

Strengthening Pharmaceutical Innovation in Africa

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



Tools and guideline for access to medicines and pharmaceutical innovation in Africa

Supporting

- African Union Pharmaceutical Manufacturing Plan
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

African Union

Council on Health Research for Development (COHRED)

New Partnership for Africa's Development (NEPAD)

With contributions from The George Institute for International Health



AFRICAN UNION



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COHRED
Council on Health Research for Development

Building dialogue for an African perspective on medicines access and pharmaceutical innovation

This study comes at an important moment in the development of Africa's pharmaceutical innovation strategy and in achieving access to essential medicines for all Africans.

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 some 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 study marks the starting point of a practical reflection between countries on what is needed to provide better access and encourage local production of medicines in Africa. It will be critically reviewed and revised at a meeting of African experts in health, science and technology and pharmaceuticals in Pretoria in January 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), 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 an initiative linked to this, '*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.

I encourage my African colleagues working in research for health and science and technology to comment on and enrich this report. 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

Approaches and tools for African decision makers

This briefing is designed to inform thinking and support strategic planning for African decision makers who are interested in improving access to medicines in their country or region. It discusses the process of 'pharmaceutical innovation' – covering the local development, production and delivery of essential drugs and other medical products that help countries meet their pressing public health needs.

The approach and evidence presented here are synthesized from *Strengthening Pharmaceutical Innovation in Africa*, a study by the Council on Health Research for Development (COHRED), the New Partnership for Africa's Development (NEPAD) with contributions from the Health Policy Division of The George Institute for International Health, in developing of the Pharmaceutical Innovation Grid. From the study, the *Pharmaceutical Innovation Framework and Grid* tools were distilled to help countries design national innovation and access strategies and put them into action.

Toward African management of Africa's pharmaceutical innovation

In Africa today, there are probably more than 200 separate activities, initiatives, programmes and organisations that do research and develop cures to neglected diseases, produce and deliver medicines, and improve access to medical products. This diverse field of players is generally shaped by the interests of international programmes and funders and often does not engage with countries and their public health needs.

This results in the peculiar situation where the pharmaceutical innovation policy for Africa today is largely directed by interests outside the continent – a practice that would be unthinkable in any other region of the world.

Two new mechanisms have emerged that aim to put countries in the driver's seat to determine and manage research, production and access of medicines and promote innovation – *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 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 assess their needs and make the right choices to support their pharmaceutical development. The *Pharmaceutical Innovation Framework and Grid* tools were designed to support countries in doing this.

Many African countries have the potential to engage in pharmaceutical innovation. For this to become a reality, decision makers and planners need to be clear on how to get started, what skills are needed in the country, or what issues they need to better understand – to design strategies and action plans to deliver better access to medicines.

What expertise and actions are needed to get started?

- Does your country have the expertise needed to design and implement a strategy?
- What mechanisms and people are needed to coordinate and manage the process?

Using the Pharmaceutical Innovation tools

The Innovation Framework and Grid are tools for decision makers in ministries and for others responsible for planning and managing national innovation and medicines access strategies in Africa.

They are designed to help decision makers better appreciate the implications of embarking on national pharmaceutical R&D and improving access to medicines. The Framework and Grid bring an important perspective to planners, by showing that providing access to medicines is about much more than production. It guides them through a process of reflection and assessment of, for example:

- Current political and policy situation.
- The need for strong regulation and regulatory authorities.
- Management mechanisms for national pharmaceutical production.
- Access and equity needs of the country.
- R&D capacity building needs
- Key partners to engage to meet national goals.

This reflection helps decision makers collect evidence and craft strategies based on country's actual needs.

At the continental level, the Framework and Grid directly support governments' efforts to put African countries in charge of governing access to medicines, on their terms.

Planning a national innovation strategy

The concept of national strategies for pharmaceutical innovation in African countries is relatively recent. There is growing interest in local production. All Health Ministers in the African Union signed the Gaborone Declaration which set a continent-wide priority to pursue local production of medicines. The answer to the simple question: *how to get started to provide better access?* - however, is a complex one, that requires detailed reflection. The local production of medicines and other medical products is not the only solution and often not the most effective way to ensure access.

The expertise needed for local medicines production extends well beyond public health. It covers areas such as research and development, intellectual property, trade and commerce, tax and tariff policies, drug regulatory and registration issues, finance, raw materials procurement, pharmaceutical manufacturing and marketing. The capacity to produce should not be viewed independently from the need to build innovative capacity.

As a starting point, decision makers in the ministry of health can reflect on how they want to improve access and why they may choose to engage in local production. This process is best done by involving all key ministries and other key players such as potential funders and external partners. Having a clear answer to this question sets the scene for further assessment.

In designing their strategies, decision makers need to consider two important questions.

- Firstly, what is the preferred path to improving the health situation in the country? Possible choices include: improved access to essential medical products, manufacturing cheaper versions of these, developing and producing formulations that are better adapted to local health needs and - eventually - more affordable.
- Secondly, if local production is my preferred choice is it for improved health or economic reasons?

There is much discussion in development circles on the potential benefits of local medicines production by low income countries. And a perception by some that embarking on pharmaceutical innovation and medicines production can generate vast profits from intellectual property revenues. This potential should be examined with a clear dose of reality. Pharmaceutical sector experience of the past 50 years shows that embarking on R&D for new medicines is not necessarily a guarantee of large profits from patented innovations. At the same time, local production may not be the path of choice if a country's priority is to improve access to medicines.

Access or commerce?

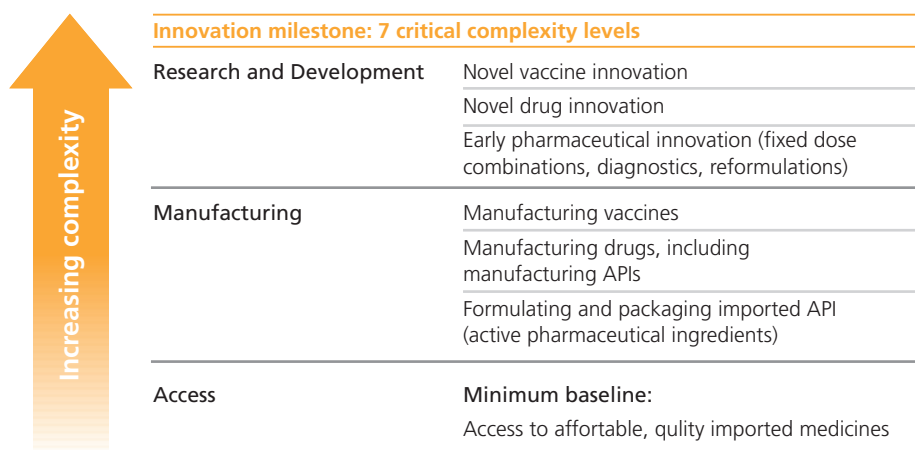
Typically, this discussion will center around two choices:

- Are we producing medicines locally to provide maximum access to our population
- Or do we want to create a pharmaceutical technology sector for economic development.

Both paths are useful but the skills and investment needed for each is different

► What is your country's priority for pharmaceutical innovation?

Providing access? Producing medicines? Discovering new drugs? Depending on your answer, the people, structures and investment levels you need will be quite different. As a first step, answer these questions, then assess your current potential to deliver on these needs and what capacity needs to be developed. This is the basis of a national plan.



In designing innovation strategies, countries will benefit from a detailed reflection on these issues. Matching this vision with the country's current skills and potential (financing, infrastructure) will show what is realistic and possible.

Assessing country needs

The next step is to assess the current situation (strengths, weaknesses, opportunities and threats) and collect accurate data. From this foundation countries can then build innovation strategies and action plans that allow them to negotiate with potential donors and partners in the pharmaceutical industry. Innovation strategies may be national, regional or continental; pooling the best of skills and services from several countries into a shared system.

Designing an effective and realistic national innovation strategy

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

Some recent examples

- **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 a 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.

Exploring regional innovation strategies

Gaining end-to-end expertise in pharmaceutical innovation is not viable for most African countries today for reasons such as skill base or financing. A regional strategy that pools the talents and investments of a group of countries can be an attractive approach. In this scenario, countries can agree to work together to develop specific parts of the pharmaceutical innovation, production and delivery chain. For example, the AU's *Pharmaceutical Manufacturing Plan of Action* is proposing groupings of countries that have a potential for regional cooperation. This is based on existing skills and potential market size.

Expert review of the Pharmaceutical Innovation tools (Framework and Grid)

The Pharmaceutical Innovation tools (Framework and Grid) for assessment, priority setting and strategy design were created by were created by COHRED, with input from The George Institute for International Health, as a result of their study *Pharmaceutical Innovation in Africa*. It is also informed by COHRED's 15 years' experience working with countries to build national health research systems. The Framework and Grid will be reviewed by the AU-NEPAD African experts meeting on pharmaceutical innovation in Africa in 2010. They will assess the relevance of this approach, to be recommended as a guideline for countries across the continent to support them in developing innovation strategies – and in their negotiations with northern partners and research funders.

What can we realistically do?

A well-structured reflection – involving different ministries and other players active in medicines access – will help you decide what can be realistically achieved. What innovative capacities do you need to develop?

Should you manufacture locally?

Do you have the skills, and can you acquire and maintain infrastructure over a 15 year horizon?

If your objective is to achieve better of medicines to these populations, a procurement and distribution programme may be quickest way to achieve that goal.

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 medicines
- Manufacturing
- Research and development

Pharmaceutical Innovation 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)									

▲ **A strong strategy rests on strong relationships.** Pharmaceutical innovation for a country is not only about industrial policy and production. Likewise, providing access to medicines extends beyond the responsibilities of the health ministry it involves the ministries of finance, foreign trade and health, and others. A positive outcome of an innovation strategy will be a strong relationship between different actors. In shaping your strategy, it is vital to consult with all relevant counterparts and get input and joint decisions agreeable to all. Developing such a strategy is not necessarily a linear process. Countries can choose starting locations and entry points, once they have a clear overview of what they want to achieve (This tool was developed by the George Institute for International Health).

Framework for developing a national pharmaceutical innovation system

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 Pharmaceutical Innovation Assessment grid 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 R&D: research policy, intellectual property management																
Human Resources	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, etc... 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	<table border="0"> <tr> <td>For example:</td> <td>R&D</td> </tr> <tr> <td>Access</td> <td>- Good research contracting;</td> </tr> <tr> <td>- Pooled procurement</td> <td>- Intellectual property management;</td> </tr> <tr> <td>- Community based delivery</td> <td>- Clinical trials ethics;</td> </tr> <tr> <td>Manufacturing</td> <td>- Merit-based promotion system of scientists</td> </tr> <tr> <td>- Technology transfer arrangements;</td> <td>All levels</td> </tr> <tr> <td>- Good manufacturing practices</td> <td>- Community demands for medical products</td> </tr> <tr> <td>- Post market quality control</td> <td>- Monitoring & evaluation</td> </tr> </table>	For example:	R&D	Access	- Good research contracting;	- Pooled procurement	- Intellectual property management;	- Community based delivery	- Clinical trials ethics;	Manufacturing	- Merit-based promotion system of scientists	- Technology transfer arrangements;	All levels	- Good manufacturing practices	- Community demands for medical products	- Post market quality control	- Monitoring & evaluation
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This framework is one component of the COHRED Framework and tools for National Health Research System strengthening www.cohred.org/framework-guides-system-strengthening.

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