Summary report of NEPAD/WHO donors and stakeholders discussion meeting on supporting African plans to harmonise medicines registration, London, 19-20 November 2009

Introduction

Interested donors and African Medicines Registration Harmonisation (AMRH) stakeholders attended a NEPAD/WHO meeting in London from 19-20 November 2009 to discuss support for medicines registration harmonisation as a key contribution to improving medicines access in Africa. The meeting was organised by the African Union's New Partnership for Africa's Development (NEPAD) and the World Health Organization (WHO) on behalf of a consortium of partners including the Pan-African Parliament (PAP), the Bill & Melinda Gates Foundation, the UK Department for International Development (DFID) and the William J. Clinton Foundation.

The meeting was opened by the Deputy Chief Executive Officer of NEPAD, Ambassador S.O. Willoughby and closed by the WHO Director of Essential Medicines and Pharmaceutical Policies, Dr Hans Hogerzeil.

The meeting sought to demonstrate the value of investing in the AMRH initiative and to identify additional donors to fund African Regional Economic Communities' (REC) plans to expedite and strengthen medicines registration through regional harmonisation. These plans are currently being developed, with the support of NEPAD and WHO, and will be ready for donor review and funding consideration in 2010. The meeting also sought to sensitise other stakeholders who might be in a position to offer in-kind support.

Besides representatives of the consortium listed above, the meeting was attended by: bilateral and multilateral donors; representatives of well-established medicines regulatory authorities, medicines access NGOS and pharmaceutical industry associations; and representatives of African RECs and National Medicines Regulatory Authorities (NMRAs) that are currently in the process of developing project proposals.

Various presentations were made and discussion sessions held, in support of the following meeting objectives:

1) Explain why AMRH is needed to improve medicine access in Africa
2) Explain NEPAD and WHO's approach to supporting RECs to develop and implement their plans to harmonise medicines registration
3) Indicate the level of broad-based support for this approach from the African Union (AU), Pan-African Parliament (PAP), RECs, NMRAs, Africa-based industry etc.
4) Share key features of emerging REC project proposals, including the estimated levels of external support needed
5) Benefit from participants insights and feedback and brainstorm ways in which they might like to get involved
6) Encourage those present to mobilise their agencies to provide financial and other forms of implementation support

Main observations

Meeting participants affirmed the importance of the AMRH initiative in promoting access to priority essential medicines, including generic versions of important treatment options and new treatments for neglected diseases. A number of meeting participants reaffirmed their commitment to providing financial and technical support to the initiative. Participants further observed and welcomed the growing political support at continental, regional and sub-regional level for AMRH in general and the AMRH initiative in particular, but stressed that high-level political mandates at continental and regional level must translate into real political commitment at the national level. More advocacy programmes at national level, involving industry and regulators as strategic partners, as well as the current drive towards freer regional trade, might offer an opportunity in this regard.

Key issues that emerged from the discussions included:

a. **A need to adopt a step-wise approach to harmonisation** which should start with generic essential medicines and only later move on to covering new medicines, vaccines and other regulatory functions. Previous harmonisation experience (both positive and negative), as well as learning from other collaborative initiatives e.g. the African Vaccines Regulatory Forum, provides an excellent basis for developing AMRH plans.

b. **A need to invest in regulatory capacity building,** e.g. through training, to strengthen the ability of NMRA staff to perform scientific evaluations/inspections as well as their ability to advise, as appropriate, the pharmaceutical industry (local and international) in meeting harmonised registration requirements.

c. **Acknowledgment that NMRAs must follow through on their mandate to promote and protect public health,** and to do so must recognise their limitations in terms of financial and human resources to ensure the most cost effective resource use. Sharing and use of information from other stringent NMRAs should be encouraged.

d. **Sustainability, transparency and trust building** are key elements of planning and implementing AMRH activities.

e. **Use of existing structures and broader REC strategies to advocate for AMRH**
   - Mechanisms to successfully implement the AMRH initiative, including a lean coordination structure and strong framework for monitoring and evaluation, need to be further explored
   - Political will at AU, REC and national level in support of harmonisation must be stimulated, including a comprehensive AU/PAP advocacy strategy targeting various key players (including NMRAs, local industry and politicians at national, sub-regional and continental level)

f. **National sovereignty must be respected,** i.e. there will be no prescribed activities. AMRH ownership by the countries themselves must be facilitated and promoted.

g. **Existing forums should be used to provide regulators with practical advocacy,** including the African Medicines Regulators Conference (AFDRAC), International Conference for Drug Regulatory Authorities (ICDRA), International Conference on Harmonisation Global Cooperation Group (ICH-GCG) and existing REC forums.

h. **Need for the Consortium to keep all stakeholders informed and involved,** e.g. using the AMRH newsletter and capitalising on offers of support to find new ways for stakeholders to engage, participate and/or work together. These might include:
   - Coordinating technical support offers among well-established regulators
   - Leveraging forums and training opportunities provided by international industry
   - Explore enabling opportunities for local manufacturers
   - Engaging civil society and donors to participate, advocate and encourage others

i. **Need to capitalise on strategic niche roles of key players including:**
   - WHO's role in providing technical assistance and guidance; its experience in medicines regulation harmonisation; its long standing investment in building NMRA capacity; its experience working with well-established NMRAs such as the European Medicines Agency; and its role in promoting global standards
   - NEPAD's strategic role under the AU, its political advocacy and continental coordination role, including its working relationship with the AU Commission, PAP and RECs
   - DFID and the Bill & Melinda Gates Foundation's continued involvement in supporting not only the AMRH initiative, but also broader programs to increase access to medicines in Africa

Next steps

1. **Finalise REC medicines registration harmonisation project proposals; engage donors and stakeholders; mobilise implementation resources; and begin implementation:**
   - Develop a clear work plan to finalise REC project proposals and continue intensive effort to mobilise and support RECs, including providing guidance to:
     - Finalise REC project proposals; and/or
     - Access donor funds and in-kind resources to support the project
   - Continue to engage donors and stakeholders and actively solicit their input and involvement (driven by the Bill & Melinda Gates Foundation and DFID on behalf of the Consortium):
     - Develop a strategy to mobilise donors and stakeholders that are committed to supporting the AMRH initiative
     - Start sharing full details of mature project proposals with interested donors

2. **Increase continental co-ordination across all sub-regions:**
   - Express the value of continental co-ordination and the need to include as many countries and regions as possible in the AMRH initiative
   - Develop plans for a lean coordination structure which provides clear roles and responsibilities, including NEPAD's political advocacy and continental coordination role and WHO's technical support and guidance role