





Strengthening Pharmaceutical Innovation in Africa

Summary and recommendations

Against the background of recent African and international intergovernmental agreements, Declarations and initiatives¹ – on health research, medicines access and production – a special meeting of the African Union's Extended Technical Committee on the Pharmaceutical Manufacturing Plan for Africa convened in Pretoria, South Africa, on February 18-20, 2010.

This meeting was held to consider the results of the study on *Strengthening Pharmaceutical Innovation in Africa* done jointly by COHRED and NEPAD, with contributions from the George Institute for International Health. The study provided the first practical tool to operationalise global and African strategies to improve access to essential medicines.

The meeting was organised by NEPAD – the New Partnership for Africa's Development, the African Union and the Council on Health Research for Development (COHRED) with support from The Netherlands Ministry of Foreign Affairs and the Swiss Agency for Development and Cooperation, and was hosted by the Ministry of Science & Technology of the Republic of South Africa.

Access to medicines: Africa's problems and challenges

The meeting addressed the problems and challenges faced by African countries in their quest to increase access to medicines and research for improved products, and to stimulate production of medicines² in Africa. The discussions contribute to the implementation of the Global Strategy and Plan of Action on Public, Innovation and Intellectual Property of the World Health Organization, and the Africa Health Strategy, the Pharmaceutical Manufacturing Plan for Africa and the Africa Science and Technology Consolidated Plan of Action of the African Union.

This was a unique cross-sectoral gathering of experts and stakeholders active in all aspects of pharmaceutical innovation on the continent. They included African government officials in health and science & technology, medicines regulators,

¹ The Gaborone Declaration (2005); Abuja Declaration (2005) calling for development of a pharmaceutical manufacturing plan for Africa within the NEPAD Framework; The African Union Pharmaceutical Manufacturing Plan (2007); The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights (2008); a growing number of national policies in Africa for medicines access and local production (2006-2010).

² This includes pharmaceutical medicines, traditional medicines, diagnostics, vaccines and medical devices

researchers and academics, the African pharmaceutical industry, civil society, public – private partnerships, the African Union, regional economic communities, international and UN organizations and development partners. This range of stakeholders provided the broad perspective and expertise needed to deal with the complexity posed by efforts to increase access to essential medicines in Africa.

A unique, cross-sectoral gathering

Participants recognized the public health challenges faced today by African countries – of limited access to medical products and capacity – in addressing issues of technology transfer, manufacturing and innovation. They recognized Africa's increasing potential to address the situation and highlighted the urgent need to further translate policies into action – as a way to address the long and shorter-term challenges of improving African peoples' access to quality, efficacious and affordable medicines. The meeting also emphasized the importance of research and development on traditional medicines.

Participants highlighted practical ways in which political and research leaders, civil society, the private sector, donors and international programmes can partner to boost countries' ability to mobilize and manage pharmaceutical innovation to meet their needs. The participants called for improved inter-sectoral consultation and collaboration to make pharmaceutical innovation a reality. They felt that successful pharmaceutical innovation at national level requires a joint effort combining political support, technical expertise and financial commitment of the health and science & technology sectors. A unique aspect of this meeting was precisely the involvement of officials from both ministries of health and science and technology.

The meeting emphasized the importance of creating an enabling environment for existing and emerging African manufacturers as well as the importance of leadership from governments to achieve this. Participants also stressed the importance of inter-African cooperation and mutual support and the role that the global health community can play to enable pharmaceutical innovation and manufacture in Africa. Country leadership, ownership and harmonization should be at the centre of all such efforts.

Pharmaceutical Innovation Tool

The meeting focused on the review and evaluation of a new tool (the "Pharmaceutical Innovation Framework and Grid") that supports countries to assess their current situation and future intentions for pharmaceutical innovation, and to design national and regional action plans for innovation, access and local production of medicines, diagnostics and vaccines. Participants found the tool useful and provided suggestions for its improvement, including reference documents and examples illustrating the range of policy instruments and resources available in countries. They emphasised that access and innovation must go hand-in-hand and that the tool should encompass all stakeholders including civil society and private sector.

Practical actions

Participants recommended a number of practical steps forward, including:

- Using the tool to make a valuable contribution to achieving the goals of the Pharmaceutical Manufacturing Plan for Africa and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.
- Providing strong support for the development and implementation of a business plan for the Pharmaceutical Manufacturing Plan for Africa; the meeting invited partners to assist in its development and implementation – by providing resources and ensuring synergies with the private pharmaceutical sector.
- Establishing short and long-term objectives and milestones for pharmaceutical innovation and manufacturing in Africa.
- Prioritizing the creation of mechanisms to stimulate research and development, and technology transfer and other conditions needed to facilitate and strengthen manufacturing in Africa.
- Creating a coordination mechanism to ensure better synergy and improved intraand 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 adapt its formulation to a language that is understandable across sectors, professional cultures and backgrounds.
- Recognizing the importance of quality assurance systems, pointing out that responsibility is located at different levels of pharmaceutical innovation.

Capacity building.

The meeting recognized that capacity building is vital to strengthening pharmaceutical innovation in Africa, and made the following recommendations:

- Activities should focus on building skills and capacities in areas such as medicines regulation, intellectual property, research collaboration and cooperation, research and business management and policy making.
- Regional centres of excellence should be developed.
- Global mechanisms for regulatory capacity building should be integrated into existing continental and regional harmonisation initiatives.
- Research and development institutions should be developed to be able to address a full range of manufacturing technologies, including traditional medicines.

Financing

Participants highlighted that sustainable financing is essential to support countries' innovation development, and recommended that:

- Alternative financing mechanisms for the research, development and manufacturing of medicines must be established, including by African institutions such as the African Development Bank.
- Africa must be an active participant in determining alternative global financing mechanisms for access to medicines and pharmaceutical innovation.
- African governments need to invest in and create incentives for all steps of the pharmaceutical innovation chain, and should consider establishing a mechanism that lends at low interest to offset the high commercial rates available in Africa for

pharmaceutical innovators. Governments should use their voice in international bodies to create a more enabling environment for African manufacturing.

The meeting concluded with a special thanks to the African Union Commission for its leadership in hosting this meeting, to NEPAD and COHRED and their partners for creating this tool that will help operationalise pharmaceutical innovation at country and regional levels, and expressed the anticipation of further leadership of the African Union Commission to make the Pharmaceutical Manufacturing Plan for Africa a reality. The meeting also expressed its sincere appreciation for the support provided from the Netherlands, Switzerland and the meeting's host, the Republic of South Africa.

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All documents and background material are at <u>www.nepad.org/African_Innovation</u>