Putting the GSOPA into action at country level

Proposed approach and tools

1. Introduction
With non communicable diseases on the rise and infectious diseases still taking a heavy toll on people’s health, many developing countries are confronted to a high disease burden. Yet, there are well known and sometimes simple solutions that could help their populations to deal with many of their problems, if only they had regular access to them. While access to essential medicines should be a universal human right, such access is far from being guaranteed to a majority of people in low and middle income countries.

Over the past decade, the international community has increasingly recognised the need to improve access of the most vulnerable populations to affordable, good quality, essential 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.

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) attempts to address the huge challenge of enabling the most disadvantaged countries to have more equitably and sustainably access to the medical products they need. Guided by the central concept of needs-driven essential health research and development, the GSPOA provides an essential conceptual umbrella that has achieved political consensus. It forms 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, national decision makers need skills, tools 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 moving forward. The approach and evidence presented here are synthesized from Supporting Pharmaceutical Innovation in Africa, a study by the Council on Health Research for Development (COHRED), the New Partnership for Africa’s Development (NEPAD); with the George Institute for International Health, in the development of the Pharmaceutical Innovation Grid.

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2. This work was supported by the Government of the Netherlands as a follow up to their joint initiative with OECD, the Noordwijk Medicines Agenda. The complementary process initiated by the Netherlands, Cameroon and COHRED came to be known as the “Yaoundé Process”
While the report *Supporting Pharmaceutical Innovation in Africa* obviously focuses on Africa, the approach taken for analysing the major elements of African innovation systems is applicable to any other country and can be adapted to specific national contexts. This report is the first step in a process aimed at providing concrete and practical tools countries can use to build their pharmaceutical innovation sectors and put the GSPA into action. The *Pharmaceutical Innovation Framework and Pharmaceutical Grid* tools were created during the study, with the objective to provide countries with a decision-support tool to better design and put into action innovation and access strategies.

2. **Approaches and tools for decision makers**
These are designed to inform thinking and support strategic planning for decision makers who are interested in improving access to medicines in their country or region. They outline the process of ‘pharmaceutical innovation’ – covering the local research, development, production and delivery of essential drugs and other medical products that help countries meet their pressing public health needs.

At this time, there are many activities, initiatives, programmes and organisations worldwide that produce and deliver medicines, improve access to medicines, and do research to develop cures to neglected disease – over 120! This very 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.

New mechanisms have emerged that aim to put countries in the driver’s seat to determine and manage access to and local production of medicines and promote innovation for health – the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* as well as regional initiatives, like the *African Union Pharmaceutical Manufacturing Plan*.

Many countries have the potential to engage in pharmaceutical innovation. However, decision-makers and planners are often not clear on how and where to get started; what skills are needed in the country; what regulatory capacity is required; or what is needed to attract external partners – to design strategies and action plans to deliver better access to medicines.

2.1. **Planning a national innovation strategy**
The concept of national strategies for pharmaceutical innovation in low and middle income countries is relatively recent. In the eighties and nineties, emerging economies like India and China were able to produce cheap generic medicines. More recently a number of countries have shown interest in production as part of their regional economic activities. For example, all Health Ministers in the African Union signed the Gaborone Declaration in 2005 which sets a continent-wide priority to pursue local production of medicines, for “making full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights and DOHA declaration on TRIPs and Public Health”.

However, the capacity to produce should not be viewed independently from the need for building innovative capacity. The answer to the simple question “How to get started to provide better access?” is indeed a complex one that requires detailed reflection. 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 innovation and 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, medicines, pharmaceutical manufacturing and marketing.

As a starting point, decision makers in Ministries of Health (or Science and Technology, for example) can reflect on how they want to improve access and promote innovation. This process is best done by involving all key ministries and other key players such as potential funders and external partners. Having clear answers sets the scene for further assessment.

In designing their strategies, decision makers need to consider carefully 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 new formulations that are better adapted to local health needs and – eventually – more affordable; and there are more.

There is much discussion in development circles on the potential benefits of local medicines production by low income countries. There is also a perception that embarking on pharmaceutical innovation and medicines production could 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.

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

2.2. **A systemic approach to innovation**

Countries are heterogeneous with regard to health research, innovation and pharmaceutical production. They will all implement the GSPOA in different ways and need to better understand where they are situated in terms of health innovation and access to essential medical products, decide where they want to go and how to get there. 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.

A systematic and evidence-based approach can help ensure that countries determine their innovation priorities and thus set realistic targets for the level and sector of innovation they can feasibly put into effect.

A show of commitment from political actors and high-level 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 among these actors. Advocacy and awareness activities may be needed to get partners’ involvement across these sectors – both from government and non-governmental institutions – to ensure that they contribute to developing and strengthening a coherent national innovation system.

*Figure 1 below sketches a framework that decision-makers can use to guide the development of a national innovation system for 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
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**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, etc…

**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
- 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 | 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

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 & development
2.3. Assessing country needs, setting up priorities and designing strategies

The first step for developing an innovation strategy is to assess the current situation and collect accurate data. Countries must develop a clear vision of how the GSPOA and other existing regional plans and international initiatives can help address specific national needs. From this foundation countries can build innovation strategies and action plans that are realistic, effective, and allow them to negotiate with potential donors and partners in the pharmaceutical industry.

Countries with full pharmaceutical innovation capacity have followed different development pathways to get there and their experiences offer various models for developing countries to move up the innovation ladder. Country governments willing to develop a domestic pharmaceutical innovation capacity face the difficult task of deciding how to move forward, how and where to get involved, what path to follow 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 boards; governance structures and policies; financing; human resources strategies; or community involvement).

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.

Difficult choices will need to be made. Access to pharmaceutical innovation can be achieved in many ways, ranging from importing drugs and vaccines through to a domestic pharmaceutical industry developing its own medicines (see Figure 2). Making the decision on which route to choose requires an assessment on the part of each country of their current capacity, the options open to them, and which of these options are likely to offer the best outcome against health and/or economic goals.

Countries will need to decide what is their major priority for pharmaceutical innovation?
Providing access? Producing medicines? Discovering new drugs? Depending on the answer, the necessary people, structures and investment levels will be quite different. Countries will assess their current potential to deliver on these needs and what capacity needs to be developed. This is the basis of a national plan.
The pharmaceutical 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 2;
- Identify gaps in their process against each innovation milestone; and
- Identify practical steps needed to achieve their next innovation milestone.

More generally, this grid can help to identify bottlenecks and opportunities for strengthening pharmaceutical innovation, and determine how countries can 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 policymakers to assess their current capacity with respect to innovation milestones:

- Ability to access low-cost, 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 Tax
- Regulatory authorities (including medicines and IP regulators)
- Industry

To better understand how the grid can be applied, an example is presented in Figure 3 below, an excerpt that focuses on the “access” milestone.

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.

In this example, a policy-maker assessing where her country is in terms of access to affordable, quality, imported medicines can read from left to right across the table. Questions that arise might include:

- Do we have 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)?

- Are we signed up for all procurement mechanisms that give access to low-cost, quality products (e.g. the Global Fund, UNICEF, GDF, AMFm)?

- Do we have the necessary customs controls to monitor the quality of products coming into the country?

- Have we reviewed and, to the maximum extent possible, minimised taxes, tariffs and duties on pharmaceuticals along the supply chain?

- Has the national patent office (or regional patent group) optimised implementation of the TRIPS flexibilities?

- Is the Medicines Regulatory Authority (MRA) able to conduct the regulatory tasks outlined in the framework, 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 selected innovation milestone, be this in manufacturing or product development.

A country that cannot answer “yes” on most points may, instead, choose to maximise their ability to access existing medicines before the move toward manufacturing or developing their own. While such a decision would be driven in part by a desire to secure the health of the nation’s population, it could also reflect the reality that before more advanced innovation milestones can be reached, earlier and more fundamental elements must be in place.

Thus, a domestic pharmaceutical industry will require 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.
2.3. Designing an effective and realistic national innovation strategy; exploring regional strategies

Not all countries have in place 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 research, produce and deliver medicines; and have made strategic choices on where they can excel in part of the pharmaceutical production chain. Gaining end-to-end expertise in pharmaceutical innovation is not viable for all low and middle income countries today for reasons that include available skill base and financing. Regional strategies that pool talents and investments of a group of countries can be an attractive approach instead. In this scenario, countries can agree to work together to develop specific parts of the pharmaceutical innovation, R&D, production and delivery chain. Innovation strategies may be national, regional or continental; pooling the best of skills and services from several countries into shared systems.

3. Implementing and testing the proposed approach and tools

The approach and tools – the Pharmaceutical Innovation Framework and Grid - were developed primarily for supporting African countries to strengthen their pharmaceutical innovation and improve their access to essential medical products. The GSPOA and the African Union’s PMPA are aspirational statements that need to be translated into concrete work plans and actions. The development of the “pharmaceutical innovation grid” aims to support countries in the translation of these global plans into actions at national, regional and continental level.

For this to happen, the report needs to be examined and adapted by the Technical Committee of the African Union on Pharmaceutical Manufacturing and other relevant stakeholders to increase its suitability to support the operationalisation of the PMPA and GSPOA in Africa. To this end, a meeting has been scheduled in Pretoria, South Africa in the beginning of 2010. The final products of the meeting will be a technical report on pharmaceutical innovation in Africa and a summary policy document for endorsement by African decision makers.

We expect that the review of the COHRED-NEPAD report by the experts of the African Union will confirm major points of convergence with the analysis they have undertaken in 2007. And we hope that the practical tools the report proposes will:

- assist for a more detailed assessment of essential resources and gaps in terms of medical, pharmaceutical and other technical staff; additional skills needed; existing infrastructure; potential partners and financing sources – elements that the PMPA group of experts has highlighted as requesting further work
- facilitate further prioritization by the African Union of activities needed in the 6 domains defined by the PMPA technical committee.

4. Monitoring GSPOA implementation

Based on recommendations from the Pretoria and subsequent Ministerial meetings, implementation will start in a few pilot countries, with particular emphasis on capacity building – through workshop series linked to the framework and grid and key technical issues; and on monitoring and evaluating the implementation of initiatives and activities aimed at strengthening innovation and putting the GSPOA into action in Africa – through further development of the
**Health Research Web** web-based platform for national health research and innovation system management, and the existing NEPAD monitoring tools for Science and Technology[^3] - in particular the ASTII (African Science and Technology Innovation Indicator) project of NEPAD.

**Health Research Web** is designed to provide national governments and research institutions with a management tool to map, assess, evaluate and compare national health research systems and performance against those elsewhere. It brings together important aspects of national health research systems, including health research priorities, relevant legislations, institutional directories, ethics review capacity and programmes, and research funding. It also allows other actors in research to upload information and to interact – a unique feature that will be essential in involving all stakeholders in the GSPOA and in providing an effective and transparent monitoring tool. And it can be fully integrated into web-based services of governments and institutions. ([www.healthresearchweb.org](http://www.healthresearchweb.org)).

**HRWeb** is an evolving platform that is adaptable to specific audiences or for particular needs, and has been selected by the EDCTP (European and Developing Countries Clinical Trial Partnership) to display African Research Ethics Review capacity; it is the basis for the joint work between WHO/PAHO and COHRED in mapping Latin American National Health Research Systems as well as by WHO/EMRO and COHRED for 2010. Finally, NEPAD has selected **HRWeb** – to be adapted to display the innovation indicators of all African countries included in the African Science and Technology Innovation Indicators project. A prototype will be on the web for comments from the end of January 2010 ([www.AfricanScienceWeb.org](http://www.AfricanScienceWeb.org)) while the fully fledged version of NEPADs ASTII web-based indicator project will be in operation by July 2010.

The essential differences between **HRWeb** and any other platform are that i) it views health research and innovation through a ‘country-lens’ – in other words, countries form the basic building block of **HRWeb** – which is exactly what is needed to monitor implementation of GSPOA at country-level, and ii) it is interactive – providing countries with their own protected information sites that can be integrated into national research reporting. These two features make it the platform of choice to display indicators of progress towards achieving GSPOA goals at the level of any low and middle income country. From there, information can be automatically collated, compared and analysed by region, sub-region, continent or globally using pre-determined analyses agreed with WHO/PHI.

Other key advantages is that it gives countries the tools to exercise appropriate governance over their own research and innovation systems, including the parts that deal with pharmaceutical innovation. It will automatically link national health research priorities with pharmaceutical innovation, and provide links to ethics review capacity – for example. It can also be structured to allow neighbouring countries to compare expertise in pharmaceutical innovation with a view of enhancing collaborations. Finally, all data in **HRWeb** are available for downloading so that specific analyses can be undertaken by anyone interested in supporting the GSPOA.

COHRED will work intensively with WHO/PHI on determination of relevant indicators and analyses and use this to programme **HRWeb**. Subsequently, individual agreements between countries and **HRWeb** are created – providing countries with their own web-space for pharmaceutical innovation.

[^3]: See other document attached on Health Research Web