innovation systems research and policy making in Africa by strengthening capacity for science and technology knowledge generation, communication and dissemination, use and mastery for sustainable development in Africa. Ongoing studies: to map health innovation systems, identifying key actors, their interactions and boundaries; to explain performance of interventions; to identify system failures that constrain innovation capacity; to develop practical options to strengthen the innovation system in which the initiatives are situated. Participating countries: Tanzania, Uganda, Kenya, Benin, Cote d'Iviore, Nigeria, Lesotho, Swaziland, South Africa	Policy Making Research Generation and Dissemination Capacity Building	www.atpsnet.org	16 member states 14 potential member states (currently have observer status)
ARIPO Africa Regional Intellectual Property Organization	Established to pool resources of its member countries in industrial property matters.	Intellectual Property	www.aripo.org	16 member states 14 potential member states (currently have observer status)
OAPI Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization)	Central registration system for 16 French speaking African States	Intellectual Property	Headquarters in Yaoundé, Cameroun http://www.oapi.int	16 member states
South African Research and Innovation Management Association (SARIMA)	1. Professional development and capacity building 2. Promotion of best practice in the management and administration of research and innovation. 3. Creation of awareness in academic and public forums of the value of a stronger research and innovation system and the contribution it can make to economic and social development. 4. Advocacy of appropriate national and institutional policy in support of research and innovation and participation in the development and testing of policy. Advancement of science, technology and innovation, including addressing the asymmetries in access to, and diffusion of, knowledge between North and South.	Capacity building Innovation and Technology Transfer Operations Research	http://www.sarima.co.za/	South Africa Department of Science and Technology (DST) DFID Carnegie Cooperation of New York SARIMA operates at institutional, national and international level, and across the research value chain, from research management to commercialization of research.
West African Research and Innovation Management Association (WARIMA)	1. Professional development and capacity building 2. Promotion of best practices 3. Increasing awareness of research and innovation issues in academic and public fora 4. Advocacy of appropriate national and institutional policy in support of research and innovation and participation in the development and testing of policy 5. Advancement of science, technology and innovation, including addressing the asymmetries in access to, and diffusion of, knowledge between North and 'South' 6. Advancement of a code of professional standards through a framework of values and principles which members are expected to follow 7. Enhancement of the profile of the profession	Capacity building Advocacy Technology Transfer Innovation	http://www.warima.org	

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Initiative to Strengthen Health Research Capacity in Africa (ISHReCA) Launched 2007	To promote the creation of self-sustaining pools of excellence capable of initiating and carrying out high-quality health research in Africa as well as translating research products into policy and practice through better integrated approaches of capacity building at individual, institutional and system levels.	Research capacity	http://www.mrc.ac.za/researchdevelopment/ISHReCAbrochure.pdf	Major sponsors: Wellcome Trust (UK) SIDA-SAREC WHO/TDR
International Network for the Rational Use of Drugs (INRUD). Established in 1989 Secretariat based in Management Sciences for Health / USA	To design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries	Access and Use	www.inrud.org	20 African, Asian, Latin American, and Eastern European countries WHO department of Medicines Policy and Standards Harvard Medical Karolinska Institute

Annex 5-C: Multi-country initiatives

Multi-country initiatives

APRIORI African Poverty Related Infection Oriented Research Initiative Duration of project 2006 – 2010	APRIORI aims at establishing a state-of-the art clinical research centre, and by involving African centres of excellence, strengthening South-South collaboration.	Capacity building for Clinical Research	Based at Kilimanjaro Medical Centre, Moshi, Tanzania www.priornetwork.org/db/overzichten/index.php	A NACCAP project with African (Ethiopia, Mali, Tanzania) and European (Denmark, Netherlands, U.K) partners
African AIDS vaccine Programme (AAVP) A WHO – UNAIDS supported programme	Mission: to advocate and support a coordinated effort to contribute to the global HIV vaccine development goals, ensuring that appropriate and affordable vaccines are developed for Africa in the shortest possible time.	Biomedical sciences; Population-based studies; Ethics, Law and Human Rights; National Strategic Planning; Advocacy and Resource Mobilization	www.who.int/vaccine_research/diseases/hiv/aavp/en/	WHO UNAIDS African Countries
Malaria Clinical Trials Alliance (MCTA)	Aim: to strengthen clinical trial capacity, share results of real, on-the-ground trial activities and to codify best practices.	Capacity Building: Human Resources and Physical Infrastructure	An INDEPTH project, funded by Gates Foundation www.indepth-network.org/mcta	MMV MVI AMANET African countries: Gabon, Gambia, Ghana, Kenya, Malawi, Mozambique, Nigeria, Senegal and Tanzania
Global Institute for BioExploration-Africa (GIBEX- Africa)	An R&D network that promotes ethical, natural product-based pharmacological bio-exploration to benefit human health in Africa. GIBEX-Africa is guided by the pioneering "Reversing the Flow" paradigm intended to bring pharmacological screens to Africa (Screens-to-Nature technology) and reverse the human brain drain.	Bioexploration	www.gibex.org	University of Yaoundé-1, Cameroon University of Nairobi, Kenya University of Dar-es-Salaam, Tanzania Makerere University, Uganda University of Botswana, Botswana University of Cape Town, South Africa Kwame Nkrumah University of Science and Technology, Ghana Olabisi Onabanjo University, Nigeria University of Lagos, Nigeria Federal University of Technology, Minna, Nigeria University Cheikh Anta Diop, Senegal University of Zambia, Lusaka,Zambia Rutgers, the State University, New Jersey USA University of Illinois at Urbana-Champaign, USA

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Africa Institute of Biomedical Science and Technology (AiBST)	Focus is on drug discovery, development and optimum clinical use of medicines in Africa in areas of malaria, tuberculosis, HIV/AIDS and other tropical diseases.	Research Education & Training Commercial Activities	www.aibst.com	University of Zimbabwe University of Nairobi (Kenya), Obafemi Awolowo University (Nigeria), Karolinska Institute (Sweden), Antwerp University (Belgium), Gothenburg University (Sweden) Astra Zeneca (Sweden) Southern African Regional Co-operation in Biochemistry, Molecular Biology and Biotechnology (SARBIO) International Society for the Study of Xenobiotics International Union of Pharmacology
African Malaria Network Trust (AMANET) Founded in 1995	Mission: To promote capacity strengthening and networking of malaria vaccine research and development in Africa.	Has a 4-year project aimed at building institutional health research ethics in Africa www.amanet-trust.org	www.aibst.com	African sites: Burkina Faso, Ghana, Kenya, Mali, Sudan, Tanzania, Uganda, Zambia European partners: Denmark, Netherlands EDCTP
ARV Access for Africa (AA4A) Based in South Africa	Mission: To provide pharmaceutical management skills and increase local capacity for public health care initiatives to ensure access to quality health care services in low and middle income countries.	Access, Pharmaceutical Supply Chain Management	www.aa4a.co.za	African countries Netherlands An IDA solutions project
Access to Medicines Index (AtM Index)	AtM index's main purpose is to raise awareness on access to drugs and to improve collaboration between stakeholders. The ATM index aims at offering objective and comparative information regarding the approaches of pharmaceutical companies to ATM issues.	Access	www.atmindex.org	Many stakeholders drawn from: Non governmental organizations and academia, Governments (WHO; DFID ; Netherlands), Pharmaceutical Industry, Investor Community, Donors
MeTA – The Medicines Transparency Alliance	To support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management.	Access, research Initial country focus in Africa: Ghana, Uganda, Zambia	Global Alliance launched in 2007 http://www.dfidhealthrc.org/MeTA/index.html	DFID WHO Health Action International (HAI)
Health Action International – Africa (HAI –Africa)	Goal: access, by all consumers, to good quality, affordable medicines that are rationally prescribed and used. HAI Africa works to achieve a more balanced structure of power within the medicines sector, as a consequence of stronger medicine-related civil society organizations (CSOs) and activists that empower consumers and promote competent providers, well informed donors and governments.	Access	www.haiafrica.org	An informal network of consumers, NGOs, health care providers, academicians and individuals in more than 20 countries in Sub-Saharan Africa promoting increased access to essential medicines

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Ecumenical Pharmaceutical Network (EPN)	EPN aims to facilitate the development of compassionate, just and sustainable quality pharmaceutical care in and through the church health care system.	Access	www.epnetwork.org	African member countries
SECOVIPI (Service commun virtuel en propriété intellectuelle - Virtual Shared IP Service) Launched 2004	3-year project set up to help address the many IP-related infrastructural and resource challenges faced by health research institutes in developing countries. Over 130 scientists, lawyers and research institution managers have been trained in key practical skills to enable them to protect, manage and exploit their research results.	Intellectual Property	http://www.ruiggian.org/research/projects/projectlg.php?ID=24	Cameroon,Gabon, Republic of Congo, Central African Republic Chad, Equitorial Guinea Colombia OAPI CEMAC commission WIPO (coordinator) Geneva International Academic Network (RUIG-GIAN) (Funder) University of Geneva Graduate Institute of International Studies (HEI), Geneva Swiss Tropical Institute, Basel; International Institute for Management Development (IMD), Lausanne Council on Health Research for Development (COHRED).
NAPRECA: Natural Products Research Network of Eastern and Central Africa	Expand existing research programs and formalize educational activities in such natural products (NP) fields as engineering, biochemistry, environmental science, pharmacology, economic development, and nutrition.	Research Capacity	http://sites.ias.edu/sig/rise/napreca	Makerere University, Uganda University of Nairobi, Kenya Sokoine University, Tanzania An active research network of 10 member countries

Annex 5-D: National initiatives

National initiatives (selected examples):				
Bioventures - South Africa	Bioventures is a biotechnology and life sciences venture capital fund that invests in South African start-up companies.	Venture Capital Fund	http://www.bioventures.co.za/	
Council for Scientific and Industrial Research (CSIR) biosciences Initiated in 1945 South Africa	CSIR's mandate is to contribute to improved quality of life and industrial competitiveness through research, development and innovation and in response to the National Research and Development Strategy and National Biotechnology Strategy.	Bioscience Nanotechnology Synthetic Biology	www.csir.co.za	The CSIR's shareholder is the South African Parliament, held in proxy by the Minister of Science and Technology. Receives an annual grant (close to 40% of its total income) from Parliament, through the Department of Science and Technology (DST).
BioPAD (Biotechnology Partners and Development) Initiated in 2002 South Africa	Mission: To broker partnerships between researchers, entrepreneurs, business, government and other stakeholders to promote innovation and create sustainable biotechnology businesses in support of South Africa's needs. At least 10 completed projects awaiting commercialization, commercialized, or licensed to other companies. Commercialized projects include molecular diagnostic kits for tick borne pathogens (RLB kit / RT-PCR assay).	Venture Capital Firm	www.biopad.org.za	One of the three Biotechnology Regional Innovation Centre (BRIC) established by the Department of Science and Technology (DST). Initiated by a group of interested biotechnology stakeholders with the aim of boosting biotechnology development in the region. The centre is governed as a Trust.

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
LIFE*lab* South Africa	Provides funding to biotechnology projects on human health and bioprocessing. Human health portfolio focus is infectious diseases (e.g. HIV/AIDS, TB and malaria).	Funding Biotechnology Capacity Building	www.lifelab.co.za	LIFE*lab* is the trade name of the East Coast Biotechnology (ECoBio) Regional Innovation Centre. One of three Biotechnology Regional Innovation Centres (BRICs) set up by the Department of Science and Technology (DST) under the auspices of its National Biotechnology Strategy.
Cape Biotech South Africa	An umbrella forum aimed at creating a biotechnology industry hub in the Western Cape. The CBI represents the interests of industry, academia, government, finance, the public and all other role players in the field of biotechnology.	Biotechnology Industry Hub	www.capebiotech.co.za	
The Innovation Hub South Africa	Africa's first internationally accredited science park and a full member of the International Association of Science Parks. Its purpose is to develop a science park environment where high-tech entrepreneurs, small and medium size enterprises, world-class businesses, academic and research organisations and venture capitalists can meet, network and prosper.	Science Park	www.theinnovationhub.com	A subsidiary of Blue IQ Investments Holdings. More than 65 resident companies within its five core focus areas: ICT, biotechnology, engineering, smart manufacturing and electronics. Has formal and operational links to academic and research institutions, government agencies and departments, and local and international business enterprises.
South African Malaria Initiative (SAMI) South Africa	Mission: To facilitate an integrated programme of malaria research and capacity development in South Africa and eventually in the rest of Africa to improve malaria prevention and control. Planned outputs include: identification and validation of drug and insecticidal targets; development of drug and insecticidal candidates; improved diagnostics; and new tools for gathering epidemiological information.	R&D	www.acgt.co.za/sami/index.html	Consortium membership, includes academic institutes, specialized research and disease control institutes, and the Medical Research Council
Bridgeworks Kenya	A venture capital company incubating and commercializing technologies addressing key global concerns associated with soil, health and education	Venture Capital Firm	www.bridgeworks.ch/bilder_inhalt/glance.pdf	
National Institute for Pharmaceutical Research and Development (NIPRD) Nigeria	Mission: To apply appropriate modern science and technology resources to stimulate local raw material production through effective collaboration with the industry and other experts within and outside Nigeria; develop herbal medicines to pilot stage for local entrepreneurs/ manufacturers; develop quality standards for herbal and orthodox drugs for the purpose of control and regulation; provide quality assurance service on all drugs used for healthcare delivery in Nigeria; provide safety data and essential information on herbal and other drugs that are used in Nigeria, and make Nigeria self – sufficient in the production of its essential drugs in such a way that would guarantee the overall health of Nigerians.	Drug Development Traditional Medicine Drug Policy	Development of Niprisan (for treatment of sickle cell disease) is one of NIPRID's milestones www.niprd.org/	NIH Howard University, U.S.A. Xechem Pharmaceutical Co. Ltd Nigerian Universities Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) Traditional Medicine Practitioners UNIDO

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Kenya Medical Research Foundation (KEMRI) Established in 1979 Kenya	Public health research institute whose aim is to improve the quality of health and human life through research.	Basic Research, Development Testing Innovation Hub, Training Site	Research institute with a production facility for products innovated at the research institute. Some achievements: Discovery, development and production of diagnostic kits for hepatitis B (Hepcell kit) and HIV (Kemcom kit) http://www.kemri.org/	Kenyan Ministries: Health; science and technology Kenyatta National Hospital Kenyan Universities Regional Partners International Partners
Navrongo Health Research Centre Ghana	Mission: to conduct research into major national and international health problems with the aim of informing policy for the improvement of health.	Clinical Trials Capacity Building	www.navrongo.org	www.navrongo.org • WHO/TDR • Meningitis Research Foundation • IDRC • Bill and Melinda Gates Foundation Rockefeller Foundation • USAID NIH
Ifakara Health Institute Founded in 1956 Tanzania	Mission: To develop and sustain a rural district based health research and development resource centre capable of generating new knowledge and relevant information regarding priority problems in health systems at district, national and international level, through research, training and services aimed at achieving better health and community development.	Research Training Research includes clinical trials, implementation research, health systems research, demographic sentinel surveillance and disease prevention	www.ihi.or.tz	Many national, regional and international collaborators that include research and training institutes and funding partners.
Mali Malaria Research Centre Initiated in 1989	Viewed by many as model as a model for research centres in developing countries, as its research is planned, directed, and executed by African scientists. Also has a robust training program for new generation of Malian scientists critical to the success and sustainability of the program. Current training programs in biology, tropical medicine, medical entomology, and epidemiology.	Malaria research including; vaccines, diagnostics, immunology and genetics, and prevention	http://obtoure.africa-web.org/MRTC.htm	Government of Mali Others include; USAID, NIH, Rockefeller foundation, WHO, IAEA
Mali Traditional Medicines Established in 1973	The official institute connected to the National Institute of Research in Public Health (INRSP: Institut National de Recherché en Santé Publique). Main activities include: registration of traditional practitioners, medicinal plants, research and development of Improved Traditional Medicines (ITMs).	Traditional medicines		WHO collaborating centre
CFWshops (Child and Family Wellness Shops) Kenya Founded in 2000	Mission: To improve access to essential drugs, basic health care and prevention services for children and their families through business models that maintain business and clinical standards, are geometrically scalable, and achieve economics of scale.	Access	Innovative solutions for access, adapt traditional franchising model distribute essential medicines in remote communities. http://www.cfwshops.org/	Project of the HealthStore Foundation MSH provides technical advisory services

Annex 5-E: Public-private product development initiatives

Public Private Product Development Partnerships (PPDPs) for neglected diseases: (Activity in Africa)

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
Drugs for Neglected Diseases Initiative (DNDi) Founded in 2003.	Research and development of new and improved treatments for neglected diseases. Research activities are at all stages of drug development; discovery, preclinical, clinical and post-clinical.	Research and Development Disease focus: Leishmaniasis, Human African Trypanosomiasis, Chaga's disease and Malaria.	In March 2007, DNDi launched (in collaboration with Sanofi-Aventis) ASAQ, a fixed dose combination of artesunate and amodiaquine www.dndi.org/	Oswaldo Cruz Foundation (Brazil) Indian Council for Medical Research Kenya Medical Research Institute Ministry of Health of Malaysia, Pasteur Institute Médecins sans Frontières (MSF) TDR
Foundation for Innovative New Diagnostics (FIND) Launched 2003	Mission: to develop rapid, accurate and affordable diagnostic tests for poverty-related diseases, through public-private partnerships	Research and Development Testing Diagnostic tools Disease focus: Tuberculosis, Human African Trypanosomiasis, and Malaria	/www.finddiagnostics.org/	TDR Diagnostics' industry Other organizations
Medicines for Malaria Venture (MMV) Established in 2000	Mission: to bring public, private and philanthropic sector partners together to fund and manage the discovery, development and registration of new medicines for the treatment and prevention of malaria in disease-endemic countries.	Research and Development Testing	Over 30 projects 19 new classes of anti-malarial drugs in discovery. www.mmv.org	
TB Alliance (Global Alliance for TB Drug Development) Launched in 2000	Mission: to ensure the widespread availability of affordable, faster and better tuberculosis drug regimens that will advance global health and prosperity.	Research and Development Testing	www.tballiance.org	A range of institutions worldwide that share a clear interest, and a significant stake, in ensuring the development of a faster, better cure for tuberculosis.
Aeras Global TB Vaccine Foundation Founded in 1997	Aim: to help develop new concepts and tools to control the global TB epidemic. Aeras goal: to develop, test, characterize, license, manufacture and distribute at least one new TB vaccine by 2015	Research and Development Testing	www.aeras.org	Partners include universities, biotechnology and pharmaceutical companies, vaccine manufacturers, foundations, advocates, and governments. Research partners in South Africa – (for phase I clinical trials), and in Kenya, Uganda (to develop field sites with EDCTP for phase II, IIb and III studies)
International Partnership for Microbicides Founded in 2002	Aim: To prevent HIV transmission by accelerating the development and availability of a safe and effective microbicide for use by women in developing countries.	Research and Development Testing	www.ipm-microbicides.org	Academic institutions, pharmaceutical and biotechnology companies, non-governmental and international organizations.
International AIDS Vaccine Initiative Founded in 1996	Mission: to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world	Research and Development Capacity Building Policy analysis Advocacy	IAVI is sponsoring HIV vaccine trials in Kenya, Rwanda, South Africa, Uganda, and Zambia, and is collaborating with local partners to collect epidemiological data and to build capacity for future large-scale trials. www.iavi.org	Global scientific and policy advocacy partners

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
South African AIDS Vaccine Initiative Formed in 1999	Established to co-ordinate the research, development and testing of AIDS vaccines in South Africa	Research and Development Testing	www.saavi.org.za	Collaborators: African AIDS Vaccine Programme (AAVP) Botswana Harvard AIDS Institute Ethiopian AIDS Vaccine Initiative (EAVI) European Developing Country Clinical Trials Partnership (EDCTP) European Union (EU) HIV Vaccine Trials Network (HVTN) International AIDS Vaccine Initiative (IAVI) National Institutes of Health (NIH) Nigerian AIDS Vaccine Programme (NAVP)

Annex 5-F: International organization initiatives

International Organizations

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
PATH Founded in 1997	PATH's mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviours.	Research and Development	Health technology focus on innovation for diagnostics, newborn health, nutrition, safe injection, safe water, vaccine delivery and woman initiated protection. Currently involved in meningitis and pneumococcal vaccine development www.path.org	Local communities, governments, NGOs, UN, Private sector (business)
Action Medeor Established in 1964	To provide basic drugs and medical equipment to developing countries One of the goals; support local development and production of drugs in collaboration with local manufacturers.	Local Production Technology Transfer	Current projects, manufacture of ARVs and ACTs in Tanzania and DR Congo. http://gb.medeor.org	German Medical Aid Organization
Médecins Sans Frontières "MSF access campaign"	Advocate for greater access and exemptions to licensing. Monitor drug prices.	Advocacy	www.accessmed-msf.org	

Annex 5-G: Pharmaceutical partnerships in Africa initiatives

Pharmaceutical Partnerships in Africa[ci]: Access (examples)

Disease Focus	Program	Program Scope and Country Focus (Africa)	Industry Partners	Other Partners
HIV/AIDS	Accelerating Access Initiative www.who.int/hiv/AAI_fs_4Q2005.pdf	Access – Pricing Developing countries, including in Africa	Abbott Boehringer-Ingelheim Bristol-Myers Squibb Gilead Sciences GlaxoSmithKline Merck & Co. Inc. Roche	UNAIDS WHO World Bank UNICEF UNFPA
	Technology Transfer & ARV Licensing in Developing Countries www.boehringer-ingelheim.com, www.bms.com, www.gilead.com, www.gsk.com, www.merck.com, www.roche.com	Access - Licensing Kenya, South Africa	Boehringer-Ingelheim Bristol-Myers Squibb Gilead Sciences GlaxoSmithKline Merck & Co. Inc. Roche	Various generic pharmaceutical manufacturers
	lisabeth Glazer Paediatric AIDS Foundation www.pedaids.org	Access - Donation Developing countries, including in Africa	Abbott Boehringer-Ingelheim Johnson and Johnson	EGPAF
	PMTCT Abbott Rapid HIV Test Donation Program www.abbottglobalcare.org	Access – Donation Sub-Saharan Africa	Abbott	Various partners
	PMTCT: Viramune® Donation Program www.boehringer-ingelheim.com	Access - Donation Developing countries, including in Africa	Boehringer-Ingelheim	EGPAF Governments Rotary International UNICEF
	HIV South Africa www.hivsa.com/hivsa/index.stm	Access – Donation South Africa	Johnson & Johnson	HIV South Africa
	J&J Health Care Training Fund www.jnj.com, www.idasolutionsdplatform.org	Capacity building – Training in health care supply chain management	Johnson & Johnson	AMREF IDA Solutions
	Pfizer Diflucan ® Partnership www.diflucanpartnership.org www.pfizerglobalhealth.com	Access - Donation	Pfizer	Various partners
	PEPFAR Partnership for Paediatric AIDS Treatment www.pepfar.gov	Access - Pricing Developing countries, including in Africa	Abbott Bristol-Myers Squibb Gilead GlaxoSmithKline Merck & Co. Inc.	PEPFAR UNAIDS UNICEF WHO
	Sikiliza Leo Project www.tibotec.com	Access – Donation Uganda	Johnson & Johnson	Sikiliza Leo
Tuberculosis	Lilly MDR-TB Partnership www.lillymdr-tb.com	Access – Pricing and licensing Worldwide, including in Africa	Lilly	WHO Other partners WHO
	Novartis TB DOTS Donation www.novartisfoundation.org	Access – Donation Tanzania	Novartis	
	Stop TB Partnership www.stoptb.org	Access – Donation, pricing Endemic countries & vulnerable populations, including in Africa	AstraZeneca GlaxoSmithKline IFPMA Lilly Novartis	Stop TB MSF Red Cross Other partners

Disease Focus	Program	Program Scope and Country Focus (Africa)	Industry Partners	Other Partners
Malaria	ACCESS II – Improving Access to Effective Malaria Treatment www.novartisfoundation.org	Access – Pricing Tanzania	Novartis	Swiss Tropical Institute Other partners
	GSK and Access to Malaria Care www.gsk.com/malaria	Access – Pricing Developing countries including in Africa	GlaxoSmithKline	Various partners
	Novartis Coartem® www.novartis.com	Access – Pricing Developing countries, including in Africa	Novartis	WHO MMV
	Millenium Villages Project www.novartisfoundation.org	Access – Donation Tanzania	Novartis	Ilolangulu Village
	Roll Back Malaria Partnership www.rollbackmalaria.org	Access – Pricing Developing countries including in Africa	GlaxoSmithKline Novartis Sanofi-aventis	Roll Back Malaria Other partners
	Sanofi-aventis: Impact Malaria www.impact-malaria.com	Access-Pricing Benin, Madagascar, Republic of Congo, Tanzania	Sanofi-aventis	Various national and international partners, including universities
Tropical Diseases	Global Alliance to Eliminate Lymphatic Filariasis (GAELF) www.filariasis.org Guinea Worm Eradication Program (GWEP) www.cartercenter.org/health/guinea_worm/index.html	Access – Donation Endemic countries, including in Africa Access – Donation 9 African countries	GlaxoSmithKline Merck & Co. Inc. Johnson & Johnson	GAELF WHO Other partners Carter Centre WHO Other partners
	International Trachoma Initiative (ITI) www.trachoma.org Leprosy Elimination www.novartisfoundation.org Merck Mectizan® Donation Program www.mectizan.com Merck Praziquantel Donation Program www.merck.de Sanofi-aventis 'Most Neglected Disease' Program www.sanofi-aventis.com Sanofi-aventis Sleeping Sickness Program www.sanofi-aventis.com Soil-Transmitted Helminthiasis www.jnj.com	Access – Donation Developing countries, including in Africa Access – Donation Developing countries including in Africa Access – Donation Lymphatic filariasis, onchocerciasis Endemic countries, including in Africa Access – Donation Schistosomiasis 8 priority control countries Access – Pricing Chad, Ethiopia, Sudan, Togo Access – Donation R&D Access – Donation	Pfizer Novartis Merck & Co. Inc. Merck KGaA Sanofi-aventis Sanofi-aventis Johnson & Johnson	Edna McConnell Clark Foundation Other partners WHO WHO World Bank Other partners WHO WHO Other partners WHO Other partners Task Force for Child Survival and Development

Pharmaceutical Partnerships in Africa: Research and Development (R&D) (examples)

Disease Focus	Program	Program Scope and Country Focus (Africa)	Industry Partners	Other Partners
HIV/AIDS	Gilead Clinical Development Partnerships www.gilead.com	Clinical research to develop new medical interventions	Gilead GlaxoSmithKline	US CDC US NIH WHO
	GSK's HIV-Collaborative Research Programme for Resource-Poor Settings www.gsk.com	Uganda, Zimbabwe Support for clinical trials	Bristol-Myers Squibb Crucell GlaxoSmithKline Merck & Co. Inc. Pfizer	Other partners IAVI Becton, Dickinson & Company Gates Foundation Rockefeller Foundation USAID World Bank
	International HIV/AIDS Vaccine Initiative (IAVI) www.iavi.org	Developing countries including in Africa Vaccine R&D Access Worldwide including in Africa		
	International Partnership for Microbicides www.ipm-microbicide.org	Development, manufacture and distribution of microbicides	Bristol-Myers Squibb Gilead Johnson & Johnson Merck & Co. Inc. Pfizer	International Partnership for Microbicides HIV Vaccines Trials Network Other partners
	Merck & Co. Inc. HIV Vaccine R&D www.merck.com	IPM has been granted royalty-free license and technology transfer by pharmaceutical company partners	Merck & Co. Inc.	
	Paediatric Formulations for ARVs www.abbott.com, www.bms.com, www.gilead.com, www.gsk.com	Rwanda, South Africa, Tanzania Vaccine R&D South Africa Clinical studies Developing countries	Abbott Bristol-Myers Squibb Gilead GlaxoSmithKline	
Tuberculosis	Stop TB Partnership www.stoptb.org	R&D Endemic countries & vulnerable populations, including in Africa	AstraZeneca GlaxoSmithKline IFPMA Lilly Novartis	Stop TB MSF Red Cross Other partners
	Aeras Global TB Vaccine Foundation www.aeras.org www.crucell.com www.gsk.com	R&D Kenya, South Africa	Crucell GlaxoSmithKline	Aeras Global TB Vaccine Foundation Other partners
	Global Alliance for TB Drug Development (TB Alliance) www.tballiance.org	R&D South Africa, Zambia	Bayer HealthCare Cumbre GlaxoSmithKline KRICT[sic] Novartis	DFID NIAID USAID Other Partners
	GSK-TB Alliance Drug Discovery Program www.gsk.com	R&D South Africa	GlaxoSmithKline	GSK-TB Alliance Drug Discovery Program Stellenbosch University
	Moxifloxacin TB Clinical Trials (Bayer HealthCare) www.bayerscheringpharma.de	R&D South Africa, Zambia	Bayer HealthCare	TB Alliance
	Sanofi-aventis R&D for TB www.sanofi-aventis.com	R&D International, including in Africa	Sanofi-aventis	TB Alliance Other partners

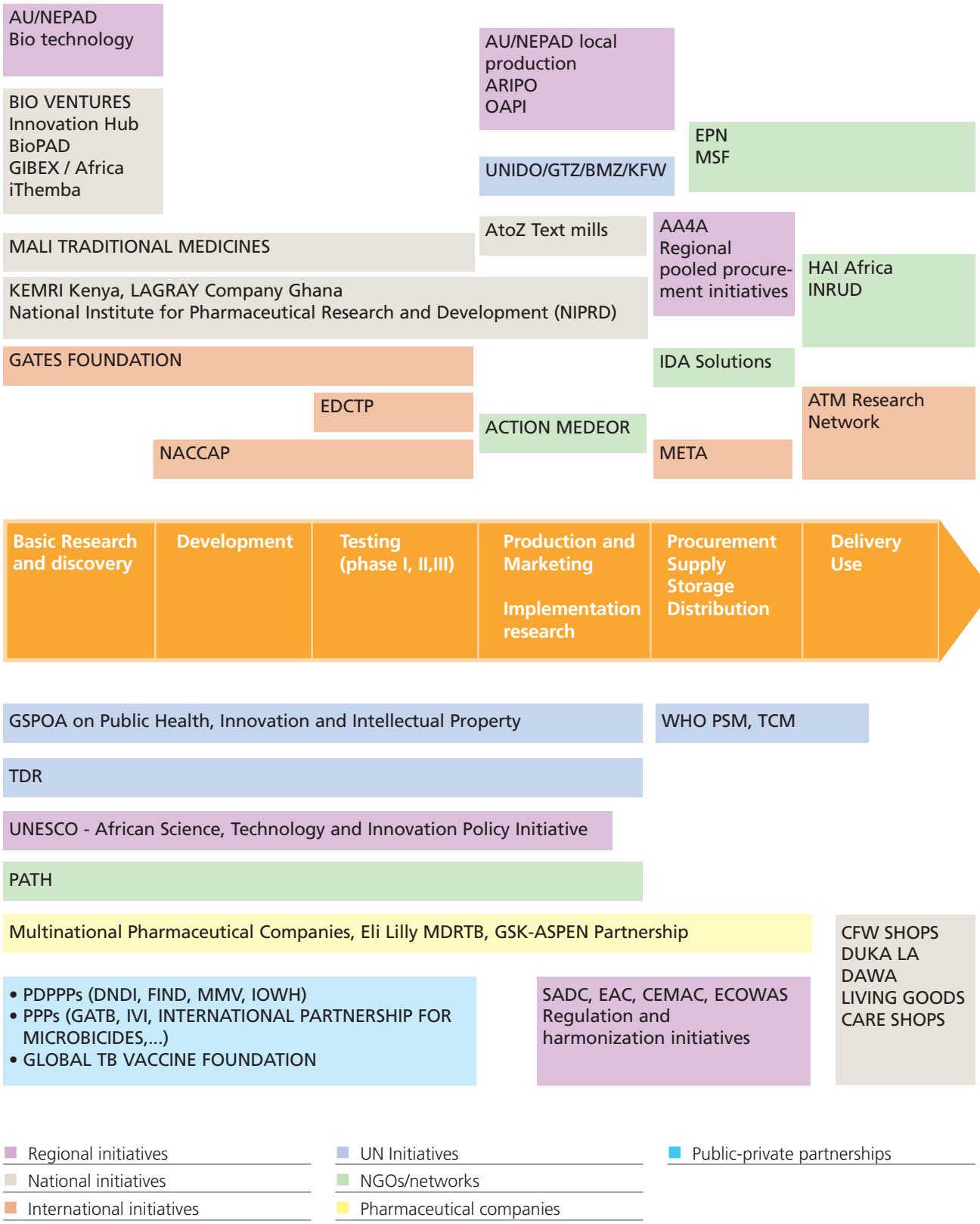
Disease Focus	Program	Program Scope and Country Focus (Africa)	Industry Partners	Other Partners
Malaria	Eurartesim™ International Development Program www.mmv.org, www.sigma-tau.org	R&D Burkina Faso, India, Kenya, Mozambique, Uganda, Zambia	Sigma-Tau	MMV
	Medicines for Malaria Venture (MMV) www.mmv.org	R&D Benin, Kenya, Mali, Mozambique, Tanzania, Zambia	Bayer HealthCare Chong Qing Holley Genzyme GlaxoSmithKline Merck & Co. Inc. Novartis Pfizer Sanofi-aventis Shin Poong Sigma-Tau	MMV Other partners
	Novartis R&D for Malaria www.novartis.com	R&D Benin, Kenya, Mali, Mozambique, Tanzania, Zambia	Novartis	TDR Other partners
	Pfizer - Zithromax®/chloroquine for Malaria www.pfizer.com/responsibility	R&D Burkina Faso, Côte d'Ivoire, Ghana, Kenya, Mali	Pfizer	Various partners
	Sanofi-aventis – DNDI Malaria Medicines www.sanofi-aventis.com www.dndi.org	R&D Cameroon, Côte d'Ivoire, Gabon, Liberia, Madagascar, Mali, Senegal, Uganda	Sanofi-aventis	DNDI Other partners
	Sanofi-aventis: Impact Malaria www.impact-malaria.com	R&D Benin, Madagascar, Republic of Congo, Tanzania	Sanofi-aventis	Various national and international partners, including universities
	Gilead – AmBisome for Leishmaniasis www.gilead.com/access_developing_world	R&D	Gilead	WHO
Tropical Diseases	GSK's Sitamaquine for Leishmaniasis www.gsk.org	R&D Kenya	GlaxoSmithKline	Various partners
	Merck Serono Collaboration with TDR www.merck.de	R&D Developing countries including in Africa	Merck KGaA	TDR Other partners
	Next-Generation Onchocerciasis Treatment R&D www.wyeth.com	R&D Democratic Republic of Congo Ghana, Liberia	Wyeth	TDR
	Nifurtimox-Eflornithine for Sleeping Sickness www.bayerscheringpharma.de, www.sanofi-aventis.com	R&D Democratic Republic of Congo Uganda	Bayer HealthCare Sanofi-aventis	TDR Other partners

Annex 5-H: National pharmaceutical industry initiatives

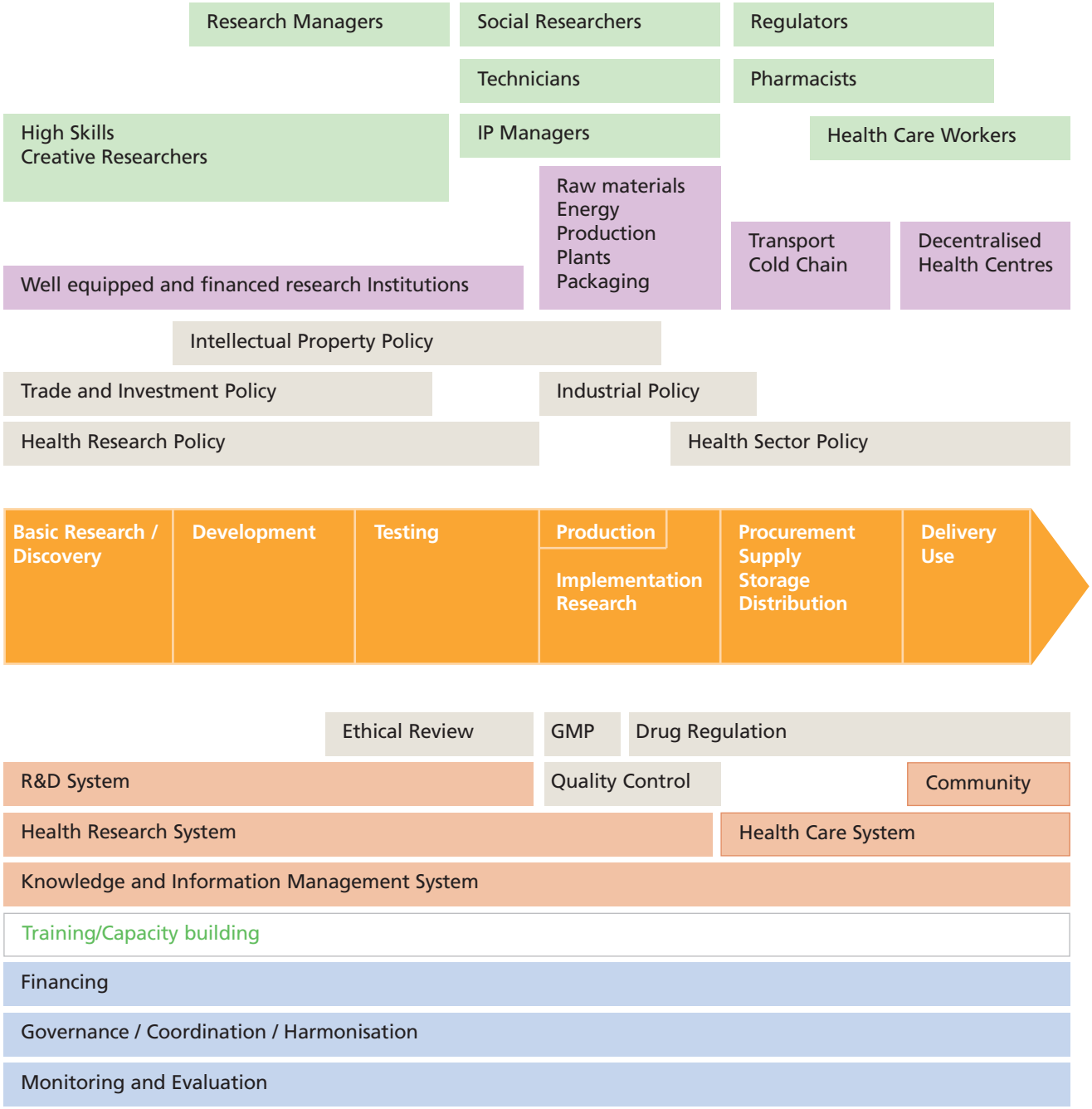
National pharmaceutical industries (selected)

Initiative	Aim / Mission/ Objectives	Focus	Comments	Partners
ASPEN Holdings /Aspen Pharmacare South Africa		Research and Development Local Production (including API and generic drugs	www.aspenpharma.com	ASPEN Holdings Licensing agreements with Eli Lilly, GlaxoSmithKline, Gilead, Bristol-Myers-Squib, Merck and Co. Pharmaceutical manufacturing facilities in South Africa, East Africa, Latin America and India
Advanced Bio-Extracts Limited Kenya A private holding company	Production of low cost, pharmaceutical grade artemisinin, and artemisinin-based derivatives.	Local Production	Main plant in Athi River, Kenya. Extracts and purifies Artemesinin from its supply chain of locally grown plant in Kenya and Tanzania, and purifies crude artemesinin from sister company in Uganda. http://www.abextracts.com	Action Medeor Acumen Fund Centre pour le dévelopment de l'entreprise Cordaid DFID EVD international ondernemen en samenwerken GTZ IFC[cvii] Mediplan Novartis Technoserve USAID
A to Z Text Mills Tanzania		Production of long lasting insecticide treated bed nets (Olyset)	Bed nets impregnated with a long-lasting insecticide, effective for up to five years instead of the usual six months, with no need for re-treatment www.olyset.net/resourcecenter/events/	• Sumitomo Chemicals, Japan • Government of Tanzania
iThemba Pharmaceuticals South Africa	iThemba Pharmaceuticals (Pty) Ltd. is an emerging drug discovery company to research and develop new and affordable medicines for infectious diseases of the poor.	Drug Discovery Small Molecule Therapies	www.ithembapharma.com	Founded by (global) researchers and eminent academicians with investments from LIFElab and BioPAD.
LaGray chemical company Ghana	Goal: to make drugs available and affordable in Sub – Saharan Africa, sustainably.	Research Development Testing Local Production	Capacity for manufacture: from API to finished dosage forms. Plans to collaborate with Howard University (USA) on drug discovery and development research. http://www.lagraychem.com/	
Xechem Nigeria Limited Founded in 2002	Xechem seeks to explore Nigeria's and other African countries' extraordinary biodiversity to develop drugs from natural sources for the treatment of life threatening illnesses and other diseases.	Basic research, development, Production	Production of NICOSAN, a plant derived breakthrough drug for treatment of sickle cell disease, discovered by Nigerian scientists. Xechem research park has state of the art cGLP/cGMP facilities in Abuja, Nigeria http://www.xechemnigeria.com/aboutus.htm	• National Institute for Pharmaceutical Research and Development (NIPRD) • Xechem International

Annex 6
Visual mapping of initiatives (COHRED)



Annex 7
Visual mapping of building blocks (COHRED)



Annex 8
Noordwijk Medicines Agenda

Noordwijk Medicines Agenda

Noordwijk-aan-Zee, Netherlands, 21 June 2007

The OECD High Level Forum on Medicines for Neglected and Emerging Infectious Disease: Policy Coherence to Enhance their Availability (HLF) was organised in collaboration with the government of the Netherlands. Improving global health is a shared responsibility. The HLF was attended by high level officials of developed and developing countries, and senior representatives from industry, the scientific community, international and non-governmental organisations who met to contribute a coherent, open agenda for action. The HLF sought to build on and complement international momentum to stimulate innovation and radically accelerate the development and delivery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases that disproportionately affect developing countries. Participants made it clear that many health issues in developing countries cannot and will not be solved by developments in health technologies alone. Nevertheless, such technologies are important and efforts to accelerate innovation and to reduce poverty and its consequences must go hand and hand. **The High Level Forum Recognises that:**

- Infectious diseases have a serious socio-economic impact in addition to the burden placed on health systems, particularly in developing countries.
- It is in the economic interest of all countries to mobilise resources for the control of neglected and emerging infectious diseases, bearing in mind that incentives to address neglected and emerging diseases may differ and that both sets of diseases require international and national attention.
- Research and development (R&D) is essential to make available innovative, safe and effective medicines, vaccines, and diagnostics for neglected and emerging infectious diseases and thus to achieve, in the long term, a sustainable response to major global health challenges. Continued investment in basic science is essential to feed innovation in health.
- Access to affordable essential drugs and availability of the benefits of new technologies is a core element of development as identified in the Millennium Development Goals (Goal 8), which calls for a global partnership in this area.
- Work to improve the availability and accessibility of medicines, vaccines and diagnostics for neglected and emerging infectious diseases that primarily affect developing countries is ongoing in international organisations such as the World Health Organisation (WHO) and in other international partnerships and bodies.
- A number of recently created public and private initiatives, (e.g. public-private product development partnerships (PDPs) and industry philanthropic programmes) have increased research and development on some neglected infectious diseases and raised international awareness of the extent of the problem.
- Many developing countries do not have the research infrastructure to address R&D for neglected diseases.
- Functioning health systems in developing countries are necessary to ensure access to care and basic medicines.
- Innovation includes both the development of new healthcare products and the delivery and diffusion of those products, and any efforts to improve the availability of medicines, vaccines, and 2 diagnostics must be accompanied by efforts to improve access to health care and to strengthen health systems.

Acknowledges that:

- In both developed and developing countries, there is an urgent need for greater policy coherence in health, science, development, trade, finance and industry policies in order to tackle neglected and emerging infectious diseases, as well as a need to increase policy makers' understanding of the interdependencies of these policy areas.
- The WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) presents a unique opportunity to reach international agreement on an integrated framework for accelerating innovation and improving access to medicines in the developing world. As well as mobilizing more concerted efforts of governments, industry, research institutes and non-governmental organizations, such a framework would help to strengthen coherence among international organizations and initiatives.
- OECD governments have taken promising initial steps to establish long-term predictable financing to meet the Millennium Development Goals, but more effort is required.
- The protection and use of intellectual property rights (IPRs) are important in encouraging investments in research and development of medicines, vaccines, and diagnostics but are not sufficient to stimulate innovation for neglected and emerging infectious diseases. Complementary reward systems may also play an important role.
- Product development partnerships (PDPs) are an innovative and potentially successful model of collaborative R&D that leverage industry investments and foster innovation to increase the availability and accessibility of health technologies. They, as well as some other recent initiatives, lack long term sustainable financing and alone are not sufficient to foster innovation throughout the entire innovation cycle, from the test tube to the patient.
- Long-term development aims for medicines for neglected diseases should include not only incentives for R&D in OECD countries, but incentives to increase R&D and technology capacity in developing countries.
- New approaches to more open innovation and collaborative research, as well as access to knowledge, can further increase the efficiency and lower the costs of developing new, safe and effective medicines, vaccines and diagnostics for neglected and emerging infectious diseases as well as broaden the involvement of researchers, academic institutions, laboratories and companies globally.
- Activities in pharmaceutical innovation, manufacturing and trade are increasingly crossing national borders, which necessitate enhanced collaboration among, and strengthening of, regulatory agencies to ensure safety, quality and efficacy of healthcare products as well as to maintain public trust.
- The capacity of developing countries and their institutions must be strengthened and utilised in order to foster their contribution to global R&D efforts, and to ensure that innovation reaches the patients most in need.
- Continued efforts must be made to engage a broad range of stakeholders to ensure policy coherence and take forward the elements of this agenda.

The High Level Forum calls upon: governments both of OECD and developing countries to demonstrate political leadership and to join with industry, product development partnerships, investors, shareholders, intergovernmental organisations and non-governmental organisations to further intensify collaborative efforts and promote coherent policies to improve the availability of and access to medicines, vaccines and diagnostics for neglected and emerging infectious diseases.

Actions should focus on the following areas: Exploring in conjunction with the WHO/IGWG process how greater efforts to collaborate in prioritising, developing and delivering innovative medicines, vaccines and diagnostics could increase investments and

the number of researchers involved in R&D for neglected and emerging infectious diseases that primarily affect developing countries. Specifically:

- Pursuing the viability of a global, virtual collaborative drug development network drawing on existing initiatives, including those of the WHO/TDR, PDPs, and regional (e.g. south-south and north-south) technology networks.
- Facilitating the development and operation of a sustainable architecture for the sharing and exchange of knowledge, data and research tools necessary for the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases.
- Identifying the infrastructure needs to underpin such efforts to accelerate the discovery of medicines, vaccines and diagnostics for neglected and emerging infectious diseases.
- Forecasting effective demand for essential medical technologies.
- Ensuring that there is sustained high level political support and adequate funding for the WHO/IGWG activities including implementation of the Global Strategy and Plan of Action.
- Considering the African Health Strategy and the Pharmaceutical Manufacturing Plan for Africa adopted by the African Union Health Ministers in April 2007.

Exploring and evaluating for-profit and not-for-profit models to promote innovation and stimulate the development of new medicines, vaccines and diagnostics for neglected and emerging infectious diseases primarily affecting developing countries. In particular explore:

- The potential value of sustainable collaborative mechanisms for IPRs (such as patent pools or other IP and data management entities). This work could be carried out by the OECD as part of its ongoing work on collaborative mechanisms for IPRs in co-operation with other relevant international organisations.
- Alternative policy mechanisms to reward innovation (e.g. advanced market commitments, prize fund models, valorisation of intellectual assets) to better understand how these could contribute to the development of medicines, vaccines and diagnostics for neglected and emerging infectious diseases. The strengths and limitations of alternative mechanisms could be considered, as well as monitoring pilot phases of existing mechanisms. This should involve empirical testing.
- Comprehensive and inclusive approaches to innovation that place delivery of new health technologies to patients at its core.
- Mechanisms to promote the transfer of technology, knowledge and technical skills to strengthen developing country innovation systems.
- Supporting and providing incentives to new models of partnerships between developing and developed countries to accelerate R&D for neglected diseases.
- Synergies and complementarities between research and development financing to support R&D in developing countries by harmonising OECD Official Development Assistance (ODA) mechanisms.
- The use of existing flexibilities of multilateral agreements to foster innovation and access.

Supporting developing countries-led efforts in strengthening their own health, local production and research systems, including prevention, to ensure availability and accessibility of medicines, vaccines, diagnostics and other preventative technologies for neglected and emerging infectious diseases in accordance with the principles of the Paris Declaration on Aid Effectiveness (March 2005). In particular:

- Improving predictability and transparency of funding including official development assistance.
- Taking steps to strengthen the capability of developing countries to manage issues of intellectual property, including using available flexibilities to the fullest extent, and to build sustainable networks and capacity for global research.

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- Information was gathered from February 2008 to May 2009.
- Keywords used for the Internet-based literature review were: 'Africa', 'developing countries', 'health innovation systems', 'pharmaceutical research and development', 'local pharmaceutical production', 'technology transfer', 'neglected tropical diseases' .
- Discussions were held with key informants in various sectors of pharmaceutical innovation in developing countries, especially in Africa. The aim was to get input from a cross-section of informants across the pharmaceutical innovation spectrum; from discovery to delivery and access.
- Documentation referred to or obtained from key informants was reviewed.
- Participating in global and regional meetings on specific aspects of pharmaceutical innovation in developing countries, including Africa, was key.

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The NEPAD Agency of the African Union (New Partnership for Africa's Development)
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